KAISER PERMANENTE®

Kaiser Permanente Washington Pre-Authorization requirements:

Kaiser Permanente Washington requires pre-authorization for most services to be covered. The information below outlines pre-authorization requirements at a high level. Some requests for pre-authorization will be reviewed by a clinician for medical necessity. The criteria used to determine medical necessity is also outlined below.

For questions regarding pre-authorization requirements for specific services, please consult your Certificate of Coverage or contact Member Services at 1-888-901-4636.

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Transplants –organ and stem cell transplants	Yes	Your physician will request authorization for all stages including pre-transplant care, transplant, and post-transplant care		Please check your Certificate of Coverage for benefit and cost share information.	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Facility admissions: ❖ Skilled Nursing facility ❖ Mental Health facility ❖ Chemical Dependency facility ❖ Long-term Care facility ❖ Rehabilitation facility ❖ Scheduled inpatient admissions to a hospital ❖ Emergency admission to a hospital	<u>Planned/Scheduled Admissions =</u> Yes	<u>Planned/Scheduled Admissions =</u> Your ordering physician will obtain pre-authorization.		Please check your Certificate of Coverage for benefit information and/or limitations for these admissions.	
	<u>Urgent/Emergent Admissions =</u> Notification of the admission to Kaiser Permanente Washington is required	<u>Urgent/Emergent Admissions =</u> The hospital should notify Kaiser Permanente Washington and you should also notify Kaiser Permanente Washington by calling the Hospital Notification line provided on the back of your Kaiser Permanente Washington ID card			

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Surgery – inpatient and outpatient	Yes	Your surgeon's office will coordinate authorization for procedures, including notification of the facility where the procedure will be performed.	Many different procedures may require medical necessity review. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information including what may not be covered.	
Durable Medical Equipment Prosthetics Orthotics	Yes	Your physician and DME vendor will work with Kaiser Permanente Washington to obtain authorization for needed equipment.	Some equipment requires medical necessity review. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information including what may not be covered.	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Home Health Care	Yes	Your physician and home health care agency will work with Kaiser Permanente Washington to obtain authorization.	Home care services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Hospice	Yes	Your hospice agency will notify Kaiser Permanente Washington when hospice is elected.	None	Please check your Certificate of Coverage for benefit information.	
Radiology – MRI, CT, MRA, PET Scans, Dexa Scans (High End Imaging)	Yes	Your ordering physician will work with Kaiser Permanente Washington to obtain pre-authorization.	None		
Radiology – Diagnostic Radiology i.e. x-rays, ultrasounds	No	N/A	None		
Genetic Testing	Yes	Your ordering physician will work with Kaiser Permanente	Genetic Tests must be medically necessary to be covered. Please consult the Kaiser Permanente		

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
		Washington to obtain pre-authorization.	Washington Clinical Review Criteria for more information.		
Laboratory/Pathology Services (excluding genetic testing)	No	N/A	Some lab/pathology must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.		
Specialty care and specialists inside the network	Yes* *See Women's Health care, and Alternative Health care for specific authorization requirements for these services	Your Primary Care Physician will refer you and obtain pre-authorization for specialty care.		Some specialty care provided at a Kaiser Permanente Washington facility may not need pre-authorization and are allowed as a self-referred service. Please check your Certificate of Coverage for benefit information. Specialty care	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
				outside of the network is not covered unless emergent or approved in advance by Kaiser Permanente Washington.	
Women's Health care	No – outpatient services do not require authorization	N/A	None	Please check your Certificate of Coverage for benefit information.	
Alternative Health Care - Spinal Manipulations	No	N/A	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	The number of visits is limited. Please check your Certificate of Coverage for limits.	
Alternative Health Care - Acupuncture	No	If required, your provider will submit the request for additional visits.	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	*Your plan may allow additional visits with pre-authorization. Please check your Certificate of Coverage for limits.	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
Alternative Health Care - Naturopathy	No	If required, your provider will submit the request for additional visits.	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	*Your plan may allow additional visits with pre-authorization. Please check your Certificate of Coverage for limits.	
Alternative Health Care - Massage Therapy	No	N/A	Services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	The number of visits for rehabilitative therapy, which includes massage, speech, physical, and occupational therapy, is limited. Please check your Certificate of Coverage for visit limits.	
Physical Therapy, Occupational Therapy, and Speech Therapy	No	N/A		The number of visits for rehabilitative therapy, which includes massage, speech, physical, and occupational therapy, is limited. Please check your	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
				Certificate of Coverage for visit limits.	
Mental Health	Yes	Contact Kaiser Permanente Washington Behavioral Health Services	Mental health services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Chemical Dependency	Yes	Contact Kaiser Permanente Washington Behavioral Health Services	Chemical dependency services must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Applied Behavioral Analysis (ABA) Therapy	Yes	Your ordering physician will obtain authorization from Kaiser Permanente Washington.	ABA Therapy must be medically necessary to be covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Please check your Certificate of Coverage for benefit information.	
Clinical Trials	Yes	Your ordering physician and trial	Services must be medically necessary to be	Please check your Certificate of	

School Employees Benefit Board – Core/Kaiser Permanente Washington					
Service	**Is pre-authorization required?**	**How do I get pre-authorization?**	**What criteria must be met for coverage?**	**Notes**	**Which providers can I see?** You must see a network provider for services to be covered. Please review the Provider Directory to see who is in your network.
		provider will work with Kaiser Permanente Washington to obtain authorization for covered services.	covered. Please consult the Kaiser Permanente Washington Clinical Review Criteria for more information.	Coverage for benefit information.	
Outpatient Emergency Care	No	N/A		Please see "Facility Admissions" above for authorization requirements if you are admitted to the hospital. Please check your Certificate of Coverage for benefit information.	You can see any provider for emergent care.
Primary Care (PCP)	No	N/A	None	Please check your Certificate of Coverage for benefit information.	

For questions regarding pre-authorization requirements for specific services, please consult your Certificate of Coverage or contact Member Services at 1-888-901-4636.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Advanced Care at Home

Criteria

For Medicare & Non-Medicare Members

As of 01/01/2023 as groups renew (please check member's contract as some groups may renew later in the year), this criteria/benefit will apply to the following plans:

- Most fully insured Large Commercial groups (Exceptions: FEHB Core and Options who have opted out for 2023 and groups with rider AR-Y)
- Self-Funded Large Commercial groups (please note: groups are able to opt out)
- Individual Medicare (all plans except the Basic plan)
- Employer Group Medicare (please note: custom groups are able to opt out)

A. To receive advanced care in the home, the member must meet **ALL of the following:**
   - The member must be referred into the advanced care program by the managing provider such as in an emergency room setting
   - Advanced Care at Home requires preauthorization based on the member's health status, treatment plan, and home setting or another appropriate care location within the service area
   - The clinical condition must meet inpatient medical necessity criteria, per MCG care inpatient hospitalization guidelines appropriate to the patient's clinical condition
   - The member must consent to receiving advanced care described in the treatment plan
   - The care location, such as the member's residence, must be within 30 minutes ground travel time of an emergency department **AND**
   - The care location, such as the member's residence, must have cell service

B. Advanced Care at Home is provided through Medically Home, Kaiser Permanente's network provider, and will provide the following services in the member's home or appropriate care location:
   - Home visits by RNs, physical therapists, occupational therapists, speech therapists, respiratory therapists, nutritionist, health aides, and other healthcare professionals in accordance with the Advanced Care at Home treatment plan and the provider's scope of practice and licensure.
   - Communication devices to allow the member to contact the medical command center 24 hours a day, 7 days a week. This includes needed communication technology to support reliable connection for communication, and a personal emergency response system alert device to contact the medical command center if the member is unable to get to a phone.

C. Additional services covered under this benefit include:
   - The following equipment necessary to ensure that the patient is monitored appropriately in home: blood pressure cuff/monitor, pulse oximeter, scale, and thermometer
   - Mobile imaging and tests such as X-rays, ultrasounds, and EKGs
   - Safety items when medically necessary, such as shower stools, raised toilet seats, grabbers, long handled shoehorn, and sock aids
   - Meals when medically necessary while patient is receiving advanced care at home

Back to Top

In addition, the following services and items are covered under this benefit when prescribed as part of the Advanced Care at Home treatment plan:

- Durable Medical Equipment
- Medical Supplies
- Member transportation to and from network facilities when member transport is medically necessary
- Physician Assistant and Nurse Practitioner house calls
- Emergency Department visits associated with this benefit

Exclusions: Private Duty Nursing; housekeeping or meal services not part of the Advanced Care at Home treatment plan; any care provided by or for a family member; any other services rendered in the home which are not specified in the member's Advanced Care at Home treatment plan

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Advanced Care at Home is a personalized, patient-centered program that provides care for patients with certain clinical conditions in their homes, or at another appropriate care location.

Advanced Care at Home services must be associated with an acute episode and the treatment plan may include restorative care associated with the acute episode. The duration of an episode of care (which includes acute and restorative phases) is limited to a total of 30 days.

Applicable Codes

Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
08/02/2022	08/02/2022[MPC], 08/01/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Applied Behavioral Analysis Therapy (ABA)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

- **For patients with a Microsoft contract**, click here to view the criteria.
- **For all other plans where the contract includes coverage for ABA therapy, see below for criteria**
- **For plans without a benefit**, the service is not covered at this time.

For all Kaiser Permanente plans with a benefit (except Microsoft)
ABA requires preauthorization for initial and continued therapy. Specific coverage may be defined in the individual member contract. The following criteria must be met:

1. The member has a diagnosis of an Autism Spectrum Disorder (DSM-V code including severity levels) according to WAC 388-823-0500 by a board-certified neurologist; board-certified psychiatrist; a licensed psychologist; an advanced registered nurse practitioner (ARNP) associated with an autism center, developmental center, or center of excellence; a licensed physician associated with an autism center, developmental center, or center of excellence; or a board certified development and behavioral pediatrician

2. The diagnostic assessment must include **All of the following** elements:
   a. Documentation of formal diagnostic procedures by an experienced clinician (e.g., Autism Diagnostic Interview-Revised, Autism Diagnostic Observation Schedule, diagnostic interview using DSM-V criteria)
   b. Description of how patient's behaviors are having an impact on development, communication or adjustment such that:
      i. The member cannot adequately participate in home, school, or community activities; and/ or the member presents a safety risk to self or others, and
      ii. Less intrusive and/or less intensive behavioral interventions have been tried and have not been successful and/or there is no equally effective alternative strategy available to address the member's behaviors

   c. Specific evaluations to determine developmental profile using **ONE or more of the following** standard tools:
      i. Adaptive/Functional skills: Vineland Adaptive Behavior Scales

Back to Top

ii. Communication skills: Preschool Language Scale-5 (PLS-5), Clinical Evaluation of Language Fundamentals-5 (CELF-5), Verbal Behavior Milestones Assessment and Placement Program (VB-MAPP)
iii. Cognitive Assessment (Wechsler scales, Kaufman scales)
iv. Social Skills Rating Scales (SSRS), Assessment of Basic Language and Learning Skills (ABLLS), Achenbach System of Empirically Based Assessment (ASEBA)
v. Behavior rating scales: ASEBA, Behavior Assessment System for Children, Third Ed. (BASC-3), Gilliam Autism Rating Scale

d. Expanded laboratory, documented routine developmental surveillance by providers at every well child visit, screening questionnaire, audiology assessment results, only if indicated.
e. There is evidence that the patient can participate in ABA therapy

3. A documented individualized treatment plan (ITP) that includes:
   a. A time-limited ITP that has been developed based on a diagnostic assessment within no more than 12 months of initiating treatment
   b. ITP is multidisciplinary in nature, member-centered, family-focused, community-based, culturally-competent and least intrusive
   c. Treatment plans that are templates or generic to a particular program are not acceptable ITP must address behaviors and symptoms that prevent the member from adequately participating in home, school, or community activities and/or present a safety risk to self or others, with a focus on parent training
   d. The ITP must address behaviors and symptoms that prevent the member from adequately participating in home, school, or community activities and/or present a safety risk to self or others, with a focus on parent training
   e. The ITP should take into account all school or other community resources available to the patient and provide evidence that the requested services are not redundant to other services already being provided. The ITP should include a review of a school-based IEP (if present) and how the ITP does not duplicate what is on the IEP. The ITP should also include a review of other treatment if present (e.g., outpatient mental health, speech therapy) and how the ITP does not duplicate these community-based resources. Coordination between the ABA provider and school and/or other service providers must take place directly between the providers, and not through parents.
   f. Coverage of ABA therapy in public or private schools is only provided under the following circumstances:
      i. Observation and assessment of behavior may take place in the school as part of the ITP assessment with the permission of school personnel
      ii. ABA may be provided on school property before and after regular school hours with the permission of school personnel
      iii. ABA may be provided during regular school hours with permission of school, when medically necessary, and the ABA intervention does not duplicate services the school could be expected to provide.
   g. ABA services do not eliminate the requirement that the school district is to provide appropriate mandatory educational services
   h. ABA services are not to be used for custodial caregiving services, including respite for caregivers

4. The ITP must include **All of the following**:
   a. The provider must use KP WA required report templates, available at Applied Behavioral Analysis Treatment for Autism | Kaiser Permanente Washington; updates will be posted on the provider site.
   b. Description of autistic behaviors that are targets for treatment. The targets for treatment should be based on where there is the most significant gap in functioning as measured by developmental and behavioral assessment including **TWO or more of the following:**

      i. ONE Norm-Referenced assessment is required to be completed during the initial ABA assessment, and to be readministered every 12 months. The provider is to use an instrument that will be suitable for serial measurements over time, and thus to measure functional progress over treatment periods. Some options for norm-based assessment are:
         - Vineland3 Adaptive Behavior Scales
         - Adaptive Behavior Assessment System (ABAS)
         - Pervasive Developmental Disorder Behavior Inventory (PDDBI)

Back to Top

- Social Skills Improvement System (SSIS)

ii. ONE Criterion-Reference assessment is required to be completed during the initial ABA assessment, and to be updated every 6 months. Some options for this assessment are:
- The Carolina Curriculum
- Verbal Behavior Milestones Assessment and Placement Program (VB MAPP)
- Preschool Language Scale-5 (PLS-5),
- Promoting Emergence of Advanced Knowledge (PEAK)
- Accept-Identify-Move (AIM)
- Assessment of Basic Language and Learning Skills (ABBLS)
- Essentials for living (EFLs)
- The Assessment of Functional Living Skills (AFLS) or similar empirically based assessment tool.

c. A comprehensive description of treatment interventions and techniques specific to each of the targeted behavioral/symptoms
d. Establishment of baseline data, measurable treatment goals, and criteria for goal attainment and objective measures of progress for each intervention specified (including baseline and targeted goals)
e. Strategies for generalizing learning skills across persons and situations. Generalization plans are monitored closely as they are key to the patient transitioning to a lower level of care.
f. A description of parent education, including measurable parenting goals with baseline and criteria for goal attainment, and description of interventions. The parent goals are to include instruction in ABA principles in order to training and support generalization and maintenance of skills. Detailed description of interventions with parents to support their active participation in ABA treatment, including a plan for transferring interventions with the patient from the ABA provider to the parents. An ITP that does not adequately feature parental involvement may be subject to denial.
g. Strategies for communication and coordinating treatment with other providers and agencies including school-based special education programs, day care, and other health care providers.
h. Hours requested are itemized for each treatment modality (e.g., parent training, certified behavior technician time, lead behavior therapist, supervision, social skills group, completion of six-month progress report)
i. Measurable discharge criteria for completing treatment and plans for continued care after a discharge plan from ABA, which include **all of the following**:
   i. Plans for transition through a continuum of less intensive treatments such that patient's symptoms can be effectively managed at a lower level of care
   ii. Specific behavioral goals that, when reached, will indicate the patient is adequately participating in home, school, or community activities and/or is no longer presently a safety risk to self or others

5. Discharge Criteria - Typically individuals no longer need ABA services if **ONE of the following** is met:
   a. Patient behaviors and/or symptoms do not prevent them from adequately participating in home, school, or community activities and/or no longer present a safety risk to self or others
   b. Their behaviors and/or symptoms can be adequately addressed through alternative methods (i.e., school, developmental disability services, parent training)
   c. Functional and measurable progress toward treatment goals is not occurring as measured by (majority of goals are not being met, there is not significant progress on behaviors and/or symptoms that prevent them from adequately participating in home, school, or community activities, and/or no longer present a safety risk to self or others), improvement is not durable over time, and/or generalizable outside the treatment setting, and there is no reasonable expectation of further progress
6. Transition to a lower level of care. Discharge is often not a discrete event, but instead is a transitional process, to prevent relapse of skills. Transition to a lower level of care could include any of the following: lowered number of treatment hours (focused ABA), enhanced focus on training parents or other caregivers, or the use of other treatment modalities e.g., mental health counseling group treatments or other community support activities.

7. Coverage of development of the ITP does include time to do baseline assessments, review of past treatment (including IEPs) and development of a plan that includes parent training and coordination with other treatment providers. Six to 10 hours is usually sufficient for the development of the ITP. However, more complex cases,

Back to Top

or cases in which a complete functional analysis *is* needed, may require up to 15-20 hours for the initial assessment and treatment planning.

8. The amount of treatment is based on medical necessity. As noted in the 2014 Agency for Healthcare Research and Quality update on A Review of Research of Therapies for Children with Autism Spectrum Disorder, early intervention programs (i.e., for children typically, under the age of six) are provided for up to 25 hours a week and can last as long as 12 weeks to 3 years. These services can include direct services to member/identified patient and/or parents by program manager/lead behavioral therapist and/or therapy assistants/behavioral technicians/paraprofessionals, supervision, and the development of a six-month progress report. In the unusual case of very acute and/or unsafe patient behavior, up to 40 hours/week of treatment may be authorized.

9. Fewer hours may be required (5-15 hours per week) for Focused ABA when the primary difficulty is in one targeted area (i.e., social skills deficits).

10. Caregiver coaching is considered best practice and needed for all ABA programs
    a. Caregiver coaching plans must include baseline behaviors, must have baselines measurable components, and mastery criteria
    b. Caregiver education must also include the teaching of ABA principles related to the patient goals (i.e., principles of reinforcement, behavior functions, schedules reinforcement, task analysis as a teaching strategy, etc.)
    c. Monthly meetings (in person or virtual) are required for generalization and maintenance of skills
    d. The initial caregiver coaching/education plan must be documented

11. Evaluation of progress: Every six months, the provider completes the KP ABA Progress Report. This document is used to review progress in treatment including the following information:
    a. How patient is progressing towards goals (i.e., what percentage of goals patient has achieved and how these goals have led to functional progress as it pertains to increasing patient's ability to adequately participate in home, school, or community activities, and/or decrease safety risk to self or others
    b. Progress towards parent goals (how parents have been active participants in the treatment, what percentage of parent goals have been passed, and progress towards transferring interventions with the patient to the parents.
    c. For goals that have not been met, describe reason for not meeting goals, how goals are being adjusted, and how interventions are being revised to meet goals.
    d. Any new goals that have been identified (if new goals are identified, include baseline and targeted performance). New goals should be geared towards progress or transition to less intensive interventions.
    e. A criterion referenced assessment is to be submitted every six months.
    f. How the patient is progressing towards discharge and/or plans for discharging from care and/or reducing intensity of intervention based on patient progress and/or the implementation of less intensive behavioral interventions. A discharge plan stating that ABA will be needed until he/she no longer meets criteria for ASD is not appropriate. A patient could still meet diagnostic criteria for ASD, but be able to be successfully and safely treated at a lower level of care.
    g. A brief description of what was done during the past six months to coordinate treatment with school and/or health care providers (i.e., phone call was made to speech therapist to make sure there is common picture communication system; a conference was held with the school to coordinate behavioral interventions for self-injurious behavior). This coordination must take place directly between the ABA provider and any other service providers, and not through the parents
    h. If functional progress is not occurring (i.e., one or two consecutive ITP's where patient is not meeting majority of goals and not making functional progress towards increased participation in home, school, or community activities and/or is not less of a safety risk to self or others) and there is not a reasonable expectation of further progress, then continuation of ABA services is not considered to be medically necessary

12. Every 12 months standardized (norm-referenced) developmental assessment should be re-administered to assess whether patient continues to be making functional and measurable progress. The provider is to use the same instrument over time as much as possible so scores can be compared over time to measure progress.

Back to Top

Date Sent: 4/29/24

13. The following are not considered to be medically necessary ABA services:
    a. More than one program manager/lead behavioral therapist for a member/identified patient at any one time.
    b. More than one agency/organization providing ABA services for a member/identified patient at any one time.
    c. If the school has determined that a child is eligible to receive services under an IEP which would overlap with ABA services and the school services are declined or discontinued by the parent.
    d. Activities and therapy modalities that do not constitute application of applied behavioral analysis techniques for treatment of autism. Examples include (but not limited to):
        i. Taking the member/identified patient to appointments or activities outside of the home (e.g., recreational activities, eating out, shopping, play activities, medical appointments), except when the member/identified patient has demonstrated a pattern of significant behavioral difficulties during such specific activities
        ii. Assisting the member/identified patient with academic work or functioning as a tutor, educational or other aide for the member/identified patient in school
        iii. Provision of services that are part of an IEP and therefore should be provided by school personnel, or other services that schools are obligated to provide
        iv. Doing housework or chores, or assisting the member/identified patient with housework or chores, except when the member has demonstrated a pattern of significant behavioral difficulties during specific housework or chores, or acquiring the skills to do specific housework or chores is part of the ABA treatment plan for the member/identified patient travel time residing in the member's home and functioning as live-in help (e.g., in an au-pair role)
14. All ABA visits with the patient and/or family should be documented. Documentation should include:
    a. Who was present at the visit?
    b. Duration of the visit
    c. What was the targeted behavior during the visit?
    d. What was the procedure/activity/intervention during visit?
    e. What was the response to procedure/activity/intervention?
    f. Intervention format (individual, group, supervision, parent training)
    g. Graphical or numerical data to track progress/participation
    h. Signature title, credentials of person completing documentation
    i. Include targeted behavior, interventions, response, modifications in techniques and plan for next visit with behavior tracking sheets that record and graph data collected for each visit

ABA Provider Qualifications and Procedure Codes

Providers delivering ABA must meet **ALL of the following** qualifications:

1. At a minimum, the lead behavioral therapist, providing treatment and clinical supervision of treatment program must demonstrate that she/he is a board-certified behavior analyst (BCBA).
2. ***Either***:
    a. Individually satisfy **ALL the following** requirements:
        i. Be a licensed health provider under Title 18, Revised Code of Washington, including but not limited to: speech therapist, occupational therapist, psychologist, pediatrician, neurologist, psychiatrist, mental health counselor, social worker; and
        ii. Be licensed to practice independently; and
        iii. Be credentialed and contracted by the Plan; ***or***
    b. Be employed by a Healthcare Delivery Organization that meets **All of the following** requirements:
        i. Be a hospital, mental health facility, home health agency or in-home agency licensed to provide home health services, or other mental health agency licensed by the Washington Department of Health; ***or*** a community mental health agency or home health agency licensed by the Washington Department of Social and Health Services; and
        ii. Be credentialed and contracted by the Plan.
        iii. Clinical supervision for unlicensed staff providing services must be provided by a lead behavioral therapist as indicated above. Must include, at a minimum bimonthly (once every 60 days) approval and review of the ITP and case review of every member receiving clinical health services; and

Back to Top

CPT code	Description
97151	Behavior Identification Assessment, administered by QHP, each 15 minutes of QHP's time face-to-face with patient and/or guardian(s)/caregivers(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior Identification Supporting Assessment, administered by one technician under the direction of QHP, face-to-face with the patient, each 15 minutes
97153	Adaptive Behavior Treatment by Protocol, administered by technician under the direction of a QHP, face-to-face with one patient, each 15 minutes
97153 w/HO modifier	
97154	Group Adaptive Behavior Treatment by Protocol, administered by technician under direction of QHP, face-to-face with 2+ patients, each 15 minutes
97155	Adaptive Behavior Treatment with Protocol Modification, administered by QHP, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family Adaptive Behavior Treatment Guidance, administered by QHP (with or without patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-Family Group Adaptive Behavior Treatment Guidance, administered by QHP (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group Adaptive Behavior Treatment with Protocol Modification, administered by QHP face-to-face with multiple patients, each 15 minutes

iv. Must include, at a minimum, at least one hour of on-site supervision, with on-site observation for at least one hour for every 40 hours of service to the member.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Autism is a neurodevelopmental disorder in the category of pervasive developmental disorders (PDD), which is a group of conditions that also include Rhett's disorder, childhood disintegrative disorder, Asperger's disorder, and pervasive developmental disorder not otherwise specified (PDD NOS). Autism is characterized by a triad of deficits involving impaired language development, reciprocal social interaction, and stereotyped repetitive patterns of behaviors and interests. The prevalence estimates released by the CDC based on 2002 data show that approximately one in fifty children in the US is autistic. These estimates indicate a dramatic increase in the recent years, which may be due to an actual increase in the occurrence of the disorder as well as the increased awareness of the disorder among the clinicians. There are no definitive medical tests to indicate the presence of any form of autism spectrum disorders (ASD). Diagnostic assessment includes use of ICD and DSM-IV diagnostic criteria and standardized methods to assess core and co-morbid conditions. Parents usually become aware of developmental problems in their child starting around the age of 18 months, but diagnosis is often not made until 2 years after the expression of parents' concerns. It may sometimes be delayed until close to the age of six (Ospina 2008, Granpeesheh 2009, Levy 2009, Spreckley 2009).

Autism is a lifelong condition with variable clinical course throughout childhood and adolescence. Many adults with autism may still require full-time care. While there is no known cure, the general agreement is that early diagnosis followed by appropriate treatment may improve outcomes in later years for most individuals. Over the past twenty years, a variety of therapies have been proposed to improve the symptoms associated with ASD, many of which have not been validated scientifically. These include pharmacological therapies, complementary therapies as diet modifications and vitamin therapy, speech and language therapy, and psychosocial treatments.

The well-researched treatment programs are based on the principles of applied behavioral analysis (ABA), sometimes called behavioral therapy or behavioral modification. The approach has been outlined by Lovaas and

Back to Top

colleagues in the 1980s and, as originally described, involves teaching appropriate behaviors by breaking tasks down into small discrete steps and training in a systematic and precise way called discrete trial training. It is delivered on a 1:1 basis, for 40 hours a week over a three-year period.

The approach of ABA is based on the concept that children with ASD have significant difficulties with learning, being unable to learn through imitation, and listening as normal children do. Its overall goal is to motivate the child to want to be successful. ABA is founded on behavioral principles of learning and motivation, consisting of reinforcement, extinction, stimulus control, and generalization. The basic learning principle at the core of ABA is the idea that the consequences of a behavior can either strengthen or weaken it; behavior that is followed by the presentation of desirable consequences will be strengthened (reinforcement), whereas behavior that is followed by aversive consequences or the removal of desirable consequences will be weakened.

A defining feature of ABA programs is that they are applied consistently. This is accomplished by the use of explicitly written programs for each skill to be taught or maladaptive behavior to be treated, and by having the behavioral analyst train everyone who works with the child to implement it. To increase the likelihood of the generalization of the treatment efforts, it is critical for the therapists and parents to be trained to implement the programs across situations, settings, and people. Typically, teaching trials are repeated until they are mastered. Maladaptive behaviors such as aggression and self-injury are not reinforced, whereas specific, appropriate alternative behaviors are either taught or maintained through positive reinforcement. Each child's program is unique to his/her needs that evolve with the child's progress. Accurate records are kept so that progress can be assessed, and programmatic changes made (Spreckley 2009, Granpeesheh 2009).

Treatment based on APA represents a wide range of early intervention strategies for children with autism. As indicated earlier, the first types of behavioral treatment programs developed, the discrete trial training, were very intensive and structured. Investigators found that children may have difficulty generalizing the information from these very structured sessions to group and community settings. One comprehensive intervention program reviewed by the National Research Council (NRC) was early intensive behavioral intervention (EIBI) based on the UCLA Young Autism Project Model. This is an intensive home-based program using the manual published by Lovaas and involves up to 40 hours of therapy per week for at least 2 years. Other EIBI programs were developed by other researchers (Howlin 2009, Reichow 2009).

Less structured more naturalistic behavior programs e.g. incidental teaching and pivot response training (PRT) have been developed but were not researched in a randomized controlled fashion. Currently, even structured sessions include naturalistic methods for increasing generalization and maintenance. Parent mediated interventions have been reported to be an important aspect of intervention. Overall, structured programs share a common core of set features including: 1. starting the intervention at the earliest possible age (3-4 years), 2. Intervention is intensive (20-40 hours per week), 3. Intervention is individualized, comprehensive, and targeting a wide range of skills, 4. Multiple behavior analytic procedures are used to develop adaptive repertoires, 5. Treatment is delivered in one-to-one format with gradual transition to group activities and natural contexts, 6. Treatment goals are guided by normal developmental sequence, and 7. Parents are, to different extents, trained and become active co-therapists (Levy 2009, Virues-Ortega 2010).

Medical Technology Assessment Committee (MTAC)

ABA Therapy

04/19/2010: MTAC REVIEW

Evidence Conclusion: There is lack of published well-conducted randomized controlled trials on behavioral interventions for young children with autism. The published trials had their limitations; they had small sample sizes, the majority were not randomized, the participants were frequently diagnosed without using standardized tools, the studies examined different treatments, with different delivery approaches and intensities, over different time spans (ranging from 12 weeks to 2 years) and had different measurement approaches for assessing outcomes. IQ was a major outcome for the majority of studies, and it might not be possible to determine whether an improved IQ results from true improvement of cognitive skills, or better test taking ability. In addition, IQ is not necessarily the main problem in autistic functioning. Autism treatment needs to address every developmental area, all areas of adaptive behavior, and then a whole set of aberrant behavioral responses, involving both positive and negative symptoms (Rogers 2008). A number of systematic reviews and meta-analyses of the published studies were conducted by several authors. The methodology of the analyses was valid in general, however even a well conducted meta-analysis is only as good as the studies it includes. The studies on intensive

Back to Top

behavioral intervention, as indicated earlier, had their limitations and biases and varied widely in the treatments intensity, duration, mode of delivery, and outcome measures; all of which limits generalization of the pooled results. The meta-analyses either pooled the results of controlled studies only or all studies with or without comparison groups. Their results were conflicting, while, Virues-Ortega (2010), Eldevik (2009), Reichow (2009), Howlin (2009) and others show that that ABA /EIBI interventions were associated with improved outcome (primarily measured by IQ) among some children with autism, Ospina (2008) and Spreckley et al (2009) showed no statistically significant additional benefit of APA/EIBI intervention vs. other interventions applied to young children with ASD.
Dawson and colleagues' study (2010), a more recently published randomized controlled trial with valid methodology, can be considered the most rigorous RCT on comprehensive development behavioral intervention. The authors randomized 48 young children to receive Early Start Denver Model (ESDM), a comprehensive behavioral intervention, or to be referred to community providers for intervention commonly available in the community. They were followed up for 2 years and the primary outcome was change in Mullen Scales of Early learning (MSEL) and the Vineland Adaptive Behavior Scales (VABS) composite standard scores. The results of the trial suggest that very young children with autistic disorders may achieve higher cognitive and adaptive scores and improvement in diagnosis after a 2-year comprehensive intervention strategy that includes parental involvement. The study however does not allow determining if the benefits gained would be sustained over time. Conclusions: There is insufficient evidence from well-conducted large randomized comparative trials with long term follow-up to determine which comprehensive treatment approach is best for young children with autism, and in particular the most effective treatment for teaching specific skills given certain profiles and characteristics of the child.
Articles: The literature search revealed around 100 articles on ABA/ EIBI for young children with autism. The majority were reviews or articles not related to the current review. There were at least 6 systematic reviews with or without meta-analyses on ABA /EIBI intervention for young children with autism. A small more recent RCT (N=48) on the Early Start Denver Model for toddlers with autism was identified. The search also revealed a systematic review by Clinical Evidence on all interventions for autism including early multidisciplinary interventions based on APA and including home-based, school based, community based or multisite interventions.
Three of the meta-analyses on ABA/EIBI for young children were selected for critical appraisal as well as the recently published randomized trial. Dawson G, Rogers S, Munson J, et al. Randomized controlled trial of an intervention for toddlers with autism: The Early Start Denver Model, Pediatrics 2010;125:1:e17-e23 See Evidence Table Eldevik S, Hastings RP, Hughes JC, et al. Meta-analysis of early intensive behavioral intervention for children with autism J Clin Child Adolesc Psych 2008;38:439-450 See Evidence Table
Spreckley M, Boyd R. Efficacy of applied behavioral intervention in preschool children with autism for improving cognitive, language, and adaptive behavior: A systematic review and meta-analysis. J Pediatr 2009; 154:338-344. See Evidence Table Virues-Ortega J. Applied behavioral analytic intervention for autism in early childhood: Meta-analysis, meta-regression and dose-response meta-analysis of multiple outcomes. Clinical Psychology Review. 2010 , doi:10.1016/j.cpr.2010.01.008 See Evidence Table

The use of applied behavioral analysis therapy (ABA), early intensive behavior interventions (EIBI) for the treatment of young children with autism does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

References

Dawson G, Rogers S, Munson J, Smith M, Winter J, Greenson J, Donaldson A, Varley J. Randomized, controlled trial of an intervention for toddlers with autism: the Early Start Denver Model. Pediatrics. 2010 Jan;125(1):e17-23. doi: 10.1542/peds.2009-0958. Epub 2009 Nov 30. PMID: 19948568; PMCID: PMC4951085.

Spreckley M, Boyd R. Efficacy of applied behavioral intervention in preschool children with autism for improving cognitive, language, and adaptive behavior: a systematic review and meta-analysis. J Pediatr. 2009 Mar;154(3):338-44. doi: 10.1016/j.jpeds.2008.09.012. Epub 2008 Oct 31. PMID: 18950798.

Virués-Ortega, Javier. Applied behavior analytic intervention for autism in early childhood: Meta-analysis, meta-regression and dose–response meta-analysis of multiple outcomes, Clinical Psychology Review, Volume 30, Issue 4, 2010, Pages 387-399, ISSN 0272-7358. Doi:10.1016/j.cpr.2010.01.008. https://www.sciencedirect.com/science/article/pii/S0272735810000218

Washington State Legislature. (2023, February 20). *How do I show that I have autism as an eligible condition?*. WAC 388-823-0500: https://apps.leg.wa.gov/wac/default.aspx?cite=388-823-0500

Applicable Codes

Back to Top

Providers must use the following codes to obtain reimbursement for ABA and ABA-related services

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes
97153 (with HO Modifier)	Adaptive behavior treatment by protocol, administered by physician or other qualified health professional, face-to-face with one patient.
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Creation Date	Review Date	Date Last Revised
05/07/2010	05/04/2010 MDCRPC, 05/03/2011 MDCRPC, 04/03/2012 MDCRPC, 12/04/2012 MDCRPC ,10/03/2013 MPC ,12/03/2013 MPC, 08/05/2014 MPC, 11/04/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC, 08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC	11/07/2023

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
02/07/2017	Revised ABA criteria for commercial members
12/05/2017	MPC approved to delete indication related to school coverage for ABA Therapy (commercial members, except MS)

Back to Top

01/09/2018	MPC approved to modify criteria to remove any language regarding school practices
11/01/2018	Removed the H codes and added the ABA Reimbursable Services
08/06/2019	Revised ABA criteria for commercial members and updated background information to highlight ITP updates
07/06/2021	MPC approved to adopt updates to clinical criteria for Non-Medicare members, with the exception of Microsoft, as there is separately maintained criteria for Microsoft members. Revisions made to clarify requirements, and a new requirement was added for two or more developmental and behavioral assessments used to measure gaps in functioning instead of one. Updated applicable coding to exclude H2017, 0362T, and 0373T. Requires 60-day notice, effective date 10/01/2021.
08/03/2021	Format change: merged separate non-Medicare criteria into main page (Microsoft criteria still a separate document)
01/03/2022	Updated Microsoft SPD language from 2022 document - replaced the terms child or dependent with ‘member’ throughout.
10/04/2022	MPC approved to modify ABA criteria to clarify coverage language.
11/07/2023	MPC approved to edit language in the current policy to reference WAC 388-823-0500 and align clinical criteria language of provider types with the WAC. MPC should remove lack of parental involvement with ABA treatment from discharge criteria but maintain parent/guardian coaching plan as an integral component of ABA treatment plan requirements.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Ankle Brachial Index Device

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Ankle Brachial Index Device*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Peripheral artery diseases (PAD) are atherosclerotic diseases resulting in occlusion of peripheral arteries (abdominal aorta, iliac, and lower extremity arteries). The prevalence of lower extremity PAD, around the globe, is estimated at 3 to 12% (Hirsch et al., 2006; Norgren et al., 2007; Olin & Sealove, 2010). Patients may experience rest pain, ulceration, claudication, hospitalizations, and even amputation of limb. PAD may also be asymptomatic. The rate of myocardial infarction, stroke, and cardiovascular mortality is significantly increased with PAD (Olin & Sealove, 2010).

Several risk factors have been identified. However, The American College of Cardiology/American Heart Association (ACC/AHA) guidelines on PAD have recognized specific risk groups with a higher prevalence of PAD. These include age ≥ 70 years, age 50 to 69 years with a history of diabetes or smoking, age 40 to 49 with diabetes and at least one other risk factor for atherosclerosis, leg symptoms indicative of claudication with

Back to Top

exertion or ischemic pain at rest, abnormal lower extremity pulse examination, known atherosclerosis at other sites (coronary, carotid, renal artery disease) (Hirsch et al., 2006).

Ankle-brachial-index (ABI) using doppler is one of the tests used to diagnose peripheral artery disease (PAD). It measures the ratio of the systolic ankle to brachial pressure. PAD is defined by an ABI ≤ 0.9. However, studies have reported a low utilization of the ABI due to lack of skills to perform the procedure (Mohler et al., 2004). ABI is also incorrectly used in primary care (Davies, Kenkre, & Williams, 2014; Nicolai et al., 2009). In addition, the procedure is time consuming and this might contribute to its low use in busy healthcare centers (Davies et al., 2014; Nicolai et al., 2009). These limitations result in underdiagnosis and undertreatment of PAD.

Several automated ABI devices have been developed to overcome the limitations of Doppler ABI. These encompass devices using oscillometric technology and plethysmographic-based technology. Oscillometric-based devices seem to be less accurate (Verberk, Kollias, & Stergiou, 2012) in computing ABI.

The plethysmographic method is based on reperfusion plethysmography. “A dual-chamber cuff applied to each limb consists of an upper occlusion chamber and a lower detection chamber. When the pressure of the upper occlusion chamber has exceeded arterial systolic pressure, the distal detection chamber detects a gradual decrease in limb volume as a result of blood redistribution in the absence of arterial blood inflow. As the pressure in the occlusion chamber is then incrementally reduced and reaches systolic pressure, arterial blood flow to the limb is restored, which is detected as a volume increase in the lower chamber. The pressure in the upper occlusion chamber at the point when this lower chamber volume increase occurs, is taken as the limb arterial systolic pressure” (Davies & Williams, 2016).

Several manufacturers have developed automated ABI machines using plethysmography technology. Manufactured by Huntleigh Diagnostics, Cardiff, UK, the Dopplex Ability is an automated device that measures ankle-brachial index (ABI) and pulse volume recordings (PVR). It uses air plethysmography technology to perform these assessments (Millen et al., 2018). The Dopplex ability provides fast and easy measurements with a printout of results from integrated software package. ABI’s are computed in three minutes (without the need to rest the patient), interpreted and displayed with pulse volume waveforms on LCD panel. The Dopplex ability system includes Dopplex ability automatic machine, one box of disposable sleeves, four pieces set of standard 8½"-14"cuffs, one pack of standard thermal paper, and one set of adhesive paper. The Dopplex ability is intended for wound care for arterial disease before deciding on compression bandaging. It is also considered for PAD detection, and congestive heart disease screening (identification of risk factors) (https://www.usamedicalsurgical.com/huntleigh-dopplex-ability-automatic-abi-system/). Other manufacturers include Newman Medical (USA), Enverdis, Skidmore Medical.

Medical Technology Assessment Committee (MTAC)

Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease
04/08/2019: MTAC REVIEW

Evidence Conclusion:

Low evidence suggests that automated ABI device using plethysmographic method (Dopplex Ability) shows:

- moderate agreement with doppler manual method and low reliability
- moderate sensitivity along with high specificity and accuracy for detection of PAD in comparison with the Doppler method as a gold standard
- a conflicting proportion of failing measurements

More studies are needed to clarify whether Dopplex Ability alone can provide enough diagnostic accuracy

Articles: PubMed was searched through March 15, 2019. Search terms include ((ABI automated system OR Dopplex Ability)) AND (peripheral artery disease OR PAD). Other terms consist of Automated plethysmography AND ankle-brachial index AND doppler ultrasound. SimpleABI system OR simpleABI automated system OR ABI Doppler system OR ABI automated system was searched. Google scholar was also searched. The search was limited to English language publications and human populations. RCTs and observational studies were included as filter in the search. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table**.**

The use of Ankle-Brachial Index device using plethysmographic method for the diagnosis of peripheral artery disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No Specific Codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
05/07/2019	05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC], 03/12/2024[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt a non-coverage policy for Ankle Brachial Index Device

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Advanced Care at Home

Criteria

For Medicare & Non-Medicare Members

As of 01/01/2023 as groups renew (please check member's contract as some groups may renew later in the year), this criteria/benefit will apply to the following plans:

- Most fully insured Large Commercial groups (Exceptions: FEHB Core and Options who have opted out for 2023 and groups with rider AR-Y)
- Self-Funded Large Commercial groups (please note: groups are able to opt out)
- Individual Medicare (all plans except the Basic plan)
- Employer Group Medicare (please note: custom groups are able to opt out)

A. To receive advanced care in the home, the member must meet **ALL of the following:**
   - The member must be referred into the advanced care program by the managing provider such as in an emergency room setting
   - Advanced Care at Home requires preauthorization based on the member's health status, treatment plan, and home setting or another appropriate care location within the service area
   - The clinical condition must meet inpatient medical necessity criteria, per MCG care inpatient hospitalization guidelines appropriate to the patient's clinical condition
   - The member must consent to receiving advanced care described in the treatment plan
   - The care location, such as the member's residence, must be within 30 minutes ground travel time of an emergency department **AND**
   - The care location, such as the member's residence, must have cell service

B. Advanced Care at Home is provided through Medically Home, Kaiser Permanente's network provider, and will provide the following services in the member's home or appropriate care location:
   - Home visits by RNs, physical therapists, occupational therapists, speech therapists, respiratory therapists, nutritionist, health aides, and other healthcare professionals in accordance with the Advanced Care at Home treatment plan and the provider's scope of practice and licensure.
   - Communication devices to allow the member to contact the medical command center 24 hours a day, 7 days a week. This includes needed communication technology to support reliable connection for communication, and a personal emergency response system alert device to contact the medical command center if the member is unable to get to a phone.

C. Additional services covered under this benefit include:
   - The following equipment necessary to ensure that the patient is monitored appropriately in home: blood pressure cuff/monitor, pulse oximeter, scale, and thermometer
   - Mobile imaging and tests such as X-rays, ultrasounds, and EKGs
   - Safety items when medically necessary, such as shower stools, raised toilet seats, grabbers, long handled shoehorn, and sock aids
   - Meals when medically necessary while patient is receiving advanced care at home

Back to Top

In addition, the following services and items are covered under this benefit when prescribed as part of the Advanced Care at Home treatment plan:

- Durable Medical Equipment
- Medical Supplies
- Member transportation to and from network facilities when member transport is medically necessary
- Physician Assistant and Nurse Practitioner house calls
- Emergency Department visits associated with this benefit

Exclusions: Private Duty Nursing; housekeeping or meal services not part of the Advanced Care at Home treatment plan; any care provided by or for a family member; any other services rendered in the home which are not specified in the member's Advanced Care at Home treatment plan

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Advanced Care at Home is a personalized, patient-centered program that provides care for patients with certain clinical conditions in their homes, or at another appropriate care location.

Advanced Care at Home services must be associated with an acute episode and the treatment plan may include restorative care associated with the acute episode. The duration of an episode of care (which includes acute and restorative phases) is limited to a total of 30 days.

Applicable Codes

Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
08/02/2022	08/02/2022[MPC], 08/01/2023[MPC]	

[MPC] Medical Policy Committee

Revision History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Autologous Chondrocyte Implantation for Treatment of Defects in Articular Cartilage of the Knee

- Matrix Autologous Chondrocyte Implantation (MACI)
- Microfracture
- Mosaicplasty
- Osteochondral Autograft Transfer System (OATS)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Autologous Chondrocyte Implantation,” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Autologous Chondrocyte Implantation (ACI) Matrix Autologous Chondrocyte Implantation (MACI)	Autologous chondrocyte implantation (ACI) or autologous chondrocyte transplantation (ACT) using the MACI™ implant is considered medically necessary when **ALL** of the following criteria have been met: • Documentation should support why an alternative cartilage restoration procedure such as OATS are contraindicated • Symptomatic single or multiple full-thickness cartilage defects of the femoral condyle, patella, or trochlea with normal surrounding cartilage (Modified Outerbridge Classification grade III or IV*) and no evidence of degenerative disease such as osteoarthritis • Severe disabling knee pain limiting ambulation • Absence of systemic disease (gout, rheumatoid arthritis, etc.) • Failure of at least 3 months of provider-directed conservative therapy such as physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs (NSAIDs) • Patient is skeletally mature (closed growth plates) and not a candidate for arthroplasty (age 15 – 55) • Knee is stable with intact or reconstructed ligaments (ACL or PCL) and menisci. A concurrent ligament stabilization or meniscal procedure at the time of ACI would be acceptable • No more than 50% partial meniscectomy in the target knee

Back to Top

Date Sent: 4/29/24

<table>
<tr><td></td><td>

Defect(s) are unipolar – there is no corresponding kissing lesion on facing cartilage
Lesion is greater than 1.0cm^{2**} (too large for bone stimulation) and less than 10cm^2, or the lesion is less than 1.0cm^2 and patient has previously failed marrow stimulation for that lesion
Has not had any knee joint surgery within the past 3 months (excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant)
Normal tibial-femoral and/or patella-femoral alignment based on weight-bearing alignment x-rays, or osteotomy is planned
BMI less than or equal to 35
Patient is able and willing to follow post-operative protocol (6 weeks limited weight bearing)
Must be authorized by Kaiser Permanente Medical Director in consultation with Orthopedics

*Modified Outerbridge Classification
The Outerbridge classification is a grading system for joint cartilage breakdown.
<table>
<tr><th></th><th>MRI Results</th></tr>
<tr><td>GRADE I</td><td>focal areas of hyperintensity with normal contour</td></tr>
<tr><td>GRADE II</td><td>blister-like swelling/fraying of articular cartilage extending to surface</td></tr>
<tr><td>GRADE III</td><td>partial thickness cartilage loss with focal ulceration</td></tr>
<tr><td>GRADE IV</td><td>full thickness cartilage loss with underlying bone reactive changes</td></tr>
</table>
**Lesions less than 1.0cm^2 should be treated with marrow stimulation
</td></tr>
<tr><td>Osteochondral Autograft Transfer System (OATS) or Mosaicplasty 27416, 29866
Microfracture (MFX)* 29879</td><td>Does not currently require medical review.</td></tr>
</table>

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Articular hyaline cartilage is a highly specialized connective tissue that covers the surface of bone in synovial joints. It is a 2-4mm thick hyaline cartilage that provides smooth low friction movement and shock absorption. Unlike most tissues, articular cartilage does not have blood vessels, nerves, or lymphatics. It is composed of a dense extracellular matrix (ECM) with a sparse distribution of highly specialized cells called chondrocytes. The ECM is principally composed of water, collagen, and proteoglycans, with other non-collagenous proteins and glycoproteins present in lesser amounts. These components help to retain water within the ECM, which is critical to maintain the unique mechanical properties of the cartilage (Fox 2009, Negrin 2013, Oussedik 2015).

The articular cartilage is prone to damage from acute high energy trauma and from repetitive shear and torsional forces applied to the surface. Lesions to the articular cartilage are often associated with pain and compromised joint function and may lead to the development and progression of osteoarthritis. The damaged cartilage has very limited capacity for self-repair due to its avascular and hypocellular nature. Surgery has thus been the standard approach for repairing articular cartilage damage. Surgical techniques intended for restoring the articular surface are classified into 3 categories: 1. Marrow stimulation procedures such as microfracture, 2. Cell-based implantation, and 3. Osteochondral grafting. Surgical interventions have also been categorized as 1. Reparative, which includes marrow stimulation such as microfracture; drilling; and abrasion arthroplasty, and 2. Reconstructive that includes allograft transplantation; osteochondral autograft transplantation (OAT); and

Back to Top

autologous chondrocyte implantation (ACI). Investigators suggest that microfracture surgeries is more effective than reconstructive surgeries for the repair of smaller cartilage defects (<100mm2) while reconstructive surgeries are more effective for larger defects (>100mm2) (Crawford 2012, Perera 2012, Negrin 2013, Mundi 2015, Li 2015).

Currently, marrow stimulation through microfracture is the standard first-line surgical treatment for articular cartilage lesions of the knee. The microfracture technique was developed by Steadman in the early 1980s. It is a single-stage arthroscopic procedure that involves penetrating the subchondral bone plate after removing the damaged hyaline cartilage. Bleeding from the subchondral bone forms a clot that attracts bone marrow cells to migrate into the cartilage defect and create a 'super clot' that eventually matures into a firm repair tissue consisting of a combination of fibrous and hyaline-like cartilage. The technique is minimally invasive, technically simple, and is associated with low morbidity. However, the repair is composed of fibrocartilaginous tissue, which is mechanically inferior to the native hyaline cartilage; it has less ability to withstand shock and shearing forces leading to deterioration in function over time. In addition, the bone marrow stem cells and growth factors are released into the joint rather than being contained in the site of the defect. Some researchers suggest that microfracture is more effective in reducing pain and improving joiny function when performed for new injuries, small focal injuries, and in younger individuals with lower body mass index (Crawford 2012, Negrin 2013, Lee 2014, Mundi 2015).

Osteochondral autograft transfer (OAT), also known as osteochondral cylinder transplantation or mosaicplasty, is a whole tissue transplantation procedure that was developed in the 1990s for hyaline cartilage repair. It is a surgical technique that uses osteochondral grafts taken from the lighter-load bearing areas of the patient's own joint to fill the focal defects. There is a concern however, with the donor site morbidity, and thus the technique may not recommend for lesions larger than 400mm2 (Li 2015, Mundi 2015).

Autologous chondrocyte implantation (ACI), also known as autologous chondrocyte transplantation is a cell-based method that was introduced in the late 1980s for the treatment of symptomatic full thickness cartilage defects of the knee. The first generation of ACI (ACI-P) is a two-stage procedure. First, a cartilage biopsy is harvested from healthy cartilage of the affected knee during an arthroscopic biopsy procedure. The specimen of live articular cartilage is sent to a cell expansion laboratory for chondrocyte culture. The cells are separated from the cartilage under a strictly controlled environment, and then multiplied using a cell-culture technique for 3-6 weeks. The cultured chondrocytes are then implanted into the cartilage defect in an open arthrotomy procedure. This procedure involves removing a periosteal flap from the proximal medial tibia, suturing it to the surrounding rim of normal tissue, and implanting the expanded chondrocytes beneath the flap to start filling the defect by producing a matrix. Unlike the MS techniques, it is reported that ACI has the ability of repairing the defect by a hyaline-like cartilage with a hybrid of fibrocartilage and hyaline like tissue, or with fibrocartilaginous material containing type-1 and type II collagen. ACI-P is an invasive, technically complicated procedure that involves two operations, has a long recovery time, and requires extensive post-surgical rehabilitation. The technique has variable success rate and may be associated with periosteal hypertrophy and overgrowth that would require additional surgeries (Crawford 2012, Niemeyer 2014, Mundi 2015).

Several modifications to the first generation ACI-P have been made to reduce the procedural technical demands associated with the tissue harvest and the use of periosteal flap in order to decrease the surgical morbidity and prevent periosteal hypertrophy and overgrowth. These modifications were described as second and third generations. The second generation ACI (ACI-C) uses bioengineered bilayer collagen covers to substitute for the periosteal flap and avoid the spill over and asymmetric distribution of chondrocytes following implantation. The third generation ACI explores the use of biomaterials to construct a 3-dimensional scaffold for chondrocyte implantation; the all-in-one grafts do not need a periosteal cover or fixing stitches and can be trimmed to fit the cartilage defect with fibrin glue. It has been reported that implantation of third generation ACI can be performed arthroscopically or with a small incision (Vasiliadis 2010, Kuroda 2011, Crawford 2012, Negrin 2013, Mundi 2015, Samsudin 2015).

Medical Technology Assessment Committee (MTAC)

Autologous Chondrocyte Implantation

02/14/2001: MTAC REVIEW

Evidence Conclusion: The existing evidence is not sufficient to determine the effect of ACI on health outcomes. The only data available are from case series report that have compromised validity and are not considered to provide high quality data. Each of the two case series articles evaluated had additional limitations beyond study type including providing little information about possible adverse effects. Peterson and colleagues are involved with a prospective randomized trial of autologous chondrocyte transplantation compared to periosteum alone or

Back to Top

subchondral drilling for the treatment of primary chondral lesions of the femoral condyle. Results of this study will provide higher-quality data.
Articles: Fourteen articles were identified. Eleven articles were not directly relevant, did not include clinical outcomes or were review articles; three articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were no meta-analyses or randomized controlled trials. The three empirical articles were all case series. Sample sizes were 8 patients, 44 patients and 94 patients. An evidence table was created for the two-case series reports with the largest number of patients: Peterson L, Minas T, Brittberg M, Nilsson A, Sjogren-Jansson E, Lindahl, A. Two-to-9-year outcome after autologous chondrocyte transplantation of the knee. Clin Orthop 2000; 374: 212-234. See Evidence Table. Minas T. Chondrocyte implantation in the repair of chondral lesions of the knee: Economics and quality of life. Am J Orthop 1998; 27: 739-44. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/17/2003: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: There were two small randomized controlled trials (Bentley et al, n=100.; Horas et al., n=40). Neither provided strong evidence that autologous chondrocyte implantation is superior to an alternate procedure for repairing osteochondral defects in the knee. The Bentley study was larger and had stronger methodology. The authors found that the overall clinical results did not differ significantly between groups (autologous chondrocyte implantation compared to mosaicplasty), but that, among the 51 patients with medial femoral defects, the autologous chondrocyte group had better post-operative knee function. The one-year arthroscopic data in the Bentley study was compromised because 40% of patients were missing from the analysis. The Horas study had inadequate randomization and several additional threats to validity. They found worse post-operative knee instability in the autologous chondrocyte transplantation group compared to a group receiving autologous osteochondral cylinder transplantation and no significant differences between groups on the two other primary measures.
Articles: Bentley G, Biant LC, Carrington RWJ et al. A prospective, randomized comparison of autologous chondrocyte implantation versus mosaicplasty for osteochondral defects in the knee. *J Bone Joint Surg (Br)* 2003; 85-B: 223-230. See Evidence Table. Horas U, Pelinkovic D, Aigne T, Schnettler R. Autologous chondrocyte implantation and osteochondral cylinder transplantation in cartilage repair of the knee joint. *J Bone Joint Surg (Br)* 2003; 85-A: 185-192.See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/14/2004: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: The evidence consists of three controlled trials (2 randomized, 1 pseudo-randomized), all comparing autologous chondrocyte implantation to other surgical procedures to restore articular cartilage. There are no sham controlled studies. None of the studies found significantly better clinical outcomes with ACI compared to the alternative intervention 1-2 years post-surgery; some may have been underpowered. Knutsen et al, the strongest study methodologically, found better results for the group receiving microfracture on one key outcome, the physical component score of the SF-36. The Bentley study found better histological results in the ACI group, but this analysis included only 60% of the randomized patients. In summary, ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture.
Articles: The Medline search yielded 42 articles, many of which were on technical aspects of the procedure or on related technologies. There were three randomized controlled trials and all three were critically appraised. References are as follows: Knutsen G, Engebretsen L, Ludvigsen TC. Autologous chondrocyte implantation compared with microfracture in the knee. *J Bone Joint Surg* 2004; 86-A: 455-464. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/05/2006: MTAC REVIEW
Autologous Chondrocyte Implantation
Evidence Conclusion: One new RCT compared autologous chondrocyte implantation to an alternative procedure. The study (Dozin et al., 2005) did not find a significant difference in the clinical success rate of patients

Back to Top

who received ACI or mocaicplasty. The study was underpowered to detect a clinically meaningful difference between groups due to low compliance rate. Only 12/22 (54%) in the ACI group and 11/22 (50%) in the mosaicplasty group actually received the surgery, which occurred 6 months after an initial debridement. The best evidence on ACI for treatment of defects in articular cartilage of the knee remains the randomized controlled trials reviewed in 2004. The conclusion from the previous MTAC report was: The evidence consists of three controlled trials (2 randomized, 1 pseudo-randomized), all comparing autologous chondrocyte implantation to other surgical procedures to restore articular cartilage. There are no sham controlled studies. None of the studies found significantly better clinical outcomes with ACI compared to the alternative intervention 1-2 years post-surgery; some may have been underpowered. Knutsen et al, the strongest study methodologically, found better results for the group receiving microfracture on one key outcome, the physical component score of the SF-36. The Bentley study found better histological results in the ACI group, but this analysis included only 60% of the randomized patients. In summary, ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture. A 2005 technology assessment conducted by the National Institute for Health and Clinical Effectiveness (NICE) in England concluded that there is inconsistent evidence on the clinical effectiveness of ACI and did not recommend ACI except in the context of ongoing clinical trials.
Articles: Three new randomized controlled trials were identified. Two trials, one by Bartlett and colleagues and the other by Gooding and colleagues, were not evaluated further because they compared two types of autologous chondrocyte replacement and did not include a control group that received an intervention other than ACI. (In addition, the Gooding study was only available as an abstract). The other trial compared ACI and mosaicplasty and was critically appraised: Dozin B, Malpeli M, Cancedda R et al. Comparative evaluation of autologous chondrocyte implantation and mosaicplasty. Clin J Sport Med 2005; 15: 220-226. See Evidence Table.

The use of Autologous Chondrocyte (Carticel®) Implantation for Treatment of Defects in Articular Cartilage of the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/21/2016: MTAC REVIEW
Autologous Chondrocyte Implantation (Autologous Chondrocyte Transplantation) For the Treatment of Chondral Defects in the Knee
Evidence Conclusion: Autologous chondrocyte Implantation (Carticel, the first generation) was previously reviewed by MTAC, four times between 1998 and 2006. At the time the best published evidence consisted of four controlled trials (three randomized and one pseudo-randomized), none of which found significantly better clinical outcomes with ACI compared to the alternative interventions at 1-2 years post-surgery. Knutsen, et al (2004), the strongest study methodologically, at the time, found better results for the group receiving microfracture on one key outcome (the physical component score of the SF-36). The Bentley et al's study (2003) found better histological results in the ACI group, but the analysis included only 60% of the randomized patients. In summary the 2006 report concluded that ACI does not provide a clear clinical advantage over other surgical procedures to heal cartilage injuries and may be inferior to microfracture. The updated literature search for the current re-review of ACI, identified a number of published comparative and non-comparative studies evaluating the effectiveness of ACI, marrow stimulation (MS, mainly with MF techniques), and OAT, in improving the clinical outcomes of patients with cartilage lesions in the knee. Different ACI generations and techniques were evaluated and /or compared to other interventions used for restoring knee function. The published studies were relatively small, and in addition to the variations in the surgical techniques and approaches used for ACI and other procedures, there were differences between the studies in the criteria for patient selection, lesion sizes, outcomes, duration of follow-up, and measures used to evaluate histological and/or functional outcomes. In addition, none of the trials was blinded and pain and function measures mainly relied on subjective evaluation, which may bias the results. Few studies showed minimal differences between ACI compared to MF, or OAT, and many others found no significant differences in outcomes with the different surgical techniques. The majority of the studies were underpowered to detect statistical differences, and a lack of significant differences between procedures does not necessarily indicate that they are equivalent or have similar effects. Combining the studies into meta-analyses increases the power, but the significant heterogeneity between the published studies on the treatment of chondral lesions in the knee precluded pooling the results of the individual studies in many cases, and/or performing subgroup analyses to determine the optimal procedure to the patient according to the lesion size, type of activity, comorbidity, and other characteristics. Few authors cautiously pooled the results of studies into meta-analyses, but these have to be interpreted with caution as the results of a meta-analysis are as good as the quality of the studies it includes.
ACI versus microfracture (MF): Mundi and colleagues (2015) (Evidence Table 1), performed a systematic review and meta-analysis of RCTs to compared ACI, MF, and OAT. The authors could only pool the results of the studies comparing ACI versus marrow stimulation (MS), mainly using the microfracture (MF) technique. The meta-analysis had valid methodology and analysis, but the included studies had their limitations, and were significantly heterogeneous. The overall pooled results showed no significant difference between ACI and MF in improving knee function and pain at intermediate-term follow-up. Oussedik and colleagues (2015) performed a systematic review to compare the outcomes of MF and ACI in patients with articular cartilage lesions of the knee.

Back to Top

The review included 34 articles only 9 of which were comparative studies, the rest were observational with no control groups, and 2 were animal model studies. The authors could not pool the results of the comparative studies into a meta-analysis due to the significant heterogeneity between the studies. They concluded that low quality (grade IV) evidence suggests that MF may be effective in smaller lesions and is usually associated with a greater proportion of fibrocartilage production which may affect its durability. They also suggested that the multiple lesions treated with MF have poorer outcomes compared with single lesions. ACI was an effective treatment that may result in a greater proportion of hyaline-like tissue at the repair site, appears to be effective for larger lesions. The authors noted however, that the variation in techniques and modifications used for repairing chondral lesions of the knee, together with the different outcomes and measures used, and lack of long-term follow up make it hard to compare techniques and /or determine the optimal procedure for the different patient groups. Negrin and colleagues (2013) (Evidence Table 2), conducted a systematic review and meta-analysis to compare the clinical outcomes of MF and ACI after equal follow-up periods. The review included 7 RCTs and 2 observational studies with at least one-year follow-up. The meta-analysis had some disadvantages which may limit generalization of its results. It included a small number of studies with relatively small population sizes, and the authors pooled the results of the RCTs together with the observational studies that used different scores and values for assessing the outcomes. They performed two meta-analyses: the first included all three ACI generations, and the second only included the second and third generations. The first analysis showed a small statistically insignificant difference between MF and all three ACI generations combined after 1 year, and the second meta-analysis showed a significant improvement with ACI after the first-generation study (Knutsen et al, 2007) was excluded. The authors noted however, that the observed statistically significant difference was clinically irrelevant. They indicated that the two procedures are complementary, and that large RCTs with long-term follow-up are needed to determine which groups of patients would benefit more from each procedure. Vanlauwe J, and colleagues (2011) published 5-year follow up results of an earlier study (Saris et al, 2008) that compared ACI using characterized chondrocyte implantation (CCI) (ChondroCelect, Belgium) vs. MF in 118 patients with a single symptomatic cartilage defect in the knee. The study had 90% power to detect a significant difference in the success rate between the two techniques. The first article reporting the results of one-year follow up showed significant clinical improvement with the two techniques when compared to baseline. There were no significant differences between the two procedures in the short-term clinical outcomes or complication rates, but the tissue regenerate was superior with ACI. The published 5-year results showed that the clinical improvements reported at 12 months and 24 months were maintained for the duration of follow-up. There were no significant differences between the two groups in clinical outcomes, radiological outcomes, or treatment failures. However, the latter tended to occur earlier with MF (in those treated in less than 3 years from onset of symptoms). Subgroup analyses showed no significant differences by age (at 35 years cutoff), and that females had more treatment failures irrespective of the procedure they underwent. Knutsen and colleagues' (2007) long-term follow-up results of the RCT that compared first generation of ACI vs. MF (published in 2004 and reviewed earlier by MTAC) showed no significant difference between the two techniques in the clinical or radiological outcomes at 5 years posttreatment. There was a 23% failure rate (need for a reoperation due to lack of healing) in each of the treatment groups at 5 years compared to only 2.5% failures in the MF and 5% with ACI at 2 years. Younger patients (<30 years of age) had better outcomes than older patients irrespective of the treatment group. One third of the patients had radiographic evidence of early osteoarthritis at 5 years. The authors noted that the study was limited by only including patients with chronic symptomatic cartilage defect of the knee, and by the lack of a control group that did not undergo surgical treatment or who were simply treated with arthroscopic lavage. The authors concluded that further long-term follow-up is needed to determine if one method is superior to the other, and to study the progression of osteoarthritis. ***ACI versus Osteochondral autograft transplantation (OAT)*** Li et al, 2015 (Evidence Table 3) performed a systematic review and meta-analysis of RCTs to compare the efficacy of OAT versus ACI in the treatment of large cartilage defects of the knee. The analysis included 5 relatively small trials two of which evaluated the same cohort at different time periods. There were differences between the studies in the surgical techniques and scoring of outcomes. The authors quantified the results into crude grades for comparisons. The overall pooled results of the trials, after performing a sensitivity analysis suggest that there were no significant differences between OAT and ACI results in the short-term, but ACI has superior outcomes on the long-term. Patients undergoing OAT were more likely to have worse conditions on the long-term when compared to those receiving ACI. The authors explained that the injuries for autografts in OAT, the absence of fill and difference in orientation may influence the patient outcomes and limit further OAT procedures. On the other hand, ACI can be performed repeatedly in the same patient using tissue engineered material. Clave, et al (2016), randomized 55 patients with isolated symptomatic femoral osteochondral defects 2.5-7.5 cm^2 to receive Cartipatch (third generation ACI) or mosaicplasty (OAT). Patients were followed-up or 2 years, and the primary outcome measure was the change in the functional outcome from baseline to month 24 postoperatively. This was subjectively measured by International Knee Documentation Committee (IKDC) score. The investigators could only recruit 55 of the 76 (72%) patients needed to provide sufficient power, 15% of those randomized were lost to follow-up, and only 54% were included in the analysis. The authors indicated that contrary to the hypothesis of the study, the results showed that mosaicplasty was superior to Cartipatch in improving IKDC score 2 years after

Back to Top

surgery. The significant difference between the two procedures was observed for defects measuring ≥ 3.5 cm^2. No significant difference was observed for smaller lesions. The trial was randomized and controlled but had several disadvantages that would limit generalization of its results. It was small in size, the patients were not blinded to the procedure they underwent, only 55% of those randomized were included in the analysis, the outcome was subjective, and the follow-up duration was insufficient to determine the long-term outcomes of the interventions. Bentley and colleagues, 2012 (included in Li et al's 2015 meta-analysis discussed earlier) published 10-year results of an earlier RCT that compared ACI to mosaicplasty among 100 patients with chronic lesions. The mean articular cartilage lesion size was 440.9 mm^2 (range 100-1050 mm^2) in the ACI group, and 399.6 mm^2 (100-2000 mm^2) in the mosaicplasty group. The early results of the trial showed significantly better outcome with ACI at 18 months post-surgery. This has been sustained over the years. At ten years, the functional outcome was significantly better with ACI vs. mosaicplasty when measured by the Cincinnati score, but insignificant with Stanmore-Bentley score. It is to be noted however, that only 15 of 48 patients randomized to OAT were included in the 10-year assessment of function. The failure rate (needed revision operations) was significantly higher in the mosaicplasty group vs. the ACI group (55% and 17% respectively). The pattern of failure was different; the ACI showed a low steady failure rate across 10 years, while the mosaicplasty group remained relatively satisfactory for the first 2 years then experienced a steep failure rate over the next 2 years. ***ACI versus any other treatment for articular cartilage lesions*** Vasiliadis and colleagues, 2010 conducted a systematic review of RCTs and quasi-randomized trials to compare ACI with any other type of treatment (including no treatment or placebo). The authors could not pool the results into a meta-analysis due to the clinical and methodological heterogeneity between the studies. They concluded that the studies show that ACI is an effective treatment for full thickness chondral defects and associated with improvement in clinical outcomes compared to baseline. The published evidence, however, does not suggest any superiority of ACI over other treatments; complications rates were comparable between the different interventions except with an increased graft hypertrophy with ACI-P (the first generation ACI). Mundi and colleagues (2015) (Evidence Table 1), systematic review and meta-analysis of RCTs (discussed earlier) compared ACI, marrow stimulation (MS mainly using MF), and OAT to determine whether a single technique has superior outcomes at an intermediate follow-up period. The review included 11 RCTs (published through April 2014) with a total of 765 patients. 5 trials compared ACI vs MS, 3 compared ACI vs. OAT, and 3 evaluated different generations of ACI. The authors could only pool the results of the RCTs comparing ACI versus MS and found no significant difference between the two procedures in improving function or reducing pain at intermediate term follow-up. They indicated that ACI, MS, and OAT are all generally efficacious in improving symptoms in patients with focal knee cartilage defects, The authors pointed to the limitations and heterogeneity of the published studies and noted that the current best evidence does not show that any of the three techniques is superior to the others in improving the intermediate-term pain and function. They concluded that high quality studies with sufficient power and long-term outcomes are needed before any specific intervention is recommended over others. Samsudin and Kamural (2015) conducted a systematic review to compare different generations of ACI to other treatment modalities. Like many other researchers, they could not pool the results of the trials into a meta-analysis due to the heterogeneity between the studies. They concluded that the literature shows a trend towards similar outcomes when comparing ACI generations with other repair techniques, and that there is insufficient evidence to conclude that that ACI and its newer generations are more effective than other techniques in in repairing articular cartilage defects of the knee. Conclusion: There is insufficient published evidence from adequately powered large RCTs with valid methodology and long-term follow-up duration to determine that ACI and its newer generations are superior to other surgical techniques in repairing articular defects of the knee. The variations between the published studies make it difficult to accurately compare one intervention versus another or to determine the optimal procedure and technique for the individual patient. The literature suggests but does not provide sufficient evidence that the newer generations of ACI may be associated with better long-term outcomes compared to microfracture in patients with larger full thickness, focal chondral defects in the knee.

Articles: The literature search revealed a large number of experimental and observational studies on autologous chondrocyte implantation. Several small randomized controlled studies compared one or more generation ACI with MF, with OAT, or versus another ACI generation. The search also identified a number of systematic reviews with or without meta-analyses on ACI compared to one or more of the other treatment modalities. The more recent meta-analysis comparing ACI with microfracture (Negrin, 2013), a meta-analysis comparing ACI to OAT (Li, 2015), an analysis comparing all three procedures (Mundi, 2015) were selected for critical appraisal. Studies comparing one generation ACI to another generation were excluded from the review. Mundi R, Bedi A, Chow L, Crouch S3 Cartilage Restoration of the Knee: A Systematic Review and Meta-Analysis of Level 1 Studies. *Am J Sports Med.* 2015 Jul 2. pii: 0363546515589167. See Evidence Table. Negrin LL, Vécsei V. Do meta-analyses reveal time-dependent differences between the clinical outcomes achieved by microfracture and autologous chondrocyte implantation in the treatment of cartilage defects of the knee? *Orthop Sci*. 2013 Nov; 18(6):940-948. See Evidence Table. Li Z, Zhu T, Fan W. Osteochondral autograft transplantation or autologous chondrocyte implantation for large cartilage defects of the knee: a meta-analysis. *Cell Tissue Bank*. 2015 Jun 12. See Evidence Table.

Back to Top

The use of Autologous Chondrocyte Implantation (Autologous Chondrocyte Transplantation) For the Treatment of Chondral Defects in the Knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/12/2021: MTAC REVIEW

Matrix-Induced Autologous Chondrocyte Implantation (MACI) for the Repair of Articular Cartilage of the Knee

Evidence Conclusion:

Hayes Review: A large, moderate-quality body of evidence suggests that MACI is associated with improved symptoms, function, QOL, and ability to perform normal ADL for young and middle-aged and typically nonobese adults with symptomatic articular cartilage defects of the knee. Evidence also suggests that benefits may be durable beyond follow-up periods of 5 years. The evidence consistently favors MACI over MFX, and more limited evidence suggests that MACI and older-generation ACI procedures have similar clinical benefit. Evidence comparing MACI with other surgical procedures was too limited to draw conclusions. Although the majority of studies reported few safety concerns, additional studies are needed to further evaluate the comparative safety of MACI. There remains uncertainty as to when MACI is optimally prescribed in the chondral defect treatment hierarchy, and definitive patient selection criteria have not been clearly elucidated.

INTC recommendations/statements: There is sufficient evidence to determine that the technology improves net health outcomes for select patients. There is insufficient evidence regarding the efficacy and safety of the technology as compared to alternative procedures for the indication. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is of insufficient quantity and/or quality. The existing evidence regarding how the technology effectively prevents or diagnoses or treats or manages the health condition is conflicting or inconsistent. There is **no** evidence on the use of this technology in the prevention or diagnosis or treatment or management of this health condition. There is sufficient evidence to determine that the technology does not improve net health outcomes for any patients.

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
27412	Autologous chondrocyte implantation, knee
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/1998	11/11/1998[MPC], 02/14/2001[MPC], 04/17/2003[MPC], 07/14/2004[MPC], 06/05/06[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC], 11/07/2023[MPC]	12/07/2021

[MPC] Medical Policy Committee

Revision History	Description
04/05/2016	Added MTAC review
11/22/2017	Added language to use Non-Medicare language for Medicare
12/07/2021	MPC approved to adopt MTACs recommendation of coverage and the clinical criteria for this medical procedure. Requires 60-day notice, effective date 05/01/2022.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Actigraphy Testing for the Evaluation of Sleep Disorders

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Polysomnography and Other Sleep Studies (L34040)
Local Coverage Article	Billing and Coding: Polysomnography and Other Sleep Studies (A57698) *(Actigraphy can be measured as part of a sleep test but will not be paid for separately)*

For Non-Medicare Members

Effective until September 1, 2024

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective September 1, 2024

Refer to Sleep Studies criteria page

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A sleep disorder (somnipathy) is a medical disorder of the sleep patterns. The international classification of sleep disorders (ICSD)-2 lists over 80 sleep disorders under eight major categories including insomnia, sleep-related breathing disorders, hypersomnia, circadian rhythm sleep disorders, parasomnia, sleep-related movement disorders, and others. It is estimated that 30-40% of Americans have a sleep complaint at any one time and that 10-15% suffer from chronic insomnia (Quan 2006).

The proper diagnosis and management of patients with sleep disorders depends on an accurate clinical history. There is a variety of sleep history questionnaires including the Epworth Sleepiness Scale (ESS) and the Pittsburgh Sleep Quality Index (PSQI). Keeping a sleep-wake diary is a standard procedure used for the subjective assessment of sleep and may give a more complete picture of the individual's sleep patterns and variability from day to day. Sleep diaries are useful for evaluating sleep over extended periods of time in the patient's home environment; they represent an important clinical tool and are often used in behavioral treatment of sleep disorders such as insomnia. However, self-documentation of sleep frequency and duration is prone to bias. The fully attended traditional polysomnography (PSG) is the basic diagnostic procedure and is considered the standard for evaluating sleep disorders. It is an overnight test performed in a sleep laboratory and comprises continuous recording of several

Back to Top

physiological variables including airflow, chest/abdominal movements, arterial oxygen saturation, electroencephalography (EEG), electrocardiogram [ECG], electromyography (EMG), and electrooculography (to measure eye movement). The EEG activity, eye movements, and muscle tone reveal the differences between wakefulness and sleep. Some investigators indicate that while the full PSG is widely considered the standard in clinical practice, it is not a true gold standard as it had not been validated. The use of PSG is limited by its high cost, time consumption, complexity, and considerable utilization of hospital resources. It may be impractical in some cases among whom sleep patterns must be assessed over extended periods of time. Moreover, PSG assesses sleep in an abnormal environment, which can alter its structure. These disadvantages of PSG have led to the search for alternative tools to diagnose and/or monitor sleep disorders in a natural environment (Bar 2003, Buysse 2005 Broughton 1996, Zou 2006, To 2009, Sunwoo 2010, Martin 2011).

Actigraphs, also called actometers or actimeters, were first used to record sleep and wakefulness based on movement in the early 1970s. The term actigraphy refers to methods utilizing miniaturized sensors that translate physical motion into a numeric presentation. Actigraphy simply measures movement, and is one dimensional, whereas polysomnography comprises at least three distinct types of data (EEG, EOG, and EMG), which jointly determine if a patient is asleep or awake. The actigraphy device may be placed on the wrist, ankle, or trunk. The best placement site for the actigraph to obtain the most reliable data is still controversial. In most studies it is worn on the nondominant wrist based on observations that wrist may detect more movements compared with the ankle and trunk, and that placement on the dominant arm detects more movement than the nondominant arm. The actigraphy device includes a small accelerometer that monitors and records the occurrence and degree of motion. It can collect data continuously over an extended period of one week or longer. Autographic data can be displayed and scored manually or downloaded to a computer for display and analysis by software and algorithms that give estimates of sleep-wake and circadian rhythm parameters. The collected data are translated into epochs (typically 30 seconds or 1 minute) of activity. Using validated algorithms, the epochs are scored as sleep or awake. The device interprets the presence of movement as time awake, and absence of movement as sleep time. Some investigators treat PSG and actigraphy measures as equally valid or alternative measures that provide an estimation of the time an individual spends sleeping and awake. However, actigraphy only measures movement; and electrographic sleep-wake status and motor activity/inactivity are not equivalent. Despite the sophisticated algorithms for actigraphy that may potentially estimate the time an individual spent sleeping and awake based on movement, actigraphy just provides an indirect estimate of sleep-wake as it is commonly defined (Broughton 1996, Lotjonen 2003, Ancoli 2003, Flemons 2003, Kuna 2010, Sanchex-Ortuno 2010, Calogiuri 2013).

Actigraphs vary widely in sizes and features and can be expanded to include sensors which monitor light, sound, temperature, and parkinsonian tremors. Some devices are programmable and allow the selection of specific modes of operation while others have only one fixed mode. New devices, scoring algorithms and operating procedures are continuously being developed and updated. Newer devices have the advantage of the small size and light weight making them more convenient for all patients. Different devices have different measuring mechanisms and scoring algorithms, but their results are usually interpreted equally between studies, despite the fact that research found that their accuracy in estimating sleep varies between population groups and from one device to the other (Broughton 1996, Lotjonen 2003, Ancoli 2003, Flemons 2003, Kuna 2010, Meltzer 2012, Blackwell 2011).

Actigraphy was reviewed by MTAC in 2007 and 2011 for detecting obstructive sleep apnea (OSA), and in 2008 for the assessment of sleep disorders, and did not meet the Committee's evaluation criteria. The technology is being re-reviewed for its use for the evaluation of insomnia and circadian rhythm disorders.

Medical Technology Assessment Committee (MTAC)

Actigraphy in the Treatment of Sleep Disorders

12/03/2007: MTAC REVIEW

Evidence Conclusion: The studies that evaluated the use of actigraphy for the assessment of sleep apnea did not use the technology alone but embedded/ or combined it with other devices as peripheral arterial tonometers (PAT), or respiratory polygraphs. Watch-PAT 100 was the device most commonly used in the published studies. The actometer estimated the total sleep time while the tests of respiratory function were used to calculate the apnea severity, and apnea hypopnea index (AHI). To date, there are no published controlled trials that would determine whether actigraphy can replace PSG or provide incremental information that would impact patient management decisions or improve health outcomes.

The population sizes of the studies varied from <20 patients to just over 200, and the majority assessed the portable monitors simultaneously with PSG in sleeping laboratories in the presence of sleep clinicians, and not in unattended settings. This would be ideal for testing the ability of the monitors to work but does not assess its performance in the patient's home where it is intended, which in turn may limit extrapolation of the results.

Back to Top

Moreover, the studies mainly included patients referred to sleep laboratories for suspected OSA. The high prevalence of the disorder among these patients would affect the sensitivity, specificity and likelihood ratios of the test that would also limit generalization of the results.
Diagnostic accuracy: Different algorithms were used for the evaluation of data. The investigators examined multiple respiratory disturbance index (RDI) thresholds for determining abnormal apnea hypopnea index (AHI) and define a positive result. The cutoff for used for AHI was arbitrary and varied between studies. Some investigators question the use of AHI as the correct reference standard. The Watch-PAT does not measure airflow and thus cannot differentiate hypopneas from apneas. Overall the results of the studies show that using PSG as the gold standards, the sensitivity of actigraphs embedded in peripheral arterial tonometers ranged from 82-90%, and specificity ranged from 68-90% depending on severity of the obstructive sleep apnea. The sensitivity tended to be lower, and specificity higher with increasing severity the disorder. The area under the curve (AUC) also varied between studies with severity of sleep apnea, and its measures. It ranged from 0.82 for patients with RDI.>10 in Bar's study, to 0.98 for AHI >30 in Garcia-Diaz study. This latter study also compared the respiratory polygraph (RP) performed in the hospital versus that at home, either with or without the addition of actigraphy. Its results showed that RP performed at the laboratory was more accurate than that done at home, and that the addition of actigraphy did not result in significant improvement but tended to overestimate sleep time. The agreement rate between actigraphy devices and PSG was reported in some studies and ranged from 80% to 93%, also depending on the severity of the obstructive sleep apnea.
Diagnostic impact: There is insufficient evidence to determine that actigraphy can provide information that may influence the management decisions for patients diagnosed with obstructive sleep apnea. Therapeutic impact: There is insufficient evidence to determine that using actigraphy for the diagnosis of obstructive sleep apnea would improve health outcomes.
Articles: The literature search revealed over 500 articles on actigraphy. The majority of the published studies used the technology to investigate patients with insomnia, circadian rhythm sleep disorders, and as an outcome measure to determine response of therapy, mainly melatonin 1. Diagnostic accuracy There were no randomized or nonrandomized trials that compared the results of actigraphy used alone, to polysomnography to determine if it can be used as an alternative to PSG in the diagnosis of obstructive sleep apnea. There were several studies that focused on the accuracy and usefulness of actigraphy in evaluating patients with obstructive sleep apnea. These studies, however, did not use actigraphs alone, but combined it with tests of respiratory function in order to calculate the apnea hypopnea index which measures the severity of apnea in these patients. The studies that compared the wrist worn devices with embedded actigraphs used PSG as the gold standard, and reported sensitivity, specificity, likelihood ratios or areas under the receiver operator curves were selected for critical appraisal. 2. Diagnostic impact the literature search did not reveal any study that would determine the influence of the technology on management decisions. 3. Therapeutic impact No studies on the impact of technology on patient outcomes were identified by the search. *The following studies were critically appraised:*
Ayas NT, Pittman S, MacDonald M, et al. Assessment of a wrist-worn device in the detection of obstructive sleep apnea. Sleep Medicine 2003;4:435-442 See Evidence Table. Bar A, Pillar G, Dvir I, et al. Evaluation of a portable device based on peripheral arterial tone for unattended sleep studies. Chest 2003;123:695-703 See Evidence Table. Garcia-Diaz E, Quintana-Gallege E, Ruiz A, et al. Respiratory polygraphy with actigraphy in the diagnosis of sleep apnea-hypopnea syndrome. Chest 2007; 131:725-732. See Evidence Table. Hedner J, Pillar G, Pittman SD, et al. A novel adaptive wrist actigraphy algorithm for sleep-wake assessment in sleep apnea patients. Sleep 2004; 27:1560-1566. See Evidence Table . Zou D, Grote L, Peker Y, et al. Validation a portable monitoring device for sleep apnea diagnosis in a population-based cohort using synchronized home polysomnography. Sleep 2006; 29:367-374. See Evidence Table.

The use of actigraphy in the treatment of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/04/2008: MTAC REVIEW
Actigraphy in the Treatment of Sleep Disorders
Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. Most studies were conducted in sleep laboratories where recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, where it is intended for use. Also, the algorithms that were validated for a specific model, mode of operation, or in a selected population may by not be equally accurate when used with a different brand of device, different gender or age group. The studies reviewed compared actigraphy to PSG, but the authors did not indicate whether the investigators interpreting the results of one test were blinded to the results of the other. The overall results of the studies reviewed, indicate that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. It was also found to overestimate the total sleep time and sleep
 Back to Top

efficiency. Actigraphy tends to overestimate sleep in people with insomnia when they are lying quietly as quiet wakefulness could be miscoded as sleep. Insomnia patients can remain inactive for a period of time attempting to fall asleep. On the other hand, actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. The use of actigraphy for the assessment of periodic leg movements in sleep was evaluated in only a few small studies with methodological limitations. It was compared with polysomnography with bilateral anterior tibialis electromyelography (BATEMG). However, EMG and leg actigraphy are not interchangeable, and each measures a different event. One records electrical activity of a certain muscle and the other records leg acceleration. Leg activity may be due to movement artifacts produced by obstructive sleep apnea. Kemlink et al (2007) did not exclude patients with suspicious sleep apnea and did not adjust for it in the analysis. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with sleep disorders.

Articles: The following questions were considered in screening the published articles:

1) What is the diagnostic accuracy of actigraphy in the evaluation of patients with sleep disorders?
2) Does the use of actigraphy influence management decisions?
3) Does actigraphy lead to better treatment outcomes?

The literature search revealed over 500 articles on actigraphy. Due to the continuing development in the actigraphic devices, operating procedures, software, and scoring algorithms, the literature was screened to identify the more recent studies. Many of these used actigraphy to assess treatment effects or compared results from one actigraphy scoring algorithm to another. Others reported on the use of actigraphy in specific groups as very young infants, children with ADHD, patients with depression, dementia, Parkinson's disease, and others. There were a number of nonrandomized studies that compared actigraphy with other tools for the evaluation of patients with insomnia, periodic leg movement, narcolepsy and other medical disorders other than sleep disorders. The literature search did not reveal any study that would determine the influence of the technology on management decisions or its impact on patient outcome. *The following studies that compared actigraphy with the gold standard of polysomnography were critically appraised:* Kushida CA, Chang A, Gadkary C, et al. comparison of actigraphic, polysomnographic, and subjective assessment of sleep parameters in sleep-disordered patients. Sleep Medicine 2001;2:389-396. See Evidence Table 3 and see Evidence Table 4. Sivertsen B, Omvik S, Havik OE, et al. A comparison of actigraphy, polysomnography in older adults treated for chronic primary insomnia. Sleep 2006; 29:1353-1358. See Evidence Table. Lichstein K, Stone KC, Donaldson J, et al. Actigraphy validation with insomnia. Sleep 2006; 29:232-239. See Evidence Table. Kemlink D, Pretl M, Sonka K, et al. A comparison of polysomnographic and actigraphic evaluation of periodic limb movement in sleep. Neurol Res 2007; 000:1-5. See Evidence Table. King MA, Jaffre MR, Morrish E, et al. The validation of a new actigraphy system for the measurement of periodic leg movement in sleep. Sleep Medicine 2005; 6:507-513. See Evidence Table.

The use of actigraphy in the treatment of sleep disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/04/2011

Actigraphy in the Treatment of Sleep Disorders

Evidence Conclusion: Accuracy of actigraphs/portable monitors for the detection of OSA. There were no published studies that compared portable monitors head-to-head. The accuracy of one devise cannot be extrapolated to others even from the same class due to the differences in the number and types of signals recorded, sensors used, and the processing of signals. It is unknown which sensors or combinations have the highest sensitivity and specificity. Moreover, differences in scoring, testing environment, and night to night variability in the apnea hypopnea index (AHI) make generalization of results difficult. The studies that evaluated the use of actigraphy for the assessment of sleep apnea did not use the technology alone but embedded or combined it with other devices such as peripheral arterial tonometers (PAT), or respiratory polygraphs. Watch-PAT 100 was the device most commonly used in published studies. The actometer estimated the total sleep time while the tests of respiratory function were used to calculate the apnea severity, and apnea hypopnea index. As indicated in the 2007 review of the technology, the overall results of the studies reviewed showed that using PSG as the gold standards, the sensitivity of actigraphs embedded in peripheral arterial tonometers ranged from 82-90%, and specificity ranged from 68-90% depending on severity of the obstructive sleep apnea. The sensitivity tended to be lower, and specificity higher with increasing severity the disorder. The agreement rate between actigraphy devices and PSG was reported in some studies and ranged from 80% to 93%, also depending on the severity of the obstructive sleep apnea. Therapeutic impact of actigraphs/portable home monitors: In a randomized controlled trial that included 106 subjects with a high likelihood of OSA, Berry and colleagues (Evidence table 1) compared a clinical pathway with the watch-PAT 100 for the diagnosis and unattended autotitrating continuous positive airway pressure (CPAP) for those with an respiratory disturbance index (RDI) > 5 events /hour) to select an effective CPAP, versus standard in-laboratory PSG for diagnosis of OSA and CPAP

 Back to Top

titration. Using a similar approach, Skomro and colleagues' trial (Evidence table 2) randomized 102 subjects with high a probability of OSA to either home-based diagnosis (using Embletta device that incorporates an actigraph) and auto-CPAP (APAP) or in-laboratory PSG. The in-home study was considered positive if the respiratory disturbance index (RDI) was > 5, and patients were offered auto-CPAP therapy for 1 week followed by fixed-pressure CPAP based on the auto-CPAP P95 results. An earlier trial (Mulgrew 2007) compared a type IV portable monitor and APAP titration to in-laboratory PSG in 68 patients (22% of the eligible population) with moderate to severe OSA and followed the patients for 3 months. All three trials showed no statistically significant differences in the Epworth Sleepiness Scale scores, quality of life scores, and other outcome studied between patients in the in-home diagnosis and auto CPAP titration group versus those in-laboratory PSG diagnosis and CPAP titration. These results however, should be interpreted with caution, and may not be generalized to the population at large due to several factors including but not limited to: participants in the studies were highly selected, had high pre-test probability of OSA, were mainly men, those with co-morbidities were excluded, short duration of follow-up, patients and/or providers were not blinded, and most of the participants in the PSG group had split-night PSG, which may lead to different outcomes of CPAP therapy than those derived from a full-night of CPAP titration. In addition, the studies were powered as superiority and not equivalence trials, and lack of significant differences does not necessarily indicate equivalence. Berry and colleagues powered their trial as noninferiority, but only for the compliance outcome. More high-quality randomized trials are needed to compare clinical outcomes of laboratory PSG versus home monitoring for sleep disorders among diverse population groups e.g. ethnic groups, women, the elderly, and patients with cardiopulmonary and neurological diseases as COPD, asthma, heart failure, neuromuscular diseases, and other sleep disorders.

Articles: The literature search revealed over 400 articles on actigraphy. The great majority were unrelated to the current review. The technology was frequently used to determine response of therapies for insomnia, mainly melatonin. There were few small validation studies on different portable monitor devices for diagnosing obstructive sleep apnea. There were no head-to- head comparisons between the devices for accuracy in detecting OSA. The search identified two published trials that compared the outcomes of in-laboratory diagnosis and treatment of OSA versus home-based diagnosis and treatment using portable monitoring devices that incorporated an actigraph. Both were critically appraised. Berry RB, Hill G, Thompson L, et al. Portable monitoring and autotitration versus polysomnography for the diagnosis and treatment of sleep apnea. Sleep 2008; 31:1423-1431. See Evidence Table. Skormo RP, Gjevra J, Reid J, et al. Outcomes of home-based diagnosis and treatment of obstructive sleep apnea. Chest 2010; 138:257-263. See Evidence Table.

The use of actigraphy in the treatment of sleep disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/19/2013: MTAC REVIEW

Actigraphy in the Treatment of Sleep Disorders

Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia as a primary outcome or in a secondary analysis were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. The majority of sleep studies were conducted in sleep laboratories where the recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, which is the primary intention for their use. In addition, the authors of the studies that compared actigraphy to PSG did not indicate whether interpretation of the results of one test was blinded to the results of the other. According to Sadeh (2011), a point that deserves attention is that actigraphic validation studies against PSG are all based on "time in bed" period whereas the main advantage of actigraphy is documenting sleep wake patterns continuously over 24-hour periods across days. Generalization of the results of the published studies may be limited to similar devices and population groups as the algorithms that were validated for a specific model, mode of operation, or in a selected population may not be equally accurate when used with a different brand of device, different gender, or age group. The results of the studies previously reviewed for MTAC showed that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. These older as well as the more recent studies showed that actigraphy in general underestimates wake and overestimates the total sleep time and sleep efficiency. Individuals with insomnia can remain inactive for a period of time attempting to fall asleep, and actigraphy tends to overestimate sleep in these people as quiet wakefulness could be miscoded as sleep. On the other hand, actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. A number of studies measured the correlation of actigraphy and PSG sleep outcomes as a measure of validity of actigraphy. These ranged between studies from 0.51-0.93 for total sleep time (TST), 0.48-0.85 for wake time after sleep onset (WASO), 0.36-0.81 for sleep efficiency (SE), and 0.30-0.95 for sleep onset latency (SOL). The MrOS Sleep Study (Blackwell et al, 2011), (Evidence Table 1) was embedded in the Osteoporotic Fractures in Men (MrOS) study and examined whether there was a difference between in home-PSG and actigraphy (using the

 Back to Top

Sleepwatch-O device) in estimating the total sleep time (TST). The authors used 3 modes for collecting actigraphic data to determine the one that corresponds highest with PSG. These modes were the proportional integration mode (PIM), time above threshold (TAT), and zero crossings mode (ZCM). PIM mode is a measure of the activity level or vigor of motion, the TAT mode measures time spent in motion or time spent in active state, and the ZCM measures the frequency of movement. The study had the advantage of including a large population size of community dwelling individuals and the use of in-home PSG as a gold standard. It however, only included men >60 years of age; and the PSG data were collected in 30-minute epochs while the actigraphy data were collected in 1-minute epochs with no synchronization in the clock time. This did not allow direct comparisons for each epoch. In addition, the authors did not explain whether the study participants were asked to complete sleep diaries. The results of the analysis showed that the three actigraphy modes either over-estimated or underestimated sleep and wake compared to PSG. The PIM mode of actigraphy corresponded more closely with PSG estimation of total sleep time (TST) than the TAT or ZCM modes, yet the correlation was weak to moderate. These results, however, may not be generalized to populations in different age groups or to other actigraphy devices. Van Den Berg and colleagues, 2008 (Evidence Table 2) measured the disagreement among actigraphy and sleep diary in estimating the total sleep time (TST) among 969 community dwelling elderly men and women participating in a cohort study that primarily investigated the incidence and risk factors of disabling disease. The participants in this sub study wore an actigraph (Actiwatch model AW4) and kept a sleep diary over a period of 5-7 consecutive days and nights. PSG was not used as the gold standard, but the authors only used the Actiwatch algorithm that was validated against polysomnography. The results of the analysis showed that, the estimated TST in the sleep diaries deviated more than one hour from that measured by actigraphy among 34% of the participants. The level of this disagreement decreased with subjective and actigraphic measures of sleep quality and increased with male gender, poor cognitive function, and functional disability. In a smaller study, Levenson and colleagues 2013 (Evidence Table 3) also compared the accuracy of actigraphy versus sleep diary among a group of older insomniac patients participating in a larger study that examined the effect of behavioral therapy on insomnia in older adults. The study included 119 participants with a mean age of 71.7 years (79 with insomnia confirmed with PSG, and 40 controls who did not undergo a PSG). The participants completed at least 7 nights of sleep diary and actigraphy (using the Minimitter Actiwatch). The results of the analyses indicate that the sleep diary parameters discriminated individuals with insomnia from good sleepers more accurately than actigraphy. The AUC of actigraphy was in the low to moderate range (0.58 for sleep efficiency, and 0.61 for total sleep time, the 95% CI contained the value of 0.5 for many of the parameters). Johnson and colleagues, 2007 (Evidence Table 4) examined the level of agreement between actigraphy and polysomnography among 181 adolescents 12-16 years of age. All participants completed an overnight PSG in a clinical research center. The week prior to the PSG and during the overnight PSG study, they wore a wrist actigraph (Octagonal Sleep watch 2.01) and completed daily sleep logs. Data were digitized in 1-minute epochs and the activity count was calculated and stored based on 1 of 3 data modes: PIM, TAT, and ZCM. The results of the analysis showed significant differences between the assessments of total sleep time by actigraphy vs. PSG. The differences were more pronounced for boys vs. girls and for those with sleep disturbed breathing. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with insomnia or circadian rhythm disorders.

Articles: The literature search revealed over 800 articles published on actigraphy and sleep in the last 5 years. The great majority was unrelated to the current review; many reported on the use of actigraphy in specific groups as very young infants, children with ADHD, patients with depression, dementia, Parkinson's disease, and others. There was a lack of published studies on the use of actigraphy in patients with circadian rhythm sleep disorders. The studies that compared the use of actigraphy versus PSG for the evaluation of insomnia were mainly embedded in larger community-based studies conducted among specific age groups and for studying different conditions and/or factors that were not necessarily related to sleep. The following studies with more valid methodology, larger population size, and used actigraphy concurrently with PSG and /or sleep diary were selected for critical review. Blackwell T, Ancoli-Israel S, Redline S, Stone KL; Osteoporotic Fractures in Men (MrOS) Study Group. Factors that may influence the classification of sleep-wake by wrist actigraphy: the MrOS Sleep Study. J Clin Sleep Med. 2011;7:357-367 See Evidence Table. Johnson NL, Kirchner HL, Rosen CL, et al. Sleep estimation using wrist actigraphy in adolescents with and without sleep disordered breathing: a comparison of three data modes. Sleep. 2007; 30:899-905. See Evidence Table. Levenson JC, Troxel WM, Begley A, et al. A quantitative approach to distinguishing older adults with insomnia from good sleeper controls. J Clin Sleep Med. 2013; 9:125-131. See Evidence Table. Van Den Berg JF, Van Rooij FJ, Vos H, et al. Disagreement between subjective and actigraphic measures of sleep duration in a population-based study of elderly persons. J Sleep Res. 2008; 17:295-302. See Evidence Table.

The use of actigraphy in the evaluation of obstructive sleep apnea does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

 Back to Top

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/20/2007	12/07/2010 MDCRPC, 04/05/2011 MDCRPC,10/04/2011 MDCRPC, 08/07/2012 MDCRPC ,06/04/2013 MDCRPC ,10/01/2013 MPC, 04/01/2014 MPC, 04/07/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC, 10/03/2023MPC, 03/12/2024MPC	02/07/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description of Change
04/01/2004	Criteria was retired
04/07/2015	Remove criteria from retired status. Medical necessity review will be effective July 5, 2015.
02/07/2017	Medicare is silent; MPC approved to adopt KAISER PERMANENTE criteria for Medicare members

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

PATIENT REFERRAL GUIDELINES
Heart Transplantation[i]

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heart Transplants (260.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Heart transplantation. These guidelines for referral for transplant evaluation and are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable active infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low [ii], [iii], [iv]. Exceptions may be made on a case-by- case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six
(6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

1.6.1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.6.2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow

[i] Note: All patients must be continuously re-evaluated for indications and contraindications. Candidates considered for re-transplantation must be evaluated using the same indications.

Back to Top

medication regimens or failure to accomplish the activities required for maintenance on the waiting list.

1.7. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.9. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR HEART TRANSPLANT

2.1. End-stage heart disease as evidenced by one or more of the following:

2.1.1. Functional class III or IV

2.1.2. Not correctable by medical or other surgical therapies

2.1.3. A low VO2 maximum: [ii]

2.1.3.1. ≤14 ml/kg/min in patients not on a beta blocker

2.1.3.2. ≤12 ml/kg/min in patients on a beta blocker [iii]

2.1.3.3. <19 ml/kg/min adjusted for lean body mass in patients with a BMI >30 kg/m^2

2.1.3.4. Less than 50% of age predicted maximum.

2.1.4. A VE/VCO2 >35 in a patient with a sub-maximal cardiopulmonary exercise test (RER <1.05)^2

2.1.5. Cardiac index < 2 L/min/m^2

2.2. Unable to wean from mechanical or inotropic support.

2.3. Amyloid Cardiomyopathy

2.3.1. TTR Amyloid

2.3.2. (AL) Amyloidosis without significant extra-cardiac involvement.

2.4. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits.

CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the *General* Principles listed above in Section1 of these guidelines):

3.1. Significant diseases such as:

3.1.1. Severe uncontrolled or poorly controlled hypertension.

3.1.2. Clinically significant vascular disease not correctable by intervention.

3.1.3. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. [iv]

3.1.3.1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg

3.1.3.2. Children: PVR > 9 Wood units

3.1.4. Severe pulmonary disease after optimal treatment of severe heart failure.[viii]

3.1.5. Severe hepatic disease after optimal treatment of severe heart failure.[viii]

[ii] Journal of Heart & Lung Transplantation, Vol.25 Number 9, pp1024 -1042. Listing Criteria for Heart Transplantation ISHLT Guidelines for the Care of Cardiac Transplant Candidates – 2006.

[iii] Patients on Beta blockers should have a cut-off of ≤12 ml/kg/min, and patients intolerant to beta blockers a VO_2 ≤14 ml/kg/min.

[iv] Circulation; 84 (3), 329 – 337. *Journal of Heart Transplantation* (1990): 526 – 537.

Back to Top

3.1.6. Kidney disease with creatinine clearance <34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. [v], [vi], [vii]

3.1.7. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.

3.1.8. Evidence of cachexia or malnutrition (BMI < 19 kg/m2 or < 80% ideal body weight).x

3.1.9. Obesity (BMI>35 kg/m2 or > 140% ideal body weight) xi has been associated with poor outcomes after cardiac transplant.

3.1.10. Diabetes with complications resulting in severe end-organ damage.

3.1.11. Auto/acquired immune disease with multi-organ manifestation

3.1.12. Acute pulmonary embolus

3.1.13. Active peptic ulcer disease

3.1.14. Severe symptomatic osteoporosis

3.1.15. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)

3.1.16. AL Amyloidosis with significant extra-cardiac manifestations

3.1.17. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.

3.1.18. Any other co-morbid condition that would limit life expectancy or quality of life.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

A heart may be irreversibly damaged by long-lasting heart disease or viral infection. When the heart can no longer adequately work, and a person is at risk of dying, a heart transplant may be appropriate.

Cardiac transplant has become increasing successful over the past several years. Adult heart transplant recipients have a one-year survival rate of eighty to ninety percent and a five-year survival rate of sixty to seventy percent. Kaiser Permanente contracts have included coverage for heart transplantation for several years. Members with coverage who meet the selection criteria are considered for transplantation.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33940	Donor cardiectomy (including cold preservation)

[v] Selected patients for possible combined or staged heart/kidney transplant will be evaluated on a case-by-case basis.

[vi] Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.

[vii] The Journal of Heart & Lung Transplantation, Vol. 35, Issue 7, p893-900. Evidence Supports Severe Renal Insufficiency as a relative contraindication to heart transplantation—2016.

Back to Top

33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

****Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/1996	07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013MDCRPC, 01/07/2014MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	04/06/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MDCRPC Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt Kaiser Permanente National Criteria for Heart Transplant
03/03/2020	MPC approved updates for Kaiser Permanente National Transplant Services patient referral guidelines
06/12/2020	Changed “criteria” to guidelines” where appropriate; updated to reflect current patient referral guidelines that were approved 03/03/2020
04/06/2021	Per National Transplant Guidelines: 1.3 added “active”

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Advanced Bronchoscopy Techniques

- Endobronchial ultrasound
- Electromagnetic navigation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Endobronchial Ultrasound"*** for medical necessity determinations. Use the Non-Medicare criteria below. Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Electromagnetic Navigation Bronchoscopy (ENB)"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members4

Service	Criteria	
Endobronchial Ultrasound *(common CPT 31652, 31653, 31654, C7512)*	Kaiser Permanente has elected to use the Endobronchial Ultrasound (A-1049) MCG* Care Guideline for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.	
Electromagnetic Navigation *(common CPT 31627, 31654)*	Biopsy of Peripheral Lesions	Electromagnetic navigation is covered when performed with biopsy of peripheral lesions.
	Fiducial Marker Placement	Electromagnetic navigation is not covered when used for Fiducial Marker Placement as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Back to Top

Date Sent: 4/29/24

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Flexible bronchoscopy (FB) is a minimally invasive procedure that is used for the diagnosis and treatment of lung cancer. Research suggests that the sensitivity of FB is approximately 88% for diagnosing central lesions and 78% for diagnosing peripheral lesions (most commonly defined as lesions that are not visible beyond the visual segmental bronchi). However, the sensitivity of FB is dependent on lesion size. FB does not perform as well for smaller peripheral lesions. It has been estimated that for peripheral lesions less than 2 cm in diameter the sensitivity of FB is approximately 34% (Rivera 2007).

Electromagnetic navigation bronchoscopy (ENB) is a relatively new bronchoscopic tool that combines CT-generated virtual bronchoscopy and electromagnetic tracking of a steerable probe to allow physicians to perform biopsy of peripheral lesion that are not accessible through conventional bronchoscopy. It has also been suggested that mediastinal lymph nodes can be biopsied using ENB. Other uses of ENB include implantation of fiducial markers for radiotherapy, implantation of brachytherapy seeds or catheters, and dye marker placement for surgical resection.

Several ENB systems have received FDA approval. ENB using the superDimensions I Logic™ System (superDimensions, Inc. Minneapolis, MN) is performed in three phases – planning, registration, and navigation and biopsy (Bechara 2011, Schwartz 2010).

1. Planning: A three-dimensional image of the patient's lungs with anatomical landmarks is constructed using previously taken CT scans and proprietary software.
2. Registration: The steerable navigation catheter is inserted through the bronchoscope. The three-dimensional image with anatomical landmarks created in the planning phase is viewed and correlated with the actual image from the video bronchoscope. The position of each landmark is marked using a foot pedal.
3. Navigation and biopsy: The steerable catheter is used to navigate to the lesion. The location of the catheter's tip is displayed on the CT images. Once the catheter reaches the target, it is locked in place, and the working guide is retracted. Once the catheter is in place, any endoscopic tool can be inserted through the channel. This includes transbronchial forceps to biopsy the lesion or guide wire for the placement of fiducial markers.

Medical Technology Assessment Committee (MTAC)

Electromagnetic Navigation Bronchoscopy

08/20/2012: MTAC REVIEW

Evidence Conclusion: Diagnostic yield A recent RCT that included 118 subjects with evidence of peripheral lung lesions or solitary primary nodules on CT evaluated the diagnostic yield of endobronchial ultrasound (EBUS), electromagnetic navigation bronchoscopy (ENB), and combined EBUS/ENB. Results from this study suggest that combined EBUS/ENB improves diagnostic yield compared to either method alone. The pneumothorax rate was 5% in the EBUS and ENB alone groups and 8% in the combined group. There was no significant difference in pneumothorax rate between the three groups (Eberhardt 2007).

Diagnostic yield (Eberhardt 2007)

EBUS	ENB	Combined
69%	59%	88%

A recent meta-analysis also evaluated the diagnostic yield of different guided bronchoscopy methods. Results from this meta-analysis suggest that the diagnostic yield of ENB is approximately 67%. Results from this meta-analysis should be interpreted with caution as the majority of the studies included in the meta-analysis were small

Back to Top

case series (Wang Memoli 2012). Since the meta-analysis two additional case-series were identified. The first case-series included 112 subjects and evaluated the diagnostic yield of ENB combined with rapid on-site cytopathologic evaluation (ROSE). Overall, the diagnostic yield in this study was 84%. In lesions less than 2 cm, the diagnostic yield was 75.6% and 89.6% in lesions greater than 2 cm. There were two cases (1.8%) of pneumothorax (Lamprecht 2012). The second case-series included 101 subjects and also evaluated the diagnostic yield of ENB combined with ROSE. The diagnostic yield from this study was 85%. There were 6 cases (5.8%) of pneumothorax (Pearlstein 2012). **Fiducial marker placement** A small observational study evaluated the transcutaneous placement of fiducial markers using either CT or fluoroscopic guidance (N=15) or transbronchial placement using ENB (N=8) in patient with small, early-stage, non-small cell lung cancer. Pneumothorax occurred in 8 patients (53%) who underwent transcutaneous placement and no patients who underwent transbronchial placement. The fiducial markers did not show substantial migration during the course of treatment for either method (Kupelian 2007). Conclusion: Diagnostic yield: Results from a RCT, a meta-analysis of mainly small case-series, and two case-series suggests that the overall diagnostic yield of ENB is approximately 59 to 85%.
Safety: The pneumothorax rate in the studies ranged from 1.8 to 8%.
Fiducial marker placement: There is insufficient evidence to determine the safety and clinical utility of ENB for the placement of fiducial markers.
Articles: Several small observational studies, a randomized controlled trial (RCT), and a meta-analysis were identified that evaluated the use of ENB for diagnosing lung cancer. The meta-analysis and the RCT were selected for review. A few small observational studies were identified that evaluated fiducial marker placement using ENB. The number of patients receiving ENB for the placement ranged from 1 to 12. Due to the small sample size none of these studies were selected for review. A summary of the results from one of the more recent studies is presented below. The following articles were selected for review: Eberhardt R, Anantham D, Ernst A, Feller-Kopman D, Herth F. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. Am J Respir Crit Care Med. 2007;176:36-41. See Evidence Table. Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-Analysis of Guided Bronchoscopy for the Evaluation of the Pulmonary Nodule. Chest. 2011. See Evidence Table.

The use of ENB for diagnosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of ENB for fiducial marker placement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Biopsy of peripheral lesions, Fiducial marker placement

CPT Codes	Description
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with computer-assisted, image-guided navigation (list separately in addition to code for primary procedure)
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s])

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Endobronchial Ultrasound

CPT Codes	Description
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s])
C7512	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s), including fluoroscopic guidance when performed

Back to Top

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	09/05/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/26/2020	Added “Kaiser Permanente Medical Policy” statement under Medicare section
02/06/2023	Added CPT code 31627 to criteria page
09/05/2023	MPC approved to adopt Endobronchial Ultrasound, MCG A-1049 for clinical coverage indications. Requires 60-day notice; effective February 1, 2024.
02/22/2024	Updated formatting for clarity.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
AVISE MTX Test for Measuring Methotrexate Polyglutamate Levels

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***AVISE MTX Test for Measuring Methotrexate Polyglutamate Levels***" for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Rheumatoid arthritis is a chronic, systemic, inflammatory disorder that affects approximately 0.5–1% of the Western population. If left untreated, this disease can result in permanent joint damage (Binker 2010). Evidence from recent studies suggests that achieving early control of rheumatoid arthritis minimizes joint destruction and increases long-term disease control.

Methotrexate is one of the most effective and commonly prescribed drugs for the treatment of rheumatoid arthritis. Although methotrexate is effective, it is not without side effects. Side effects of methotrexate include gastrointestinal disturbance, mucositis, fatigue, alopecia, elevated serum transaminase levels, and bone marrow toxicity. Frequent blood tests are required to monitor for the development of these adverse effects. Additionally, patient response to methotrexate, both in terms of efficacy and toxicity is highly variable. It is estimated that approximately 30–40% of patients with rheumatoid arthritis taking methotrexate do not adequately respond to treatment (Danilia 2010, Goodman 2010). Currently, there is no reliable means of predicting patient response to methotrexate.

Back to Top

After administration and absorption, serum methotrexate levels fall rapidly as it is actively transported into a variety of cells. In the cells, up to six additional glutamate residues are added, converting methotrexate into the more stable polyglutamate form. Methotrexate polyglutamate can be converted back to methotrexate to permit efflux from the cell. The therapeutic effect of methotrexate depends on its conversion to methotrexate polyglutamate. It has been suggested that if methotrexate polyglutamate levels were associated with adverse events or therapeutic response then knowledge of these levels could be used to help optimize methotrexate therapy in rheumatoid arthritis (Binker 2010, Danilia 2010, Goodman 2010).The Avise PG test (Cypress Bioscience, San Diego, CA) measures methotrexate polyglutamate levels and was developed to aid in dosage optimization for rheumatoid arthritis patients who have been on methotrexate for at least three months. Results of the Avise PG test are reported as therapeutic (> 60 nmol/L), intermediate (20-60 nmol/L), and subtherapeutic (< 20 nmol/L).

Medical Technology Assessment Committee (MTAC)

Avise PG Test for Measuring Methotrexate Polyglutamate Levels

06/20/2011: MTAC REVIEW

Evidence Conclusion: Analytic validity - There are a variety of rapid, sensitive, and accurate methods for the detection of methotrexate polyglutamate (Dervieux 2003, Li 2007). Clinical validity - Two cross-sectional studies that examined the association between methotrexate polyglutamate levels and disease activity were selected for review. The first study included 192 subjects with rheumatoid arthritis who had been taking methotrexate for at least 3 months and had a stable dose for at least a month prior to study entry. Before adjusting for confounding factors results suggest that higher disease activity, measured using the swollen joint count (SJC), the physician's global assessment, the physician's assessment of response to methotrexate, the Disease Activity Score in 28 joints (DAS28), the Clinical Disease Activity Index (CDAI), and the Simplified Disease Activity Index (SDAI), was associated with higher MTX PG concentrations (MTX PG_4, MTX PG_5, MTX PG_{1-5}, and MTX PG_{3-5}). After adjusting for confounding factors, patients with higher disease activity measured using TJC, SJC, and DAS28 still had higher MTX PG_5 concentrations. There was no association between methotrexate polyglutamate concentration and adverse events (Stamp 2010). Two other studies also failed to find an association between methotrexate polyglutamate concentration and adverse events (Dervieux 2006, Angelis-Stoforidis 1999). The second study included 226 subjects with rheumatoid arthritis who had been taking methotrexate for at least 3 months. After controlling for confounding factors, low methotrexate polyglutamate levels were associated with poor clinical status (high number of tender and swollen joints, physician's assessment of disease activity, and the modified Health Assessment Questionnaire) (Dervieux 2005). The same group of authors also conducted two other studies that examined the relationship between methotrexate polyglutamate levels and clinical status. Both of these studies along with two other observational studies also found that low methotrexate polyglutamate levels were associated with poor clinical status (Angelis-Stoforidis 1999, Dervieux 2004, Dervieux 2006, Hornung 2008).
Clinical utility -
No studies were identified that addressed the clinical utility of measuring methotrexate polyglutamate levels to aid in dosage optimization for rheumatoid arthritis patients.
Conclusion: Analytic validity: There are a variety of rapid, sensitive, and accurate methods for the detection of methotrexate polyglutamate. Clinical validity: Several observational studies have investigated the association between methotrexate polyglutamate levels and clinical status. While the majority of these studies found that low methotrexate polyglutamate levels were associated with poor clinical response, not all studies have found this association. Clinical utility: There is insufficient evidence to determine the clinical utility of measuring methotrexate polyglutamate levels to aid in dosage optimization for rheumatoid arthritis patients.
Articles: Two studies were identified that address analytic validity. Several observational studies were identified that examined the relationship between methotrexate polyglutamate levels and clinical status (clinical validity). Two of the larger studies were selected for review. No studies were identified that addressed the clinical utility of measuring methotrexate polyglutamate to aid in dosage optimization for rheumatoid arthritis patients. The following studies were critically appraised: Stamp LK, O'Donnell JL, Chapman PT, et al. Methotrexate polyglutamate concentrations are not associated with disease control in rheumatoid arthritis patients receiving long-term methotrexate therapy. *Arthritis Rheum 2010;* 62:359-638. See Evidence Table. Dervieux T, Frust D, Lein DO, et al. Pharmacogenetic and metabolite measurements are associated with clinical status in patient's rheumatoid arthritis treated with methotrexate: results of a multicentered cross sectional observational study. *Ann Rheum Dis 2005;* 64:1180-1185. See Evidence Table**.**

The use of Avise PG test for measuring methotrexate polyglutamate levels does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

Applicable Codes

Considered Not Covered:

CPT® Codes	Description
84999	Unlisted chemistry procedure
ICD-10 Codes	**Description**
M05.60-M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70-M05.79	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80-M05.89	Other rheumatoid arthritis with rheumatoid factor
M06.00-M06.09	Rheumatoid arthritis without rheumatoid factor

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
07/05/2011	07/05/2011[MDCRPC], 07/03/2012[MDCRPC] ,05/07/2013 [MDCRPC] ,03/04/2014 [MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/05/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	Added CPT code 84999 and rheumatoid arthritis ICD-10 codes M05.60-M06.09
05/06/2022	Medicare retired LCA A54378 Billing and Coding: MolDX: Avise PG Assay

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Air Ambulance

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 10 - Ambulance Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Rural Air Ambulance Service Protocols A52917

For Non-Medicare Members

Air Ambulance Services

Medically appropriate air ambulance transportation is a covered service regardless of the State or region in which it is rendered. However, KPWA will approve claims only if the beneficiary's medical condition is such that transportation by either basic or advanced life support ground ambulance is not appropriate.

There are two categories of air ambulance services: fixed wing (airplane) and rotary wing (helicopter) aircraft. The higher operational costs of the two types of aircraft are recognized with two distinct payment amounts for air ambulance mileage. The air ambulance mileage rate is calculated per actual loaded (patient on board) miles flown and is expressed in statute miles (not nautical miles).

1. Fixed Wing Air Ambulance (FW)
   a. Fixed wing air ambulance is furnished when the beneficiary's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, transport by fixed wing air ambulance may be necessary because the beneficiary's condition requires rapid transport to a treatment facility, and either great distances or other obstacles, e.g., heavy traffic, preclude such rapid delivery to the nearest appropriate facility. Transport by fixed wing air ambulance may also be necessary because the beneficiary is inaccessible by a ground or water ambulance vehicle.
2. Rotary Wing Air Ambulance (RW)
   a. Rotary wing air ambulance is furnished when the beneficiary's medical condition is such that transport by ground ambulance, in whole or in part, is not appropriate. Generally, transport by rotary wing air ambulance may be necessary because the beneficiary's condition requires rapid transport to a treatment facility, and either great distances or other obstacles, e.g., heavy traffic, preclude such rapid delivery to the nearest appropriate facility. Transport by rotary wing air ambulance may also be necessary because the beneficiary is inaccessible by a ground or water ambulance vehicle.

Coverage Requirements

Air ambulance transportation services, either by means of a helicopter or fixed wing aircraft, may be determined to be covered only if **ALL the following** are met:

1. The vehicle and crew requirements described in §10.1* are met; and
2. The beneficiary's medical condition required immediate and rapid ambulance transportation that could not have been provided by ground ambulance; and either

a. The point of pickup is inaccessible by ground vehicle (this condition could be met in Hawaii, Alaska, and in other remote or sparsely populated areas. or
b. Great distances or other obstacles are involved in getting the patient to the nearest hospital with appropriate facilities as described in §10.4.4. *

3. Transport is only to the nearest acute care facility equipped to provide the appropriate treatment for the patient's condition.

Medical Reasonableness
Medical reasonableness is only established when the beneficiary's condition is such that the time needed to transport a beneficiary by ground, or the instability of transportation by ground, poses a threat to the beneficiary's survival or seriously endangers the beneficiary's health. Following is an advisory list of examples of cases for which air ambulance could be justified. The list is not inclusive of all situations that justify air transportation, nor is it intended to justify air transportation in all locales in the circumstances listed.

1. Intracranial bleeding - requiring neurosurgical intervention;
2. Cardiogenic shock;
3. Burns requiring treatment in a burn center;
4. Conditions requiring treatment in a Hyperbaric Oxygen Unit;
5. Multiple severe injuries; or
6. Life-threatening trauma.

Time Needed for Ground Transport
Differing Statewide Emergency Medical Services (EMS) systems determine the amount and level of basic and advanced life support ground transportation available. However, there are very limited emergency cases where ground transportation is available but the time required to transport the patient by ground as opposed to air endangers the beneficiary's life or health. As a general guideline, when it would take a ground ambulance 30-60 minutes or more to transport a beneficiary whose medical condition at the time of pick-up required immediate and rapid transport due to the nature and/or severity of the beneficiary's illness/injury, KPWA will consider air transportation to be appropriate.

Hospital to Hospital Transport
Air ambulance transport is covered for transfer of a patient from one hospital to another if the medical appropriateness criteria are met, that is, transportation by ground ambulance would endanger the beneficiary's health and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient. Examples of such specialized medical services that are generally not available at all type of facilities may include but are not limited to: burn care, cardiac care, trauma care, and critical care. A patient transported from one hospital to another hospital is covered only if the hospital to which the patient is transferred is the nearest one with appropriate facilities which are not available at the patient's current location. Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or the patient's family prefer a specific hospital or physician.

Special Coverage Rule
Air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office, or a beneficiary's home.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A0430	Ambulance service, conventional air services, transport, one way (fixed wing)
A0431	Ambulance service, conventional air services, transport, one way (rotary wing)
A0435	Fixed wing air mileage, per statute mile

Date Sent: 4/29/24

A0436	Rotary wing air mileage, per statute mile

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/03/2018	04/03/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	04/03/2018

[MPC] Medical Policy Committee

Revision History	Description

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Allogeneic Meniscal Transplant

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Allogeneic Meniscal Transplant***," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Meniscal Allograft Transplant (A-0216) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedics/podiatry)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The knee meniscus is a fibrocartilaginous crescent-shaped structure that plays an important part in the biomechanics of the joint. It functions as load bearing, shock absorption, stabilization of the joint as well as lubrication. Partial or complete loss of the meniscus alters the joint function and predisposes the articular cartilage to degenerative changes. In the past, total or subtotal meniscectomy was routinely performed for patients with meniscal tears. More recently, repair of the meniscus has become the standard treatment for tears. If un-repairable, arthroscopic partial meniscectomy of only the torn segments is recommended (Yoldas 2003). Subtotal or complete meniscectomy is however performed when the entire meniscus is torn and irreparable. Meniscectomy leads to deterioration of the articular cartilage and narrowing of the knee joint. Allograft meniscal transplantation has become an option for these patients and is believed to prevent progression of degenerative changes of the knee.

Back to Top

The first meniscal allograft was performed in 1984 by Milachowski and Wirth. The technique of the transplantation has evolved over the years, and different graft types were used. These include meniscus prosthesis, scaffolds, genetically engineered tissue, meniscus xenografts, meniscus autografts, and meniscus allografts. The allografts used are fresh, fresh-frozen, lyophilized, or cryopreserved menisci. Fresh menisci are thought to be superior as the architecture is unchanged, and chondrocytes and other cells are still viable. However, fresh grafts are logistically difficult to obtain. Fresh-frozen and cryopreserved menisci are reported to have good results but are associated with storage and availability problems. The Lyophilized and freeze-dried menisci can be stored for a long time but have the disadvantage of the decay of ground substance and destruction of the architecture in the freeze-dried menisci, and shrinkage in the lyophilized. Cryopreservation may maintain fibrochondrocytes for 2-4 weeks but is very expensive in cost. The success of the transplantation depends on the revascularization and the cell proliferation for the restitution of the lost ground substance. Sizing of the meniscus before transplantation is also important to have a good geometrical fit in the joint, and a proper function.

The indications of the transplantation are not well defined. Persistent pain after meniscectomy is a common indication. Some authors believe that a knee with minimal or no arthritic changes is the ideal for transplantation, and others indicate it only for knees with degenerative changes. Some investigators in the US (Felix N, and Paulos L 2003), indicate meniscal transplantation for those <40 years old, with pain and swelling not responding to conservative treatment, minimal degenerative changes, stable knee, and axial alignment. In other countries e.g., Germany (Peters 2003) the indications include total meniscectomy with early arthritis, loss of anterior cruciate ligament, concomitant osteotomy, and prophylactic transplantation. It is contraindicated in patients with severe degenerative changes in the joint, instability, malalignment, and history of infection of the joint.

Medical Technology Assessment Committee (MTAC)

Allogeneic Meniscal Transplant

07/14/2004: MTAC REVIEW

Evidence Conclusion: The results of the studies reviewed are promising but do not provide sufficient evidence, on the effectiveness of the meniscal allograft transplantation in restoring the knee function and preventing degenerative osteoarthritis. The prospective study, the two-case series appraised, as well as the other published case series and reports were small, included heterogeneous patients at different ages, and with different indications for the meniscal transplantation. None of the studies used a consistent protocol. The grafts used were fresh, deep-frozen, cryopreserved, or lyophilized allografts. The duration from the meniscectomy to the transplant varied among patients from few months to more than 30 years. In several reports and within studies some patients received an anterior cruciate ligament repair, together with the meniscal transplant. In others, patients underwent different procedures after the transplantation. The rehabilitation programs varied between and within studies, as well as the duration of follow-up. Overall the results of the studies show that meniscal transplantation may alleviate pain and improve the knee function. However, there is insufficient data to determine which patients will benefit most, and if benefits observed would be maintained over time, and whether the transplantation will prevent degenerative changes from occurring within the joint.

Articles: The search yielded 75 articles many of which were review articles. There were no meta-analyses or randomized controlled trials. One prospective cohort study and several case series reports with limited number of patients were identified. The prospective cohort study and two case series reports were selected for critical appraisal. Selection for the case series reports for review was based on the population size, duration of follow-up, and/or primary outcomes. *Evidence tables were created for the following studies:*

Wirth CJ, Peters G, Milachowaski KA, et al. Long-term results off meniscal allograft transplantation. *Am J Sports Med* 2002;30:174-181.See Evidence Table van Arkel ERA, and de Boer HH. Survival analysis of human meniscal transplantations. *J Bone Joint Surg* 2002;84-B:227-31. See Evidence Table Rath E, Richmond JC, Yassir W et al. Meniscal allograft transplantation. Two-to eight-year results. *Am J Sports Med* 2001; 29:174-181. See Evidence Table

The use of allogeneic meniscal transplant in the treatment of knee pain and swelling does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Back to Top

Applicable Codes

Considered Not Covered:

CPT® Codes	Description
29868	Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/14/2004	05/03/2011[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 04/01/2014[MDCRPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018MPC, 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	06/14/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD Non-Covered Services (L34886)
06/14/2016	Revised Medicare language and added date that code was taken off the non-covered services list

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Ambulatory Monitoring for Extended Duration

- CardioNet®
- CardioNet ECG Monitor
- eVolution
- Implantable Loop Recorder
- MCOT
- Zio®Patch

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	NCD Manual, Part 1 – Electrocardiographic Services Electrocardiographic Services (20.15)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	For Implantable Loop Recorder requests Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, for Implantable Loop Recorder medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Implantable Loop Recorder

An implantable loop recorder (cardiac event monitor) may be indicated for **1 or more of the following**:

A. Atrial fibrillation, known or suspected, as indicated by **ALL of the following**:
   - Cryptogenic stroke confirmed by neurology
   - Noninvasive cardiac monitor contraindicated, or results unrevealing or inconclusive after minimum 14-day period
   - Recurrent paroxysmal atrial fibrillation suspected, and test results may impact patient management

B. Syncope as indicated by **ALL of the following**:
   i. Cardiac etiology of syncope, suspected, as indicated by **1 or more of the following**:
      - ECG results abnormal (eg, cardiac rhythm other than normal sinus, significant conduction abnormalities, Brugada ECG pattern, long QT syndrome)
      - Family history of sudden death
      - History of chronic heart failure
      - History of structural heart disease (eg, valvular aortic stenosis, congenital heart disease, hypertrophic cardiomyopathy) or severe coronary heart disease
      - Recent history of palpitations, abnormal heart rate, or symptomatic arrhythmia

Back to Top

- Use of medication known to cause malignant arrhythmias (eg, antiarrhythmics, antidepressants, antihistamines)

ii. Recurrent syncope, suspected

iii. Test results negative or inconclusive, as indicated by **1 or more of the following**:

- Electrophysiologic study
- Non-implantable (external) loop recorder, worn for 14 days at a minimum
- Tilt table testing

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

Service	Criteria
CardioNet® CardioNet ECG Monitor eVolution MCOT Zio®Patch	Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Cardiac rhythm abnormalities are common. Many are harmless, but some cause symptoms such as palpitation, chest pain, pre-syncope and syncope, and others may be a signal for potential stroke or cardiac arrest. Electrocardiographic (ECG) documentation of the cardiac rhythm during symptoms is necessary for making accurate diagnosis, therapeutic decisions, assessing the effectiveness of suppression, and monitoring adverse drug effects. However, symptoms of arrhythmia are often infrequent and episodic, and the underlying heart rhythm may not be detected during physical examination and routine ECG that permits a few seconds of recording. It is thus essential to have extended periods of ECG recording while the patients are pursuing their normal routine (Kowey 2003, Naccarelli 2007, and Saarel 2008).

Devices used:

- *Holter monitors* are portable devices that record heart rhythms continuously for up to 48 hours. These devices are used to record events that occur at least once a day.
- *Non-implantable cardiac event monitors* are portable devices that record heart rhythms intermittently for up to 30 days. These devices capture ECG data before, during and after the time of activation.
- *Standard loop recorders* have just a few minutes of memory. Newer, more sophisticated devices have extended memory features that can store up to several hours of ECG data. Recording can be patient-activated when symptoms occur or automatically triggered based on a computer algorithm designed to detect arrhythmias. These devices are used to record infrequent or irregular events.
- *External mobile cardiovascular telemetry* consists of a monitor that continuously records the electrocardiographic rhythm from external electrodes placed on the patient's body. Segments of the ECG data are automatically (i.e., without patient intervention) transmitted to a remote surveillance location by cellular or landline telephone signal. The transmitted events are triggered automatically by preprogrammed algorithms or by the patient during a symptomatic episode. There is continuous, real-time data analysis in the device and attended surveillance of the transmitted rhythm segments by a surveillance center technician. The surveillance center technician reviews the data and notifies the physician depending on the prescribed criteria. These devices are used to record suspected asymptomatic arrhythmias.

The most commonly used method for extended ECG recording is the Holter monitor which records an ECG continuously for 24 to 48 hours via leads placed on the chest to yield 2 or 3 channels of ECG data. The Holter monitor provides complete rhythm recording and excellent quality tracing. However, it has a diagnostic yield of

Back to Top

only 5-28% due to its limited time of recording which is usually too short to capture infrequent arrhythmias. In addition, some clinically important arrhythmias such as atrial fibrillation may be asymptomatic and pass unnoticed by the Holter recording (Kowey 2003, Naccarelli 2007, Rothman 2007, Saarel 2008).

External patient-activated loop event monitoring (LOOP) devices were found by researchers to improve the diagnostic yield of arrhythmias up to 63%. These may be used for up to 30 days; however, they have limited storage, and require appropriate patient activation during the occurrence of symptoms. Patient activation may be a difficult task for the elderly or those whose arrhythmias cause functional impairment. It was reported that one in four patients does not activate the recorder during symptomatic episodes despite the education received on operating the device. Developments are continuously being made to improve the diagnostic yield of the rhythm monitors. Newer loop recorders continually record and erase so that data gathered from 1 to 4 minutes before, and those recorded 30-60 seconds after activation of the device can be retained. Other loop monitors are automatically activated and start the recording once an abnormal rhythm of any kind is detected, without patient activation. An implantable form of continuous-loop event recorder is also currently available. It is a small device in the size of pacemaker that is implanted subcutaneously to the right or left side of the sternum and is triggered by placing an activator over it. The device has a programmable antegrade and retrograde memory and may be left in place for up to 18 months and can be explanted once the diagnosis is made or battery life has ended. Data from the device however, cannot be transmitted wirelessly (Zimetbaum 1999, Kowey 2003, Naccarelli 2007 Rothman 2007).

Mobile Cardiac Outpatient Telemetry (MCOT, CardioNet®, CardioNet device or recorder) was introduced in 1999 for continuous real-time ambulatory electrographic monitoring and analysis. The device consists of a three-electrode, and a two-channel sensor that transmits wirelessly to a small PDA sized portable monitor which can be clipped to the waist or worn on a strap around the neck. Rhythm strips are recorded continuously and analyzed by an automated arrhythmia analysis algorithm. When an arrhythmia is detected (according to the physicians 'predesignated thresholds) the monitor can transmit the ECG data to the monitoring center utilizing a cellular modem or telephone data line. Patients are monitored for 24 hours/day for up to 30 days, by central station technicians with immediate referral to the prescribing physician for evaluation of rate and rhythm changes and their symptoms. The patient can also initiate the recording and transmission of ECG data if symptoms are felt. MCOT thus potentially improves diagnosis of arrhythmias by allowing continuous monitoring of cardiac rhythm for extended periods of time, detecting asymptomatic arrhythmias, and allowing the patients to submit their symptoms and level of activity from a menu to the device (FDA web page, Rothman 2007, Naccarelli 2007).

The CardioNet ECG monitor was approved by the Food and Drug Administration in 2002 for cardiac monitoring for non-life-threatening arrhythmia detection, its evaluation, and monitoring of antiarrhythmic therapy.

Medical Technology Assessment Committee (MTAC)

Mobile Cardiac Outpatient Telemetry (MCOT)

06/04/2008: MTAC REVIEW

Evidence Conclusion: The literature search revealed only one randomized controlled study (Rothman 2007), and several observational studies. Rothman and colleagues' study were a multicenter, randomized, controlled study that compared the diagnostic yield of the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) with the patient-activated external loop devices (LOOP). Patients with symptoms of syncope, pre-syncope or severe palpitations, and a nondiagnostic 24-hour Holter, were randomized to receive one of the two monitoring devices for up to 30 days. The patients and investigators were not blinded to the monitor received, but the electrophysiologist who reviewed the monitor strips and verified the diagnosis was blinded to the patient allocation. There was a higher noncompliance rate in the MCOT group, and 14% of all participants did not complete the study. The study compared the MCOT (CardioNet) system with the patient-activated external loop device and not to the auto-triggered or the implanted loop systems which are known to have better diagnostic yield.

Overall, the results of the study show that diagnosis (confirmation or exclusion) of arrhythmias was made in 88% of the patients randomized to the MCOT group, vs. 75% of the patients in the LOOP group ($P<0.001$). A significant difference was also observed for patients with syncope or presyncope, where a diagnosis was made in 89% of patients in the MCOT group vs.69% in the LOOP group ($p=0.008$). Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is no published evidence to date to determine that the device is superior to the auto-triggered loop system that was found to have better diagnostic yield, or to the implanted loop system. There is insufficient evidence to determine the efficacy and safety of the CardioNet system for detecting less frequent syncopal episodes. There is insufficient evidence on the efficacy of CardioNet

 Back to Top

system in assessing the safety and efficacy of antiarrhythmic agents, or outpatient monitoring for medication titration and dose adjustments.
Articles: The search yielded around 50 articles. Many were reviews, or articles that dealt with the analysis of data or feasibility of using the device. Only one randomized controlled study (Rothman 2007) that compared the diagnostic yield of MCOT to the external patient-activated loop event monitoring up to 30 days, was identified. There were a few other relatively small observational prospective and retrospective studies that evaluated the safety and diagnostic yield of the CardioNet system. Rothman and colleagues' RCT were selected for critical appraisal. Rothman SA, Laughlin JC, Seltzer J, et al. The diagnosis of cardiac arrhythmias: A prospective multi-center randomized study comparing mobile cardiac outpatient telemetry versus standard loop event monitoring. J Cardiovasc Electrophysiol 2007; 18:241-247. See Evidence Table.

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/03/2009: MTAC REVIEW
Mobile Cardiac Outpatient Telemetry (MCOT)
Evidence Conclusion: There is no new published evidence that would alter the conclusion of the previous MTAC review. The only published RCT (Rothman 2007) that compared mobile cardiac outpatient telemetry to LOOP event monitoring was reviewed earlier in 2008. The study was randomized, controlled and multicenter. However, it was not blinded, had a 14% drop-out rate, non-compliance was more common in the MCOT group, and analysis was not based on intention to treat. Moreover, the mobile cardiac outpatient telemetry (MCOT) system (CardioNet, USA) was compared with the patient-activated external looping event recorders. The study did not compare MCOT with the implanted loop recorders and was not designed to compare it with the auto-trigger loop recorders which were used in only 16% of the patients in the LOOP group. Both the implanted and auto-trigger loop recorders are reported to have higher diagnostic yield than the patient activated loop recorders. Overall the results of the study indicate that MCOT was superior to loop recordings with a diagnosis made in 88% MCOT patients vs. 75% LOOP patients (p=0.008). A significant difference in the diagnostic yield was also observed for patients with syncope or presyncope (89% vs. 69% respectively, p=0.008). More recently only retrospective case series (Saarel 2008, and Tayal 2008) on the use of MCOT for the detection of suspected arrhythmias were published. Saarel and colleagues (2008) reported on the use of MCOT among 54 children and adolescents with suspected arrhythmia. Thirty-three subjects transmitted ECGs during symptoms yielding a diagnostic rate of 61%. The remaining 21 (39%) failed to transmit ECG while experiencing symptoms. Comparing the diagnostic yield of MCOT with historical data from transtelephonic electrocardiographic event monitors (TTMs) showed no significant differences between the two systems. Tayal and colleagues (2008) performed a retrospective analysis of 56 patients with cryptogenic stroke (undetermined cause). This showed that MCOT detected 27 asymptomatic atrial fibrillations in thirteen patients (23%). 23 (85%) of these episodes were less than 30 seconds in duration, and the remaining 4 (15%) were 4-24 hours in duration. None of the published studies to date indicate that the MCOT (CardioNet system) is superior to the auto-trigger LOOP device currently used, or that it leads to an improvement in net health outcome. Conclusion: There is fair evidence from one RCT with limitations, that CardioNet system may have a higher diagnostic yield compared to the patient-activated external loop device for up to one month. There is insufficient evidence however to determine that the device is superior to the auto-triggered or the implanted loop systems that were found to have better diagnostic yield than the patient-activated external loop monitors. There is insufficient evidence to determine that CardioNet system improves the management of patients e.g. monitoring for medication titration and dose adjustments. There is insufficient evidence to determine that CardioNet system improves patients' health outcomes.
Articles: The search did not reveal any controlled trial on MCOT published after the RCT reviewed earlier in MTAC. Only two relatively small retrospective case series were identified; one reported on the use of MCOT among adult patients with stroke, and the other evaluated its use among children and adolescents with suspected arrhythmias. None were selected for critical appraisal.

The use of Mobile Cardiac Outpatient Telemetry (MCOT) in the detection of arrhythmias does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Zio®Patch
12/16/2013: MTAC REVIEW
Evidence Conclusion: There is a lack of published literature on the use of Zio®Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic or symptomatic patients. A pilot study conducted by Rosenberg and colleagues (2013) compared the Zio®Patch with the traditional 24 hours Holter monitor in 74 patients with paroxysmal atrial fibrillation who were referred to Holter monitoring for evaluation. The Zio®Patch was well tolerated and had a mean monitoring period of 10.8 +2.8 days (range 4-14 days). During the simultaneous 24-
 Back to Top

hour recording time when the patients wore both devices, there was a strong correlation between the Zio®Patch and the Holter monitor (r=0.96) for identifying AV events and estimation AF burden.18 additional cardiac events were recorded with the Zio®Patch due to longer duration of use. Other clinically relevant cardiac events recorded by the Zio®Patch after the 24 hours of monitoring, including symptomatic ventricular pauses, led to change in medications or referrals for pacemaker placement. Overall clinical management was changed in 28.4% of the patients as a result of the Zio®Patch findings. The authors concluded that the Zio®Patch was well tolerated and allowed longer monitoring that resulted in meaningful changes in clinical management. They indicated that more studies are needed to examine the long-term impact of the device in AF management. The other published study (Turakhia et al, 2013) was only a retrospective analysis of data obtained from the device manufacturer. No comparison was made with Holter monitor or any other ambulatory cardiac rhythm monitor. There are no published studies, to date, that compared the Zio®Patch to any of the other longer-term outpatient ambulatory cardiac rhythm monitors. Conclusion: There is weak evidence from one small single-center pilot study that Zio®Patch was well tolerated and allowed longer monitoring than Holter monitoring. This resulted in the detection of more AF episodes and cardiac events in symptomatic patients and making changes in the clinical management among more than one fourth of the study participants. There is insufficient published evidence on the use of Zio®Patch for detecting atrial fibrillation and other arrhythmias in asymptomatic patients with AF. There is insufficient evidence to determine the equivalence or superiority of Zio®Patch to any of the other longer-term outpatient ambulatory cardiac rhythm monitors.

Articles: The literature search revealed only two published studies on the use of Zio®Patch as a noninvasive monitoring device for arrhythmias in general in one study, and for atrial fibrillation in the other. A retrospective study among 285 patients seen in emergency departments was identified from a review article, but it was not published in a peer review journal; it was only presented in a conference. The two published studies were critically appraised. Rosenberg MA, Samuel M, Thosani A, et al. Use of a noninvasive continuous monitoring device in the management of atrial fibrillation: a pilot study. *Pacing Clin Electrophysiol*. 2013;36:328-333.See Evidence Table, Turakhia MP, Hoang DD, Zimetbaum P, et al. Diagnostic utility of a novel leadless arrhythmia monitoring device. *Am J Cardiol*. 2013; 112:520-524. See Evidence Table.

The use of Zio®Patch the detection of arrhythmias does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Implantable Loop Recorder

BACKGROUND

Syncope has a complex differential diagnosis. Syncope that remains unexplained after standard evaluation does not appear to be associated with excess mortality (Savage et al., 1985) or serious adverse cardiovascular events (Kapoor, 1990). However, syncope recurrences are associated with fractures, automobile accidents and other complications (Kapoor, 1987).

Standard techniques for diagnosing syncope include history and physical examination, laboratory testing, exercise stress testing, Holter monitoring, tilt table testing and external loop recording. External loop recorders (“King of Hearts” model) store ECG data up to 4 minutes prior to and 1 minute after activation by a patient. They are worn on the wrist or around the waist, generally for up to 1 month.

The implantable loop recorder (ILR) is a new diagnostic tool for unexplained infrequent syncope. The ILR is a 61x19x8mm, recording device produced by Medtronic Reveal. It stores an ECG signal in a circular buffer capable of retaining 21 minutes of uncompressed signal or 42 minutes of compressed signal (can be divided into 1-3 parts). The ILR requires the patient or family member to use a hand-held pager-sized activator to “freeze” the memory buffer during or immediately following an episode of syncope. The device is implanted into the left infraclavicular region. Using local anesthesia, a 2 cm incision is made, a pocket the size and shape of the device is made and the ILR is placed in the pocket. The ILR can monitor patients for up to 14 months. The device is removed after a diagnosis of syncope is made or at the end of battery life.

Medicare approved coverage for this implantable device effective 10/1/1999. Kaiser Permanente added it to the medical criteria subject area at that time.

MTAC reviewed this device at the February 2000 meeting and found the technology appears to be promising and safe for patients whose syncope is undiagnosed but there is not enough evidence to draw conclusions regarding reproducibility, safety and accuracy. The Health Plan Medical Director Group at their February 2000 meeting reviewed the MTAC findings and determined that there was good reason to recommend coverage for patients who had infrequent, undiagnosed episodes of syncope.

 Back to Top

02/10/1999: MTAC REVIEW
Evidence Conclusion*:* The one study evaluating the potential of the ILR to diagnose unexplained syncope obtained a diagnostic yield of 59% during a mean of 10.5 months of recording. Possible selection bias, conflict of interest on the part of the investigators and a lack of comparison with external loop recorders limit the ability of this study to determine efficacy of the ILR. Two studies evaluating the external loop recorders found point estimates for diagnostic findings of 25% and 36% after approximately one month of recording.
Articles: Krahn D, Klein G, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. Circulation 1999; 99: 406-410. See Evidence Link.

The use of implantable loop recorder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Implantable Loop Recorder - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
HCPC Codes	**Description**
C1764	Event recorder, cardiac (implantable)
E0616	Implantable cardiac event recorder with memory, activator, and programmer

External Loop Recorder –

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Medical Necessity review no longer required

CPT® Codes	Description
93228	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional
93229	External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional
93270	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)
93271	External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; transmission and analysis

External Patient Activated EKG -

Medicare - Considered not medically necessary
Non-Medicare - Medical Necessity review no longer required

Back to Top

CPT® Codes	Description
No specific codes	

Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
07/17/08	06/04/2008, 08/03/2009, 5/4/2010 MDCRPC, 3/1/2011 MDCRPC, 1/03/2012MDCRPC,11/06/2012 MDCRPC, 09/03/2013 MPC , 03/04/2014MPC, 11/03/2015MPC , 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC, 03/12/2024MPC	12/15/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/05/2016	Added “Following a cryptogenic stroke” as an indication
08/09/2016	Merged Implantable Loop Recorder into one policy as External Loop Recorder
02/01/2017	Medical management approved medical necessity no longer required
03/06/2018	MPC approved commercial criteria for Implantable Loop Recorder effective date 7/1/2018
05/05/2020	Removed deleted codes 33282 and 33284 (ILR)
07/07/2020	MPC approved to adopt updates to the *Implantable Loop Recorder* clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020.
08/06/2020	Removed CPT code 33286
05/04/2021	Updated applicable coding
12/15/2022	Updated Medicare Policy to defer to KP non-Medicare criteria for Implantable Loop Recorder. *Per email dated 12/14/2022 from Noridian. *Noridian does not have a specific LCD for Implantable Loop Recorders and coverage would be based on medical necessity.*
08/08/2023	Removed deleted codes 0497T & 0498T
4/17/2024	Removed deleted code G2066.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Artificial Spinal Discs for Lumbar or Cervical Disc Disease

- Bryan™
- Charité™
- Prestige™ Artificial Discs
- ProDisc-C™
- ProDisc-L™
- Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Lumbar Artificial Disc Replacement (LADR) (150.10) Per NCD - this service is not covered for Medicare beneficiaries over 60 years of age.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for lumbar artificial disc replacement for Medicare members under 60 years of age or for cervical artificial disc replacement, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Artificial Spinal Discs for Lumbar or Cervical Disc Disease"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

I. Artificial cervical discs may be considered medically necessary for the following:
   A. For treatment in adults with symptomatic cervical degenerative disc disease when **ALL** of the following are met:
      1. FDA-approved prosthetic intervertebral discs are used;
      2. Performed at one level or two contiguous levels from C3-C7;
      3. Objective evidence in the clinical record documents cervical radiculopathy and/or myelopathy; and
      4. Patients have failed at least six weeks of conservative management (which may include rest, application of heat/ice, physical therapy, exercise, pain and/or anti-inflammatory medications).
   B. A subsequent, second-level, anterior total cervical disc replacement using an artificial intervertebral disc following complete decompression may be considered medically necessary in skeletally mature patients with symptomatic cervical disc degeneration when **ALL** of the following are met:
      1. The planned subsequent procedure is at a different cervical level then the initial cervical artificial disc replacement; and
      2. Clinical documentation that the initial cervical artificial disc replacement is fully healed; and
      3. Criteria A, 1-4 are met

II. Prosthetic intervertebral discs are considered investigational for **ALL** of the following:

Back to Top

- In patients with isolated axial neck pain without cervical radiculopathy or myelopathy;
- When requested adjacent to a prior fusion; or
- At a level of prior surgery
- When more than two levels are requested

III. Lumbar Disc
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes from requesting provider &/or specialist that include a current history and physical exam
- Detailed documentation of extent and response to non-operative conservative therapy or procedural interventions
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Degeneration of the intervertebral disc, also known as degenerative disc disease (DDD) is the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration can occur at any level of the spine but is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment, however the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels (Lee 2004, Mobbs et al, 2007, Sasso 2008, Yang 2008, Heidecke 2008).

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear (Yang 2008, Burkus 2010, Cepoiu-Martin 2011).

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), and Prestige Cervical Disc (Medtronic Sofamor Danek). ProDisc-C

Back to Top

has a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and PRESTIGE has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. FDA clearing of the artificial disc systems required post-approval studies to evaluate the long-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate 3, 5, 7, and 10-year data for cervical discs.

Lumbar

The Charité ® (DePuy) and ProDisc®-L (Synthes Spine) have received approval from the US Food and Drug Administration. The approval was contingent on completion of post-marketing studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate the 5-year data for lumbar discs. The Charité ® and ProDisc®-L devices are indicated for:

1. Spinal arthroplasty in skeletally mature patients, with pain from degenerative disc disease (DDD).
2. One level of the spine (L3-S1 for the ProDisc-L, L4-S1 for the Charité).
3. Patient may have no more than a grade 1 spondylolisthesis.
4. Patients must have failed to find pain relief after at least 6 months of non-surgical therapies.

Contraindications to total lumbar disc replacement include active infection, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and DDD at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Cervical

The cervical artificial discs are FDA approved for the following:

1. Reconstruction of cervical disc from C3-C7 following single-level discectomy for intractable.
2. Symptomatic cervical disc disease confirmed by imaging.
3. Patient is skeletally mature.
4. Cervical disc disease should have failed at least six weeks of non-operative treatment prior to implantation.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Medical Technology Assessment Committee (MTAC)

Artificial Disc in the Treatment of Back Pain

02/07/2005: MTAC REVIEW

Evidence Conclusion: The trial reviewed on Charité artificial spinal disc was randomized, controlled, and multicenter, but had some limitations. Authors concluded that the clinical outcomes and incidence if major neurological complications at 2 years of follow-up were equivalent to those of BAK fusion. The trial, however, was not designed as an equivalence study. Equivalence trials are planned and analyzed differently from superiority studies, and generally require larger sample sizes. Lack of significant superiority is not necessarily the same as equivalence, and the absence of statistical significance may be due to insufficient power to detect differences between the study groups. The comparison group in this trial was the BAK fusion technique, which was the preferred fusion procedure at the time, but might not be the current up-to-date procedure. Moreover, the 24-months follow-up period might not sufficient to determine the long-term safety and effectiveness of the implant as well as its impact on other discs and on the bony structures on the back of the spine.

Articles: The search yielded 56 articles. The majority were review articles, or reports that dealt with the design, technical aspects and/or evolution of the technology. The search revealed four articles published by the same group of authors reporting on the Charité artificial disc evaluated in a multicenter RCT in the US. The article that reported the results of the trial in all centers was selected for critical appraisal.

Back to Top

The search also revealed a report on the early 6 months results for the first 53 patients randomized in an ongoing multicenter RCT of ProDisc in the United States. The system is not currently FDA approved.
Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. *L Neurosurg (Spine 2)2004;1:143-154.* See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

10/04/2006: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence that artificial discs approved by the FDA or pending approval are effective, particularly in the long-term. There is only one completed RCT and this is on the Charité device. There are no completed published RCTs on the Prestige or ProDisc devices. The Charité RCT may not have used appropriate equivalence trial methods, including failure to compare the new device to an intervention with proven effectiveness. The safety of the artificial discs after a minimum of 2 years appears similar to that of surgical fusion. Authors of the Charité had financial links to the manufacturer, which could introduce bias.
Articles: An April 2005 Blue Cross BlueShield TEC report was identified. In their literature search, they found one completed RCT, the same study included in the first MTAC review. There was also a systematic review (Freeman & Davenport, 2006) that searched the literature through April 2006 and also identified the same single completed RCT. *Literature on individual devices identified through Medline search:*
Charité device: Several additional publications on the RCT previously reviewed by MTAC (Geisler et al., 2004) were identified: Blumenthal et al. (2005) reported updated data on primary outcomes (more patients had reached 24-month follow-up). McAfee et al. (2005) reported on radiographic outcomes e.g. restoration of disc height. Regan et al. (2006) examined outcomes in the treatment group according to centers' surgical volume. McAfee et al. (2006) reported on the re-operation rate of patients in the RCT as well as other patients, for a total sample size of 688. The updated study on the primary outcomes (Blumenthal et al., 2005) and the study on re-operation rates (McAfee et al., 2006) were critically appraised. The other publications were not evaluated further because they do not add substantially to our ability to evaluate the long-term safety and efficacy of the Charité device. ProDisc device: The RCT identified in the previous MTAC search comparing ProDisc to surgical fusion is still ongoing. The study is taking place at 19 centers and has an enrollment goal of 500 patients. At the time of the first MTAC review, an article reporting initial findings for 53 patients at one center was identified. A 2005 article was identified that reported additional preliminary findings from the same center, this time for 78 patients. This study was not critically appraised because results from all centers are not yet available. Prestige device (not included in 2005 MTAC review): There was a 2004 publication reporting on preliminary findings from a randomized controlled trial on Prestige II conducted at four sites in Europe. This study was critically appraised. The article appears to report on all randomized patients, although not all patients had completed the final follow-up. No subsequent publications on outcomes of this RCT were identified. In addition, an older case series with 17 patients using the Prestige I device was identified, but not evaluated further due to the small size and the availability of higher-grade evidence. Blumenthal S et al. A prospective, randomized, multicenter food and drug administration investigational device exemptions study of lumbar total disc replacement with the Charité artificial disc versus lumbar fusion. Spine 2005; 30: 1568-1575. See Evidence Table. McAfee PC et al. Revisability of the Charité artificial disc replacement. Spine 2006; 31: 1217-1226. See Evidence Table. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurgery Focus 2004; 17: 36-43. See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

10/01/2007: MTAC REVIEW

Evidence Conclusion: The Prestige cervical disc system was first reviewed by MTAC before final FDA approval. At that time, there was one relatively small published RCT reporting preliminary findings (Porchet & Metcalf, 2004). At the time of data analysis, the investigators did not find a significant difference in pain and disability outcomes at 12 months for patients who underwent either artificial disc replacement or anterior cervical fusion. Limitations of this RCT included insufficient follow-up (only about two-thirds of participants had completed the 12-month follow-up and about 15% had completed the 24-month follow-up), unclear equivalence study methods, and funding from the device manufacturer. A larger multicenter RCT among patients with symptomatic single-level

 Back to Top

cervical degenerative disc disease (DDD) was identified for the evidence update (Mummanemi et al., 2007). Mummanemi and colleagues randomized 541 patients to receive either the Prestige cervical disc system or anterior cervical discectomy and fusion. Using a composite success measure developed by the investigators that considered efficacy and safety, the Prestige artificial disc system was found to be superior to ACDF in a completer analysis. In an intention to treat analysis with a "worst case scenario" analysis, Prestige was found to be non-inferior to ACDF. Advantages of the Mummanemi study were that it was randomized and there was a high follow-up rate. Disadvantages are that the study was non-blinded, and the authors have financial links with the manufacturer. In conclusion, there is fair evidence from one reasonably valid multicenter RCT that use of the Prestige artificial disc in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety. The evidence would be strengthened by longer-term follow-up data and studies conducted by impartial researchers. The Porchet & Metcalf, 2004 study does not add substantially to the body of evidence, especially since only preliminary findings were reported in the published literature.

Articles: At the time of the previous MTAC review of artificial discs (October 2006), there was one published randomized controlled trial on the Prestige disc with 55 patients from 4 sites in Europe. The article reported preliminary findings of the RCT (Porchet & Metcalf, 2004). No follow-up publication was identified that reported final results of this RCT. The updated literature search identified a new, larger RCT. This study randomized 541 patients at 32 sites in the United States to discectomy with artificial disc replacement or ACDF (Mummaneni et al., 2007). This was the key study submitted to the FDA for device approval. The Mummaneni et al. RCT was critically appraised: Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table.

The use of Prestige artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/01/2010: MTAC REVIEW

Evidence Conclusion: The published randomized controlled trials on lumbar and cervical artificial disc replacement, reviewed for this report, were all US FDA investigational device exemption (IDE) studies designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD, or ACDF for cervical disc disease (non -inferiority design). Lumbar total disc replacement with artificial intervertebral discs (Charité, and ProDisc-L). The trials on artificial total lumbar disc replacement compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the CHARITE IDE trial had a maximum study duration of two years which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration.

CHARITE IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with non-blinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated.

In conclusion, there is insufficient evidence to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration. Cervical total disc replacement with artificial intervertebral discs (ProDisc-C, Bryan, and PRESTIGE). The trials on artificial total cervical disc replacement compared the procedure in conjunction with discectomy to anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with radiculopathy or myelopathy from a single-level cervical disc disease From C3 to C7, that failed conservative treatment of at least 6 weeks. The trials were randomized, controlled and multicenter, but were not blinded, the postoperative care was not standardized and left to the

 Back to Top

discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturer, all of which are sources of bias. Moreover the 2-year follow-up duration insufficient to examine the long-term efficacy, safety, and durability of the artificial disc replacement, or to determine whether it is associated with the risk of adjacent risk degeneration. In conclusion, the short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or PRESTIGE artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease.

Articles: *Lumbar artificial disc replacement* the updated literature search identified two randomized controlled trials that compared total lumbar disc replacement with Charité (Guyer 2009) or ProDisc-L (Zigler 2007) systems versus lumbar fusion. Guyer et al reported on 5-year follow up of patients enrolled in the Charité IDE trial that was the key study submitted to the FDA for device approval. Zigler et al's trial was also the key trial for FDA approval for ProDisc-L. Both RCTs was critically appraised. Guyer RD, McAfee PC, Banco RJ, et al. Prospective, randomized multicenter Food and drug Administration investigational device exemption study of lumbar total disc replacement with the Charité artificial disc and versus lumbar fusion: Five-year follow-up. Spine J. 2009; 9:374-386. See Evidence Table. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine. 2007; 22:1155-1162. See Evidence Table *Cervical artificial disc replacement:* The literature search revealed two RCTs on ProDisc-C total disc replacement as well as two trials on Bryan cervical disc arthroplasty (conducted by the same principle investigators, and published in 5 articles). Two studies, one for each system (Murrey 2009 for ProDisc-C, and Heller 2009 for Bryan cervical disc arthroplasty), were selected for critical appraisal based on the methodological quality of the trial, population size and duration of follow-up. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine. 2009; 9:275-286. See Evidence Table. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:107-107. See Evidence Table.

The use of artificial spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: *CERVICAL* The three large published trials on cervical arthroplasty were industry sponsored studies submitted to the U.S. Food and Drug Administration for premarket approval of the devices: Prestige, ProDisc-C, and Bryan cervical disc. All three trials were designed as noninferiority trials i.e. attempting to show that cervical artificial disc replacement is at least as good as ACDF for cervical disc disease. They had similar inclusion and exclusion criteria, similar follow-up schedules, and similar outcome measures and success criteria defined by the FDA. The three trials are still ongoing as the FDA required that the investigators conduct post-approval studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to provide 3, 5, 7, and 10-year data for cervical discs. Each of the three studies compared total replacement with an artificial disc (Prestige, ProDisc-C, or Bryan) in conjunction with discectomy to a single-level anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with a single level cervical radiculopathy or myelopathy between C- 3 and C-7 that had failed conservative treatment of at least 6 weeks. The trials were relatively large, randomized, controlled, and multicenter, but were not blinded, the postoperative care was not standardized and left to the discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturers who supported the trials, all of which are sources of bias. The 24 months interim analyses of the three trials were previously reviewed by MTAC. The conclusion of the last 2010 MTAC assessment of the technology was as follows, "The short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or Prestige artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease." After the last MTAC review of 2010, mid-term follow-up data were published for all three trials: 48 months postoperative data for ProDisc and Bryan artificial discs and 60 months postoperative data for Prestige cervical disc. These mid-term follow-up data were only available for just over two thirds of the

 Back to Top

population in the Bryan disc trails, and around 50% for each of the 60 months follow-up data for the Prestige disc trials and the 48 months follow-up for ProDisc-C trial. The published results of all three studies show that the one level cervical disc arthroplasty appears to be at least as effective as cervical fusion in up to 2 years of follow-up. The results the extended, mid-term analyses suggest that the outcomes the artificial disc arthroplasty continues to be noninferior to those of fusion. However, the follow-up rates are poor, and the results on sustained effect and durability should be interpreted with caution. The 48 and even 60 months follow-up duration is still insufficient to determine the long-term efficacy, durability, and safety of the system, and the potential risk on adjacent risk degeneration. The trials are still ongoing and long-term results for up to 10 years follow-up are expected. In conclusion, the additional information does not change the conclusions of the previous reports; data on long-term safety and efficacy is still lacking, and there is no evidence to date to determine if one of these three FDA approved artificial discs is superior to the others. A recent update of the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) (November 2011) concluded that artificial intervertebral disc arthroplasty for the treatment of patients with cervical degenerative disc disease does not meet their criteria. The TEC update however did not include Sasso et al's 2011 article that reports on the 48 months outcomes of all participating centers in the Bryan cervical disc trial. At the time of the TEC review only one center had published the 48-month follow-up results (BCBS 2011). *LUMBAR* As indicated in the last 2010 MTAC review, the published randomized controlled trials on lumbar artificial disc replacement were U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) studies that were designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD. The studies (reviewed in earlier reports) compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the Charite IDE trial had a maximum study duration of two years, which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration. Charite IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with nonblinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated. Yajun, et al's meta-analysis, 2010 (Evidence table 1) pooled the results of five studies involving 837 patients. The meta-analysis had valid methodology and analysis, and according to its reviewers, four of the five trials had good methodological quality. They indicated however, that the studies had limited population sizes and did not indicate that the assessors of the outcomes were blinded. The pooled results of the analysis showed that at 2 years of follow-up the patient functioning ability as measured by the Oswestry Disability Index (ODI) in the total disc replacement (TDR) group was better than the fusion group but, according to the authors a mean difference of 4 Oswestry points is not clinically relevant. There was also a statistically significant but clinically irrelevant difference in the pain score in favor of the TDR. After performing a sensitivity analysis excluding one large study that compared TDR with BAK cages, the difference in ODI, pain, and patient satisfaction were no longer significant. The authors concluded that TDR is not superior to fusion in treating lumbar degenerative disc disease. In conclusion, there is still insufficient published evidence to date, to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration.

Articles: *CERVICAL DISC* The literature search revealed four articles reporting on long-term outcomes of three pivotal clinical trials on Prestige ST, ProDisc-C, and Bryan artificial discs (one in a single center, and the other on the entire population studied). The search also identified an RCT on KineflexIC artificial disc with 2-year follow-up, and a recent meta-analysis (Cheerag, et al. 2011) that pooled the 2-year follow-up results of the three first trials. No trials comparing the three FDA approved artificial disc systems to one another were identified.

All three initial studies on Bryan, ProDisc, and Prestige cervical discs initial trials with 2-year outcomes that were submitted to the FDA for premarket approval were previously reviewed by MTAC. The reports on long-term follow-up outcomes of the studies were reviewed and their results added to the last MTAC report to update the findings and conclusions. The meta-analysis was not critically appraised as it does not add more evidence to 24 months interim results of the individual trials. Pooling these results still provide 2-year results when long-term safety, durability, and efficacy are needed. The recent RCT on KineflexIC was also not selected for appraisal as it only provides 24 months data. The following initial trials and more recent publications were critically appraised:

 Back to Top

Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with The Prestige disc: results from a prospective randomized controlled trial. J Neurosurg Spine 2010; 13:308-318. See Evidence Table. Delamarter, RB, Murrey D. Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients SAS Journal. 2010; 4:122–128. See Evidence Table**.** Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:101-107. See Evidence Table**.** Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. 2009; 9:275-286. See Evidence Table**.** Sasso RC, Anderson PA, Riew D, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: Four-year clinical outcomes in a prospective randomized, controlled, trial. J Bone Joint Surg A. 2011; 93:1684-1692. See Evidence Table**.** *LUMBAR* The literature search for studies published after the MTAC 2010 re-review of the technology, did not identify more recent reports on extended follow-up of the key trials on the Charité IDE or ProDisc-L used for the treatment of a single level generative disc disease (DDD). There was a recently published RCT (Delamarter et al 2011) conducted by the same investigators of Pro-disc-L total replacement, but for the treatment of two-level lumbar DDD which the focus of the current review is not. The search also revealed one meta-analysis of studies on artificial lumbar disc replacement for single level DDD, a systematic review, and once case series on with a 2-7 years follow-up of 57 patients who received an artificial Charite III total disc arthroplasty. The meta-analysis was selected for critical appraisal: Yajun W, Yue Z, Xiuxin H. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease*. Eur Spine J.* 2010; 19:1250-1261. See Evidence Table.

The use of cervical artificial disc in the treatment of back pain meeting the *Kaiser Permanente Medical Technology Assessment Criteria* is inconclusive.

The use of artificial lumbar spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

BACKGROUND

Degenerative disc disease (DDD) is defined as any changes that occur at any level of the spine. It's the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment. However, the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [1-4].

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. In addition, many trials [5, 6] have shown that cervical disc arthroplasty (CDA) is as safe and effective as ACDF for the treatment of CDD at a single level. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear [3, 7, 8].

Back to Top

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité ™ (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), Prestige Cervical Disc (Medtronic Sofamor Danek), Mobi-C Cervical Disc (LDR Spine USA), and Kineflex|C Spinal System (SpinalMotion Inc.). ProDisc-C have a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and Prestige has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received the US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. The Mobi-C has received the US Food and Drug Administration (FDA) premarket application approval on August 2013.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

09/21/2016: MTAC REVIEW
Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease
Evidence Conclusion: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) (evidence table 1) This meta-analysis of RCT aimed to determine the safety and efficacy of cervical disc arthroplasty (CDA) at two contiguous levels cervical disc degeneration. The search was performed between January 2000 and July 2015. Evaluation of study quality was performed using the Cochrane Collaboration's tool for assessing risk of bias. Mean follow-up of included studies ranged from 20-48 months. CDA group patients showed fewer blood loss, lower post-operative complications, lower reoperation rate and better range of motion at all angles and levels. No significant difference was identified in mean surgical time, neck disability index and neck and arm pain VAS scores. Limitations remain in the variety of artificial intervertebral disc types. Furthermore, there is limited number of articles on artificial cervical disc for 2 levels.
Overall, CDA is more effective; the study has valid methodology with some limitations.

Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) (evidence Table 2) This multicenter RCT, FDA investigational device exemption pivotal trial aimed to compare the Mobi-C cervical artificial disc to anterior discectomy and fusion (ACDF) for treatment of cervical DDD at 2 contiguous levels of the cervical spine. This study shows that the overall study success rates met the non-inferiority margin and provided statistical superiority of the total disc replacement (TDR) treatment over ACDF. Results should be interpreted with caution since several authors had received clinical or research support for this study from LDR, the sponsor. In addition, many other authors had financial ties with LDR.

Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) (evidence Table 3) This is a 4-year follow-up result of the study performed by the same author in 2013. The follow up in the 2013 study presented earlier is 24 months. The current study follow-up is 48 months. At 48 months, total disc replacement (TDR) had greater improvement than ACDF in: neck disability index scores, 12-Item Short Form Health Survey Physical Component Summary scores, patient satisfaction, and overall success. In addition, TDR patients had lower subsequent surgery rates and showed a lower rate of adjacent-segment degeneration; TDR also maintained segmental range of motion. The study shows that TDR continue to be safe, effective and superior to ACDF at 48 months for the treatment of degenerative disc disease at 2 contiguous cervical levels.

A systematic review and meta-analysis of RCTs [9] indicated that CDA is more effective and safer than ACDF for the treatment of symptomatic cervical disc disease in mid- to long-term follow-up. However, only one study

 Back to Top

including 2-level was included in the review. A prospective, randomized study [10] compared the safety and effectiveness of the Bryan Cervical Disc in patients with myelopathy caused by two-level cervical disc disease in Han Nationality. The authors found that the Bryan Cervical Disc replacement was shown to be reliable and safe for the treatment of patients with two-level cervical disc disease.

Conclusion:

- Two-level cervical artificial disc replacement shows positive outcomes on the short-term
- There is low evidence to support the effectiveness and safety of two-level cervical artificial disc replacement over anterior cervical discectomy and fusion (ACDF) on the short-term for the treatment of cervical degenerative disc disease
- Studies with longer term follow-up are needed to confirm these findings

Articles: The literature revealed a number of articles; the following articles were selected for critical appraisal: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) See Evidence Table 1. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) See Evidence Table 2. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) See Evidence Table 3.

The use of Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Cervical:

CPT® or HCPC Codes	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

Considered Not Medically Necessary:
Lumbar:

CPT® or HCPC Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

 Back to Top

0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/07/2005	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 03/06/2012[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	01/04/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34866 and L35008
10/04/2016	Added MTAC review
11/01/2016	MPC approved criteria for two contiguous levels from C3-C7
06/04/2020	Removed deleted and inaccurate CPT code 0357T
01/04/2022	Defer to KPWA policy for Medicare members for lumbar disc replacement if younger than 60 years old and for cervical disc replacement for all ages.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Patient Referral Guidelines for Use of Mechanical Circulatory Support Devices as a Bridge to Cardiac Transplant

Artificial Hearts
- AbioCor
- SynCardia

Ventricular Assistive Devices
- Implanted Ventricular Assist Devices (VAD)
- Percutaneous Left Ventricular Assist Device (PLVAD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Artificial Hearts and Related Devices (20.9) Ventricular Assist Devices (20.9.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Percutaneous Endovascular Cardiac Assist Procedures and Devices (A52967)

For Non-Medicare Members

OVERVIEW

These guidelines have been developed from the major clinical trials. However, acute changes occur in this group of patients and it is often uncertain which parameters are reversible. It is important to know that these are guidelines and should be applied together with careful clinical judgment.

Devices: The type of device used is dependent upon the implanting center and the device used by the center. Common devices include Heartmate I, II or III, HeartWare and Total Artificial Heart. Non-durable devices include Impella, ECMO, V-A ECMO. These are common devices and *not* an all-inclusive list.

Inclusion Guidelines (one or more should be present to indicate the patient is ill enough to warrant MCS support):

1. NYHA class III-IV symptoms, and/or intractable ventricular arrhythmia, approved by Kaiser Permanente for, and currently listed by UNOS as a candidate for heart transplant, or are being evaluated as a candidate for transplant.
2. INTERMACS Profile 1, 2, 3, or 4 (see Appendix 1).
3. One or more objective indicators of failing support despite maximum reasonable and tolerated medical therapy may include one or more of the following:

Back to Top

3.1. Systemic mean BP < 60mmHg or systolic BP <80 mmHg

3.2. Cardiac index < 2.0 L/min/m^2

3.3. Pulmonary capillary wedge pressure (or PA diastolic) > 20 mmHg

3.4. A low VO_2 maximum[1]

3.4.1. VO_2 < 12 mL/kg/min on a beta-blocker

3.4.2. VO_2 < 14 mL/kg/min off beta-blockade

3.4.3. VO_2 < 19 mL/kg/min adjusted for lean body mass in patients with a BMI > 30 kg/m^2.

3.4.4. Less than 50% of age predicted maximum.

3.5. A VE/VCO_2 > 35 in a patient with a submaximal cardiopulmonary exercise test (RER <1.05)[1]

3.6. Inability to wean from other mechanical or inotropic support

3.7. Refractory Life-Threatening Arrhythmias

4. Exclusion guidelines include:

4.1. Severe renal dysfunction unlikely to be reversible such as creatinine > 3.0 mg/dl (unless patient is listed for combined heart/kidney transplant).

4.2. Severe hepatic dysfunction unlikely to be reversible such as bilirubin > 5.0 mg/dl,

4.3. Infection as evidenced by ongoing fever (T > 38°C), WBC > 15,000/mm3 or positive blood cultures or specific site of infection (e.g. pneumonia, diverticulitis, pyelonephritis),

4.3. Platelet or coagulation disorder likely to compromise survival with the anticoagulation protocol required with the device,

4.4. Other conditions which would negate transplant candidacy such as peripheral or cerebral vascular disease, or cancer,

4.5. Co-morbidities, which alone may not be considered contraindications to transplantation but, taken together, may make the combination of MCS use and transplantation unreasonable or ill-advised.

5. Special Considerations:

5.1. Aortic Valve Disease Patients with mechanical prosthetic aortic valve or uncorrected valvular disease, such as severe aortic insufficiency, will require additional surgical intervention at the time of MCS implant.

5.2. Right Ventricular Dysfunction Evidence of right-sided cardiac dysfunction may indicate the need for biventricular support.

5.3. Pulmonary hypertension not reversible by drug manipulation (PVR >4-6 Wood units or transpulmonary gradient >15mmHg, despite maximum tolerated medical management) is not a contraindication to MCS implantation. Some patients may experience reversal of pulmonary hypertension with MCS implantation and may then become eligible for cardiac transplantation.

Appendix 1

INTERMACS Profiles:

1 = Critical cardiogenic shock
2 = Progressive decline on Inotropic support
3 = Inotrope dependent but stable
4 = Resting symptoms on home oral therapy
5 = Exertion intolerant

Back to Top

6 = Exertion limited
7 = Advanced NYHA class III

REVISED BY CMS: AUGUST 6, 2019

ADVISORY COUNCIL APPROVED EFFECTIVE DATE: OCTOBER 24, 2019

If requesting this service, please send the following documentation to support medical necessity:

- Last 2 Cardiology/Cardiovascular Surgery consults

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Artificial Hearts

Congestive heart failure is a major health problem affecting more that five million patients in the United States. There is a wide variety of options for medical management of heart failure, but many patients eventually deteriorate and fail to respond to any of the medical therapies and require mechanical circulatory support for survival. In order to provide long-term systemic flow for patients with end-stage heart failure, the National Heart Institute established the artificial heart program in the mid 1960s with the intent to develop a totally implantable mechanical heart.

The AbioCor (Abiomed Inc, Danvers, MA, USA) is the world's first fully implantable total artificial heart. This was first implanted in 2001 at the Jewish Hospital in Louisville, KY. AbioCor is a pneumatically-driven biventricular cardiac support device designed to last at least 18 months. It is made of titanium and Angioflex, a proprietary polyurethane plastic and can produce a flow of up to 8 L/min, sufficient for moderate activity. It is divided into the implantable components and the external drive system. The implanted components consist of the thoracic unit, controller, Transcutaneous Energy Transmission system, and a battery that provides about 30 minutes of power that is designed to allow patients to conduct activities such as taking a shower without an external power source. The external drive system consists of the AbioCor console and support electronics worn or carried by the patient in a waist belt (providing power for 2-4 hours) and an RF communication system for a computer (Samuels 2003, Meyer 2011).

In September 2006, the FDA granted restricted approval of the AbioCor device through the Humanitarian Use Device (HUD) provision. A HUD is a device that the FDA determines is intended to benefit fewer than 4,000 U.S. patients per year. The FDA approval included an agreement by the manufacturer to conduct a post-marketing study, evaluating the AbioCor device in an additional 25 patients. According to the FDA, the AbioCor artificial heart is indicated for use in patients who have both ventricles failing, have end-stage heart disease, are not transplant candidates, are less than 75 years old, are not treatable by single left ventricular heart assist devices for destination therapy, and are not able to be withdrawn from heart support measures. It should not be used for patients who are eligible for a heart transplant, have only left sided heart failure, cannot be successfully treated for blood clotting disorders, or in those where the device will not fit (FDA webpage accessed November 2011).

SynCardia temporary CardioWest™ Total Artificial Heart (TAH), originally developed 30 years ago as the Jarvik TAH and later renamed the CardioWest TAH, continues to be used clinically in over 50 centers within the US and Europe. This is an implantable artificial heart intended to keep hospitalized patients alive while they are waiting for a heart transplant. It is a pulsating bi-ventricular device that is implanted into the chest to replace the patient's left and right ventricles and all four valves of the native heart. The device is sewn to the patient's remaining atria. Hospitalized patients are connected by tubes from the heart through their chest wall to a large power-generating console, which operates and monitors the device. SynCardia was approved by the FDA in 2004 for use only in the hospital as a "bridge to transplant" for patients waiting for a heart transplant who have both sides of their heart failing (biventricular heart failure), do not respond to other treatments, are at imminent risk of death, and are waiting for a donor heart. The temporary CardioWest™ TAH is should not be used in patients who are not eligible for a heart transplant, do not fit the device, cannot be adequately anticoagulated, or have left sided heart failure only (Meyer 2011, FDA Web page accessed November 2011).

Back to Top

SynCardia temporary CardioWest™ Total Artificial Heart (TAH) has not been previously reviewed by MTAC; AbioCor was reviewed by MTAC in 2007 and did not meet its evaluation criteria. The technology is being reviewed due to the coverage of SynCardia temporary CardioWest™ Total Artificial Heart by other health plans as a bridge to heart transplant.

Medical Technology Assessment Committee (MTAC)

AbioCor

04/02/2007: MTAC REVIEW

Evidence Conclusion: There are no published empirical studies on the safety and efficacy of the AbioCor permanent total artificial heart. Unpublished data consists of a feasibility study with 14 patients submitted to the FDA by the device manufacturer. The 12 patients who survived the operation experienced multiple serious adverse effects; only 1 was discharged from the hospital.

Articles: The Medline search yielded 32 articles. These consisted of reviews/commentaries, several empirical studies on technical aspects of the device or device implantation, case reports and 2 case series reporting on 7 patients. The study submitted to the FDA, which included 14 patients, has not been published.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/19/2011: MTAC REVIEW

AbioCor

Evidence Conclusion: *AbioCor TAH* There is no new published evidence after the initial small feasibility study conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. *SynCardia temporary CardioWest™ Total Artificial Heart* The published evidence on CardioWest TAH consists of a retrospective study, and a few case series of patients receiving the device as a bridge to transplantation. Due to the eligibility criteria for the implantation, it would be unethical to conduct a randomized trial. The only valid control would be no intervention as the eligible patients for the implant are those who failed medical therapy and are not candidates for left ventricular assist device (LVAD). The results of Copeland and colleagues' case series (Evidence table 1) show that 68% of the critically ill patients who received the CardioWest implant survived to heart transplantation and hospital discharge. Adverse events included bleeding in 20% of cases and device malfunction in 5% of cases. Other complications that occurred at a lower rate included mediastinal infection, fit complications, and stroke. The cause of death was multi-organ failure in 50% of the cases, and sepsis or valve entrapment among the rest. A similar experience was observed in a French study among 42 patients. In this series 12 (28.5%) patients died while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively. Causes of death during device support included multi-organ failure (50%), sepsis, acute respiratory distress syndrome, and alveolar hemorrhage. There were no device malfunctions that led to patient death. Adverse events included stroke in 3 patients (7%) and infections in 35 patients (85%) during support.

Articles: The literature search for AbioCor total heart transplant did not reveal any study conducted after the initial small feasibility study (Dawling 2003) conducted by the AbioCor manufacturer among 14 patients with end-stage heart failure who were not transplant candidates. The search for SynCardia CardioWest temporary TAH identified a few case series for patients who received the device as a bridge to transplantation, and a retrospective study comparing the device to left ventricular assist devices. The larger case series was selected for critical appraisal. Copeland JG, Smith RG, Arabia FA, et al. Total artificial heart bridge to transplantation: A 9-year experience with 62 patients. *J Heart Lung Transplant* 2004; 23:823-831. See Evidence Table.

The use of the AbioCor implantable replacement heart in the treatment of irreversible heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of the SynCardia implantable replacement heart in the treatment of irreversible heart failure does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Background

Implanted Ventricular Assist Devices (VAD)

Heart failure is a clinical condition characterized by the heart's inability to generate a cardiac output sufficient to meet the body's circulation demands. It is a major and growing public health problem responsible for high morbidity and mortality, in addition to the economic impact of medical costs, disability, and loss of employment. According to the Heart Failure Society of America, nearly 5 million people suffer from CHF in the United States and it is responsible for about 200,000 deaths each year (Abraham 1998).

 Back to Top

The cause of heart failure in many patients is pump failure due to poor left ventricular systolic function, which is often due to myocardial infarction or dilated cardiomyopathy. In approximately 30% of patients with chronic heart failure, the disease process not only depresses cardiac contractility, but also affects the conduction pathways by causing a delay in the onset of right or left ventricular systole, and in turn the loss of coordination of ventricular contraction. This dyssynchronous pattern of ventricular contraction is believed to reduce the already diminished contractile reserve of the heart (Nelson 2001).
Patients in end-stage heart failure have two primary treatment options:

1. Pharmacological therapy (including digoxin, ACE inhibitors, diuretics and inotropes), and
2. Heart transplantation.

Both treatments have their limitations. Pharmacological therapy is only palliative and improves the short-term survival for patients. Moreover, as the heart failure worsens, medication becomes ineffective in treating the low contractility and pulmonary venous stasis resulting from the increased dilatation of the heart. Cardiac transplantation on the other hand, is limited to the number of available hearts, and the criteria for being a transplant candidate.

In September 1994, the FDA approved the first pneumatically driven left ventricular assist device (LVAD) from TCI for bridging end-stage patients to cardiac transplantation. Patients on these devices had to stay in the hospital connected to a pneumatic console or could go home with extensive home health care support. (FDA News 2002). Four years later, in September 1998, the FDA approved two portable heart assist devices (HeartMate and Novocar LVAS) to support patients outside the hospital while they wait for a transplant. These two devices were approved as a bridge to transplant for patients eligible for heart transplants and waiting for an available heart. Eligible patients were those with irreversible heart failure and a rapidly deteriorating condition. In addition, they had to be on their hospital's transplant list in order to qualify for one of these devices (FDA News, September 1998).

The LVAD does not replace the heart. It works along with the patient's own heart to provide additional strength to the weakened left ventricle to pump blood throughout the body. The portable device consists of a blood pump implanted in the abdominal area and attached to both the left ventricle and the aorta. Blood from the heart flows into the device which then pumps it through the aorta to the rest of the body. The system is also connected by a cable through the skin to a small external computer (the "controller") worn on the waist. The computer can be powered by a base unit that is plugged into the wall or by batteries worn at the waist or, in the case of the HeartMate device, under the arms.

There are risks associated with the surgery to implant the HeartMate, as well as risks and complications with the device itself such as infections, bleeding, thromboembolism, and stroke. Implanting the device requires a major surgery for already seriously sick patients. Moreover, the device requires a percutaneous line that can become a medium for bacterial and fungal infections that are difficult to treat and may require a change of the device, which increases the morbidity and mortality. Another complication reported by Rose et al (2000), is aortic stenosis of variable severity that may be caused by the device. LVAD may also lead to significant changes in the systemic immunologic and thrombostatic functions of the patients (Itesu S, 2000). Failure and malfunctioning of the device may also occur which may contribute to higher morbidity, mortality, and cost.

In November 2002, the FDA expanded the use of the HeartMate device to be implanted permanently in certain terminally ill patients; those who have a severe end-stage CHF, are ineligible for heart transplant, and have a body surface area >1.5 sq. m. It required that the manufacturer (Thoratec) conduct a post-approval study to assess the device's long-term safety and effectiveness for permanent use.

Percutaneous Left Ventricular Assist Device (PLVAD)
Cardiogenic shock is a state of inadequate tissue perfusion due to cardiac dysfunction. It occurs in a variety of settings such as myocardial infarction, post-cardiotomy shock, decompensated chronic heart failure, acute valve failure, and myocarditis. Despite the major advances in the treatment and aggressive perfusion strategies, cardiogenic shock is still associated with high in-hospital mortality rates that range from 40% to 80% depending on the clinical circumstances. The Intra-Aortic Balloon Pump (IABP) is the left ventricular mechanical assistance device most commonly used to stabilize patients in cardiogenic shock. It decreases afterload, increases coronary perfusion, and improves cardiac output. However, IABP pump delivers an output of only 0.5 L/min, lacks active cardiac support, does not decrease infarct size, or improve clinical outcomes of patients with acute ST-segment elevation myocardial infarction. New technologies such as percutaneous left ventricular assist devices (LVADs) have been developed to provide more effective hemodynamic short-term support for the failing heart. The three main indications for percutaneous LVAD support include: 1. Reversible left ventricular failure to provide

 Back to Top

temporary circulatory support until recovery or revascularization, 2. Large ischemic area at risk to provide temporary circulatory support during high-risk percutaneous or surgical revascularization, and 3. Bridging therapy to provide temporary circulatory support as a bridge to a permanent surgical assist device or heart transplantation (Burkoff 2006, Windecker 2007, Seyfarth 2008, Cheng 2009).

Currently two percutaneous LVADs are available for clinical use: The TandemHeart and the Impella Recover system. The TandemHeart utilizes a drainage cannula placed via transseptal puncture into the left atrium to aspirate oxygenated blood, which is then injected through a transfugal pump into the femoral artery, establishing a left-atrial-to-femoral arterial bypass. The Impella Recover is based on a miniaturized impeller (microaxial pump) that can be advanced into the left ventricle through an arterial vascular system. It has a caged blood flow inlet that is placed retrograde into the left ventricle to aspirate oxygenated blood, which is then injected by means of a microaxial pump into the ascending aorta establishing a left ventricular to aortic by-pass. The TandemHeart requires both venous and arterial femoral access whereas the Impella Recover system requires only femoral arterial access. Currently two Impella Recover systems are available: The Impella Recover LP 2.5 and the Impella Recover LP 5.0 models. The Impella LP 2.5 (Abiomed Europe GnbH, Aachen, Germany) is a catheter suitable for percutaneous implantation, while the Impella Recover LP 5.0 catheter requires surgical cut of the femoral artery for device insertion (Windecker 2007).

The Impella Recover LP 2.5 is a catheter-based, impeller-driven, axial -flow pump. It has a diameter of 6.4 mm at the body of the pump and 7.3 mm diameter at the level of the outflow opening. A small electric motor is built into the device, and a thin 2.8 mm cable leading to the device contains the electrical power supply, which is connected to an external control unit as well as a purge line connected to a purge perfuser. Through this perfuser, heparin (in a glucose solution) is flushed continuously in the motor housing and throughout the pump, and the patient does not need systemic anticoagulation. A pressure sensor within the device continuously monitors pressure differences between inflow and outflow. The pump is inserted percutaneously in the catheterization laboratory via a standard guidewire through the femoral artery into the left ventricle. The circulatory support provided by the device can be adjusted at nine different levels of speed. At its maximal rotation speed of 50,000 rpm, the pump can deliver an output of up to 2.5 liters of blood per minute from the left ventricle into the ascending aorta. This actively unloads the ventricle, increases the cardiac output, and increases both coronary and end-organ perfusion. The Impella pumps are indicated for temporary use (up to 6 hours) however, it has been reported that the device can be safely left in place to support hemodynamics for up to 5 days. (Seyfarth 2008, Vecchio 2008, Cheng 2009, Wiktor 2010).

Impella Recover 2.5 and 5.0 devices (ABIOMED Inc) have both received FDA clearance for circulatory support for periods up to 6 hours. The current review focuses on the use of the Impella Recover 2.5.

Medical Technology Assessment Committee (MTAC)

LVAD in the treatment of End Stage Heart Failure

08/13/2003: MTAC REVIEW

Evidence Conclusion: The REMATCH trial reviewed was conducted among a highly selected group of patients with end stage heart failure, and contraindication for heart transplantation. The trial compared the patients who received the LVAD to those who were treated medically. The methodology of the trial was generally valid; however, it was not blinded. Blinding in such a trial is not possible, and non-blinding may be a source of observation bias. The authors tried to partly overcome this limitation by using independent blinded observers to measure the outcome events. In this trial survival was higher among patients receiving LVAD vs. those in the optimum medical management group. The difference between the two groups was statistically significant, at one year (NNT=4), but not at 2 years. The two years survival among patients receiving the LVAD was only 22%, and according to the survival graph, the 26 months survival was 8%. The LVAD was associated with serious adverse events. Sepsis and device failure were responsible for the majority of deaths in the LVAD group (41.5%, and 17.1% respectively), and left ventricular dysfunction was the cause of death in 92% of the cases in the medical treatment group. The authors concluded that the quality of life was better among LVAD recipients, however the analysis of QoL was only performed among survivors who were able to complete the questionnaires (35% in the LVAD group, and 18% in the medical treatment group). In conclusion the REMATCH trial provides some evidence that LVAD may improve survival, however for a short duration, and not without serious adverse events, among a selected group of patients with and end stage heart failure, and who are not candidates for heart transplantation. It does not provide evidence that LVAD may be used as an alternative to transplantation, in patients eligible for a heart transplant.

Articles: The search yielded 32 articles many of which were reviews, opinion pieces, or dealt with the technical aspects of the procedure. One randomized controlled trial, 5 case series and several case reports were

Back to Top

identified. The RCT was selected for critical appraisal. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. N Engl J Med 2001; 345:1435-43. See Evidence Table.

The use of LVAD in the treatment of End Stage Heart Failure does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/14/2011: MTAC REVIEW
Percutaneous Cardiac Support Systems
Evidence Conclusion: The literature search revealed only one small randomized controlled trial that evaluated the safety and efficacy of the Impella Recover LP 2.5 for the treatment of cardiogenic shock caused by myocardial infarction. The trial compared the Impella device with the IABP, the most commonly used device to treat cardiogenic shock. However, the study was too small, blinding and randomization method were not discussed, and it was only powered to detect the difference between the two devices in hemodynamic improvements. It was not powered to evaluate impact on clinical outcomes. The results of the RCT (Evidence table 1) show that the Impella LP 2.5 resulted in better hemodynamic improvement compared to the IABP. However, this was not translated to an improvement in the 30-day survival of the patients in cardiogenic shock after an acute myocardial infarction.
Patients treated with the Impella device tended to have more device-related bleeding, and more limb ischemia.
Articles: The literature search identified one small randomized controlled trial that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock, a meta-analysis of RCTs comparing percutaneous LVAD to IABP for the treatment of cardiogenic shock, and three other case series evaluating the feasibility and safety of the device. The meta-analysis (Cheng 2009) pooled the results of three trials; two evaluated the TandemHeart, and the third evaluated the Impella Recover 2.5 device. The RCT that compared Impella Recover LP 2.5 device to IABP for the treatment of cardiogenic shock was selected for critical appraisal. Seyfarth M, Sibbing D, Bauer I, A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction. J Am Coll Cardiol 2008; 52:1584-1588. See Evidence Table.

The use of percutaneous cardiac support systems in the treatment of End Stage Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Artificial Hearts - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33927	Implantation of a total replacement heart system (artificial heart) with recipient cardiectomy
33928	Removal and replacement of total replacement heart system (artificial heart)
33929	Removal of a total replacement heart system (artificial heart) for heart transplantation (List separately in addition to code for primary procedure)

Ventricular Assistive Devices - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
33975	Insertion of ventricular assist device; extracorporeal, single ventricle
33976	Insertion of ventricular assist device; extracorporeal, biventricular
33979	Insertion of ventricular assist device, implantable intracorporeal, single ventricle
33981	Replacement of extracorporeal ventricular assist device, single or biventricular, pump(s), single or each pump
33982	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, without cardiopulmonary bypass
33983	Replacement of ventricular assist device pump(s); implantable intracorporeal, single ventricle, with cardiopulmonary bypass
33990	Insertion of ventricular assist device, percutaneous including radiological supervision and

Back to Top

	interpretation; arterial access only
33991	Insertion of ventricular assist device, percutaneous including radiological supervision and interpretation; both arterial and venous access, with transseptal puncture
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/07/2020	07/07/2020 MPC, 07/06/2021MPC, 07/05/2022MPC, 07/011/2023MPC	07/06/2021

Revision History	Description
09/08/2016 (VAD)	Added the LCA A52967
03/12/2020 (VAD)	Added statement for medical director to consult with cardiology re Impella (PLVAD) as needed
04/07/2020	MPC approved to adopt KP National coverage policy. Combined Artificial Heart and Ventricular Assistive Devices criteria. Removed deleted codes 0051T, 0052T and 0053T.
07/07/2020	Added CPT codes 33981, 33982 and 33983
07/06/2021	Coding update, added new CPT code 33995

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Ambulatory Surgery Center (ASC) - Site of Care Policy

Benton, Kitsap, Spokane, and Whatcom counties

King and Thurston Counties (Benton, Kitsap, Spokane, Whatcom counties AND King, and Thurston counties)

Background

Surgery may safely be performed in various settings. Some of the common settings used are an inpatient hospital or medical center, an off-campus outpatient hospital or medical center, an on-campus outpatient hospital or medical center, an ambulatory surgical center, or a doctor's office. Costs for surgical procedures may vary among these different settings. To encourage the use of the most safe and appropriate, cost-effective sites of care for certain medically necessary outpatient surgical procedures, prior authorization is required* to ensure the appropriate site of care for the surgical procedures linked below.

We will review the site of care for medical necessity for certain elective surgical procedures. Site of care is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.*

Policy

For Non-Medicare Members

This will be implemented using a phased approach, starting with Benton, Kitsap, Spokane, and Whatcom counties.

I. Certain planned surgical procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets **ANY of the following** criteria:
- Advanced liver disease (MELD Score > 8)
- Advance surgical planning determines an individual requires overnight recovery and care following a surgical procedure
- Anticipated need for transfusion
- Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect
- Brittle Diabetes
- Cardiac arrhythmia (symptomatic arrhythmia despite medication)
- Chronic obstructive pulmonary disease (COPD) (FEV1 <50%)
- Coronary artery disease ([CAD]/peripheral vascular disease [PVD]) (ongoing cardiac ischemia requiring medical management recently placed [within 1 year] drug eluting stent)
- Developmental stage or cognitive status warranting use of a hospital outpatient department
- End stage renal disease ([hyperkalemia above reference range]; peritoneal or hemodialysis)
- History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event [< 3 months])
- History of myocardial infarction (MI) (recent event [< 3 months])

Back to Top

- Individuals with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia
- Age 15 or younger
- Ongoing evidence of myocardial ischemia
- Poorly Controlled asthma (FEV1 < 80% despite medical management)
- Pregnancy
- Prolonged surgery (> 3 hours)
- Resistant hypertension (Poorly Controlled)
- Severe valvular heart disease
- Sleep apnea (moderate to severe Obstructive Sleep Apnea (OSA)
- Uncompensated chronic heart failure (CHF) (NYHA class III or IV)

II. A planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center for the procedure due to **ANY one of the following**:
- There is no geographically accessible ambulatory surgical center that has the necessary equipment for the procedure; or
- There is no geographically accessible ambulatory surgical center available at which the individual's physician has privileges; or
- An ASC's specific guideline regarding the individual's weight or health conditions that prevents the use of an ASC

When an elective surgery is requested at an inpatient hospital/medical center, this site may be considered medically necessary only when the patient has clinical conditions that places him or her at risk of complications. Examples include:
- Anesthesia risk
- Cardiovascular, liver, pulmonary, or renal risk
- Morbid obesity
- Pregnancy
- Bleeding disorder
- Anticipated need for transfusions

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific contract and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Gastroenterology: (*Benton, Kitsap, Spokane, Whatcom counties* **AND** *King, and Thurston counties)*

CPT® or HCPC Codes	Description
43191	Esophagoscopy, rigid, transoral; diagnostic, including collection of specimen(s) by brushing or washing when performed (separate procedure)
43202	Esophagoscopy, flexible, transoral; with biopsy, single or multiple
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43233	Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple

Back to Top

43241	Esophagogastroduodenoscopy, flexible, transoral; with insertion of intraluminal tube or catheter
43242	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration/biopsy(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)
43245	Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)
43246	Esophagogastroduodenoscopy, flexible, transoral; with directed placement of percutaneous gastrostomy tube
43247	Esophagogastroduodenoscopy, flexible, transoral; with removal of foreign body(s)
43248	Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
43251	Esophagogastroduodenoscopy, flexible, transoral; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
43254	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic mucosal resection
43255	Esophagogastroduodenoscopy, flexible, transoral; with control of bleeding, any method
43259	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination, including the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis
43270	Esophagogastroduodenoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
43450	Dilation of esophagus, by unguided sound or bougie, single or multiple passes
43453	Dilation of esophagus, over guide wire
44360	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
44361	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, not including ileum; with biopsy, single or multiple
44376	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure)
44377	Small intestinal endoscopy, enteroscopy beyond second portion of duodenum, including ileum; with biopsy, single or multiple
44382	Ileoscopy, through stoma; with biopsy, single or multiple
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
44389	Colonoscopy through stoma; with biopsy, single or multiple
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45100	Biopsy of anorectal wall, anal approach (eg, congenital megacolon)
45171	Excision of rectal tumor, transanal approach; not including muscularis propria (ie, partial thickness)
45172	Excision of rectal tumor, transanal approach; including muscularis propria (ie, full thickness)
45190	Destruction of rectal tumor (eg, electrodesiccation, electrosurgery, laser ablation, laser resection, cryosurgery) transanal approach
45305	Proctosigmoidoscopy, rigid; with biopsy, single or multiple
45334	Sigmoidoscopy, flexible; with control of bleeding, any method
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s)
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection

Back to Top

45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45379	Colonoscopy, flexible; with removal of foreign body(s)
45380	Colonoscopy, flexible; with biopsy, single or multiple
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance
45382	Colonoscopy, flexible; with control of bleeding, any method
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
45386	Colonoscopy, flexible; with transendoscopic balloon dilation
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed)
45390	Colonoscopy, flexible; with endoscopic mucosal resection
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed
45398	Colonoscopy, flexible; with band ligation(s) (eg, hemorrhoids)
G0105	Colorectal cancer screening; colonoscopy on individual at high risk
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk

General Surgery: *(Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or HCPC Codes	Description
19000	Puncture aspiration of cyst of breast;
19001	Puncture aspiration of cyst of breast; each additional cyst (List separately in addition to code for primary procedure)
19020	Mastotomy with exploration or drainage of abscess, deep
19030	Injection procedure only for mammary ductogram or galactogram
19100	Biopsy of breast; percutaneous, needle core, not using imaging guidance (separate procedure)
19101	Biopsy of breast; open, incisional
19110	Nipple exploration, with or without excision of a solitary lactiferous duct or a papilloma lactiferous duct
19112	Excision of lactiferous duct fistula
19120	Excision of cyst, fibroadenoma, or other benign or malignant tumor, aberrant breast tissue, duct lesion, nipple or areolar lesion (except 19300), open, male or female, 1 or more lesions
19125	Excision of breast lesion identified by preoperative placement of radiological marker, open; single lesion
19126	Excision of breast lesion identified by preoperative placement of radiological marker, open; each additional lesion separately identified by a preoperative radiological marker (List separately in addition to code for primary procedure)
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
38520	Biopsy or excision of lymph node(s); open, deep cervical node(s) with excision scalene fat pad
38525	Biopsy or excision of lymph node(s); open, deep axillary node(s)
38530	Biopsy or excision of lymph node(s); open, internal mammary node(s)
38531	Biopsy or excision of lymph node(s); open, inguinofemoral node(s)
45500	Proctoplasty; for stenosis
45505	Proctoplasty; for prolapse of mucous membrane
45520	Perirectal injection of sclerosing solution for prolapse

Back to Top

45541	Proctopexy (e.g., for prolapse); perineal approach
45560	Repair of rectocele (separate procedure)
45900	Reduction of procidentia (separate procedure) under anesthesia
45905	Dilation of anal sphincter (separate procedure) under anesthesia other than local
45910	Dilation of rectal stricture (separate procedure) under anesthesia other than local
45915	Removal of fecal impaction or foreign body (separate procedure) under anesthesia
45990	Anorectal exam, surgical, requiring anesthesia (general, spinal, or epidural), diagnostic
46020	Placement of seton
46030	Removal of anal seton, other marker
46040	Incision and drainage of ischiorectal and/or perirectal abscess (separate procedure)
46045	Incision and drainage of intramural, intramuscular, or submucosal abscess, transanal, under anesthesia
46050	Incision and drainage, perianal abscess, superficial
46060	Incision and drainage of ischiorectal or intramural abscess, with fistulectomy or fistulotomy, submuscular, with or without placement of seton
46080	Sphincterotomy, anal, division of sphincter (separate procedure)
46083	Incision of thrombosed hemorrhoid, external
46200	Fissurectomy, including sphincterotomy, when performed
46220	Excision of single external papilla or tag, anus
46221	Hemorrhoidectomy, internal, by rubber band ligation(s)
46230	Excision of multiple external papillae or tags, anus
46250	Hemorrhoidectomy, external, 2 or more columns/groups
46255	Hemorrhoidectomy, internal and external, single column/group
46257	Hemorrhoidectomy, internal and external, single column/group; with fissurectomy
46258	Hemorrhoidectomy, internal and external, single column/group; with fistulectomy, including fissurectomy, when performed
46260	Hemorrhoidectomy, internal and external, 2 or more columns/groups;
46261	Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fissurectomy
46262	Hemorrhoidectomy, internal and external, 2 or more columns/groups; with fistulectomy, including fissurectomy, when performed
46270	Surgical treatment of anal fistula (fistulectomy/fistulotomy); subcutaneous
46275	Surgical treatment of anal fistula (fistulectomy/fistulotomy); inter-sphincteric
46280	Surgical treatment of anal fistula (fistulectomy/fistulotomy); trans sphincteric, suprasphincteric, extra sphincteric or multiple, including placement of seton, when performed
46285	Surgical treatment of anal fistula (fistulectomy/fistulotomy); second stage
46288	Closure of anal fistula with rectal advancement flap
46320	Excision of thrombosed hemorrhoid, external
46505	Chemodenervation of internal anal sphincter
46706	Repair of anal fistula with fibrin glue
46707	Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS])
46750	Sphincteroplasty, anal, for incontinence or prolapse; adult
46753	Graft (Thiersch operation) for rectal incontinence and/or prolapse
46754	Removal of Thiersch wire or suture, anal canal
46760	Sphincteroplasty, anal, for incontinence, adult; muscle transplant
46761	Sphincteroplasty, anal, for incontinence, adult; levator muscle imbrication (Park posterior anal repair)
46900	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; chemical
46910	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; electrodesiccation
46916	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; cryosurgery
46917	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; laser surgery

Back to Top

46922	Destruction of lesion(s), anus (eg, condyloma, papilloma, molluscum contagiosum, herpetic vesicle), simple; surgical excision
46924	Destruction of lesion(s), anus (e.g., condyloma, papilloma, molluscum contagiosum, herpetic vesicle), extensive (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery)
46930	Destruction of internal hemorrhoid(s) by thermal energy (e.g., infrared coagulation, cautery, radiofrequency)
46940*	Curettage or cautery of anal fissure, including dilation of anal sphincter (separate procedure); initial
46942	Curettage or cautery of anal fissure, including dilation of anal sphincter (separate procedure); subsequent
46945	Hemorrhoidectomy, internal, by ligation other than rubber band; single hemorrhoid column/group
46946	Hemorrhoidectomy, internal, by ligation other than rubber band; 2 or more hemorrhoid columns/groups
46947	Hemorrhoidopexy (e.g., for prolapsing internal hemorrhoids) by stapling
46948	Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed
47562	Laparoscopy, surgical; cholecystectomy
47563	Laparoscopy, surgical; cholecystectomy with cholangiography
47564	Laparoscopy, surgical; cholecystectomy with exploration of common duct
49505	Repair initial inguinal hernia, age 5 years or older; reducible
49507	Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated
49520	Repair recurrent inguinal hernia, any age; reducible
49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated
49525	Repair inguinal hernia, sliding, any age
49550	Repair initial femoral hernia, any age; reducible
49553	Repair initial femoral hernia, any age; incarcerated or strangulated
49555	Repair recurrent femoral hernia; reducible
49557	Repair recurrent femoral hernia; incarcerated or strangulated
49591	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49593	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible
49595	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible
49613	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); less than 3 cm, reducible
49615	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, reducible
49617	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including implantation of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible
49621	Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including implantation of mesh or other prosthesis, when performed; reducible
49623	Removal of total or near total non-infected mesh or other prosthesis at the time of initial or recurrent anterior abdominal hernia repair or parastomal hernia repair, any approach (ie, open, laparoscopic, robotic) (List separately in addition to code for primary procedure)
49650	Laparoscopy, surgical; repair initial inguinal hernia
49651	Laparoscopy, surgical; repair recurrent inguinal hernia

Plastic surgery: *(Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or	Description

Back to Top

HCPC Codes	
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14020	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10 sq cm or less
14021	Adjacent tissue transfer or rearrangement, scalp, arms and/or legs; defect 10.1 sq cm to 30.0 sq cm
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
14061	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
14350	Filleted finger or toe flap, including preparation of recipient site
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)

Orthopedics/Podiatry: *(Benton, Kitsap, Spokane, and Whatcom counties)*

CPT® or HCPC Codes	Description
20200	Biopsy, muscle; superficial
20205	Biopsy, muscle; deep
20206	Biopsy, muscle, percutaneous needle
20220	Biopsy, bone, trocar, or needle; superficial (e.g., ilium, sternum, spinous process, ribs)
20225	Biopsy, bone, trocar, or needle; deep (e.g., vertebral body, femur)
20240	Biopsy, bone, open; superficial (e.g., sternum, spinous process, rib, patella, olecranon process, calcaneus, tarsal, metatarsal, carpal, metacarpal, phalanx)
20245	Biopsy, bone, open; deep (e.g., humeral shaft, ischium, femoral shaft)
20924	Tendon graft, from a distance (eg, palmaris, toe extensor, plantaris)
23130	Acromioplasty or acromionectomy, partial, with or without coracoacromial ligament release
23140	Excision or curettage of bone cyst or benign tumor of clavicle or scapula
23145	Excision or curettage of bone cyst or benign tumor of clavicle or scapula; with autograft (includes obtaining graft)

Back to Top

23150	Excision or curettage of bone cyst or benign tumor of proximal humerus
23155	Excision or curettage of bone cyst or benign tumor of proximal humerus; with autograft (includes obtaining graft)
23156	Excision or curettage of bone cyst or benign tumor of proximal humerus; with allograft
23405	Tenotomy, shoulder area; single tendon
23406	Tenotomy, shoulder area; multiple tendons through same incision
23410	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; acute
23412	Repair of ruptured musculotendinous cuff (eg, rotator cuff) open; chronic
23415	Coracoacromial ligament release, with or without acromioplasty
23420	Reconstruction of complete shoulder (rotator) cuff avulsion, chronic (includes acromioplasty)
23430	Tenodesis of long tendon of biceps
23440	Resection or transplantation of long tendon of biceps
23450	Capsulorrhaphy, anterior; Putti-Platt procedure or Magnuson type operation
23455	Capsulorrhaphy, anterior; with labral repair (eg, Bankart procedure)
23460	Capsulorrhaphy, anterior, any type; with bone block
23462	Capsulorrhaphy, anterior, any type; with coracoid process transfer
23465	Capsulorrhaphy, glenohumeral joint, posterior, with or without bone block
23466	Capsulorrhaphy, glenohumeral joint, any type multi-directional instability
23480	Osteotomy, clavicle, with or without internal fixation
23485	Osteotomy, clavicle, with or without internal fixation; with bone graft for nonunion or malunion (includes obtaining graft and/or necessary fixation)
23700	Manipulation under anesthesia, shoulder joint, including application of fixation apparatus (dislocation excluded)
23930	Incision and drainage, upper arm or elbow area; deep abscess or hematoma
23931	Incision and drainage, upper arm or elbow area; bursa
23935	Incision, deep, with opening of bone cortex (eg, for osteomyelitis or bone abscess), humerus or elbow
24000	Arthrotomy, elbow, including exploration, drainage, or removal of foreign body
24006	Arthrotomy of the elbow, with capsular excision for capsular release (separate procedure)
24100	Arthrotomy, elbow; with synovial biopsy only
24101	Arthrotomy, elbow; with joint exploration, with or without biopsy, with or without removal of loose or foreign body
24102	Arthrotomy, elbow; with synovectomy
24105	Excision, olecranon bursa
24110	Excision or curettage of bone cyst or benign tumor, humerus
24115	Excision or curettage of bone cyst or benign tumor, humerus; with autograft (includes obtaining graft)
24116	Excision or curettage of bone cyst or benign tumor, humerus; with allograft
24120	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process
24125	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with autograft (includes obtaining graft)
24126	Excision or curettage of bone cyst or benign tumor of head or neck of radius or olecranon process; with allograft
24130	Excision, radial head
24134	Sequestrectomy (eg, for osteomyelitis or bone abscess), shaft or distal humerus
24136	Sequestrectomy (eg, for osteomyelitis or bone abscess), radial head or neck
24138	Sequestrectomy (eg, for osteomyelitis or bone abscess), olecranon process
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), humerus
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), radial head or neck
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process
24149	Radical resection of capsule, soft tissue, and heterotopic bone, elbow, with contracture release (separate procedure)

Back to Top

24150	Radical resection of tumor, shaft or distal humerus
24152	Radical resection of tumor, radial head or neck
24155	Resection of elbow joint (arthrectomy)
24160	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and ulnar components
24164	Removal of prosthesis, includes debridement and synovectomy when performed; radial head
24200	Removal of foreign body, upper arm or elbow area; subcutaneous
24201	Removal of foreign body, upper arm or elbow area; deep (subfascial or intramuscular)
24220	Injection procedure for elbow arthrography
24300	Manipulation, elbow, under anesthesia
24301	Muscle or tendon transfer, any type, upper arm or elbow, single (excluding 24320-24331)
24305	Tendon lengthening, upper arm or elbow, each tendon
24310	Tenotomy, open, elbow to shoulder, each tendon
24330	Flexor-plasty, elbow (eg, Steindler type advancement);
24331	Flexor-plasty, elbow (eg, Steindler type advancement); with extensor advancement
24332	Tenolysis, triceps
24340	Tenodesis of biceps tendon at elbow (separate procedure)
24341	Repair, tendon or muscle, upper arm or elbow, each tendon or muscle, primary or secondary (excludes rotator cuff)
24342	Reinsertion of ruptured biceps or triceps tendon, distal, with or without tendon graft
24343	Repair lateral collateral ligament, elbow, with local tissue
24344	Reconstruction lateral collateral ligament, elbow, with tendon graft (includes harvesting of graft)
24345	Repair medial collateral ligament, elbow, with local tissue
24346	Reconstruction medial collateral ligament, elbow, with tendon graft (includes harvesting of graft)
24357	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); percutaneous
24358	Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open
24359	Tenotomy, elbow, lateral or medial (eg, epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open with tendon repair or reattachment
24360	Arthroplasty, elbow; with membrane (eg, fascial)
24361	Arthroplasty, elbow; with distal humeral prosthetic replacement
24362	Arthroplasty, elbow; with implant and fascia lata ligament reconstruction
24363	Arthroplasty, elbow; with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)
24365	Arthroplasty, radial head;
24366	Arthroplasty, radial head; with implant
24370	Revision of total elbow arthroplasty, including allograft when performed; humeral or ulnar component
24371	Revision of total elbow arthroplasty, including allograft when performed; humeral and ulnar component
24400	Osteotomy, humerus, with or without internal fixation
24410	Multiple osteotomies with realignment on intramedullary rod, humeral shaft (Sofield type procedure)
24420	Osteoplasty, humerus (eg, shortening or lengthening) (excluding 64876)
24430	Repair of nonunion or malunion, humerus; without graft (eg, compression technique)
24435	Repair of nonunion or malunion, humerus; with iliac or other autograft (includes obtaining graft)
24470	Hemiepiphyseal arrest (eg, cubitus varus or valgus, distal humerus)
24495	Decompression fasciotomy, forearm, with brachial artery exploration
24498	Prophylactic treatment (nailing, pinning, plating or wiring), with or without methylmethacrylate, humeral shaft
25000	Incision, extensor tendon sheath, wrist (eg, deQuervains disease)
25001	Incision, flexor tendon sheath, wrist (eg, flexor carpi radialis)
25085	Capsulotomy, wrist (e.g., contracture)
25100	Arthrotomy, wrist joint; with biopsy

Back to Top

25101	Arthrotomy, wrist joint; with joint exploration, with or without biopsy, with or without removal of loose or foreign body
25105	Arthrotomy, wrist joint; with synovectomy
25107	Arthrotomy, distal radioulnar joint including repair of triangular cartilage, complex
25109	Excision of tendon, forearm and/or wrist, flexor or extensor, each
25110	Excision, lesion of tendon sheath, forearm and/or wrist
25111	Excision, lesion of tendon sheath, forearm and/or wrist
25112	Excision of ganglion, wrist (dorsal or volar); recurrent
25115	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); flexors
25116	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum
25118	Synovectomy, extensor tendon sheath, wrist, single compartment
25119	Synovectomy, extensor tendon sheath, wrist, single compartment; with resection of distal ulna
25120	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process)
25125	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with autograft (includes obtaining graft)
25126	Excision or curettage of bone cyst or benign tumor of radius or ulna (excluding head or neck of radius and olecranon process); with allograft
25130	Excision or curettage of bone cyst or benign tumor of carpal bones
25135	Excision or curettage of bone cyst or benign tumor of carpal bones; with autograft (includes obtaining graft)
25136	Excision or curettage of bone cyst or benign tumor of carpal bones; with allograft
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (eg, for osteomyelitis); ulna
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); radius
25210	Carpectomy; 1 bone
25215	Carpectomy; all bones of proximal row
25230	Radial styloidectomy (separate procedure)
25240	Excision distal ulna partial or complete (e.g., Darrach type or matched resection)
25260	Repair, tendon or muscle, flexor, forearm and/or wrist; primary, single, each tendon or muscle
25263	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, single, each tendon or muscle
25265	Repair, tendon or muscle, flexor, forearm and/or wrist; secondary, with free graft (includes obtaining graft), each tendon or muscle
25270	Repair, tendon or muscle, extensor, forearm and/or wrist; primary, single, each tendon or muscle
25272	Repair, tendon or muscle, extensor, forearm and/or wrist; secondary, single, each tendon or muscle
25274	Repair, tendon or muscle, extensor, forearm and/or wrist; secondary, with free graft (includes obtaining graft), each tendon or muscle
25275	Repair, tendon sheath, extensor, forearm and/or wrist, with free graft (includes obtaining graft) (e.g., for extensor carpi ulnaris subluxation)
25280	Lengthening or shortening of flexor or extensor tendon, forearm and/or wrist, single, each tendon
25290	Tenotomy, open, flexor or extensor tendon, forearm and/or wrist, single, each tendon
25295	Tenolysis, flexor or extensor tendon, forearm and/or wrist, single, each tendon
25300	Tenodesis at wrist; flexors of fingers
25301	Tenodesis at wrist; extensors of fingers
25310	Radical excision of bursa, synovia of wrist, or forearm tendon sheaths (eg, tenosynovitis, fungus, Tbc, or other granulomas, rheumatoid arthritis); extensors, with or without transposition of dorsal retinaculum
25312	Tendon transplantation or transfer, flexor or extensor, forearm and/or wrist, single; with tendon graft(s) (includes obtaining graft), each tendon
25315	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist;

Back to Top

25316	Flexor origin slide (eg, for cerebral palsy, Volkmann contracture), forearm and/or wrist; with tendon(s) transfer
25320	Capsulorrhaphy or reconstruction, wrist, open (eg, capsulodesis, ligament repair, tendon transfer or graft) (includes synovectomy, capsulotomy and open reduction) for carpal instability
25332	Arthroplasty, wrist, with or without interposition, with or without external or internal fixation
25335	Centralization of wrist on ulna (eg, radial club hand)
25337	Reconstruction for stabilization of unstable distal ulna or distal radioulnar joint, secondary by soft tissue stabilization (eg, tendon transfer, tendon graft or weave, or tenodesis) with or without open reduction of distal radioulnar joint
25350	Osteotomy, radius; distal third
25355	Osteotomy, radius; middle or proximal third
25360	Osteotomy; ulna
25365	Osteotomy; radius AND ulna
25370	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius OR ulna
25375	Multiple osteotomies, with realignment on intramedullary rod (Sofield type procedure); radius AND ulna
25390	Osteoplasty, radius OR ulna; shortening
25391	Osteoplasty, radius OR ulna; lengthening with autograft
25392	Osteoplasty, radius AND ulna; shortening (excluding 64876)
25393	Osteoplasty, radius AND ulna; lengthening with autograft
25394	Osteoplasty, carpal bone, shortening
25400	Repair of nonunion or malunion, radius OR ulna; without graft (eg, compression technique)
25405	Repair of nonunion or malunion, radius OR ulna; with autograft (includes obtaining graft)
25415	Repair of nonunion or malunion, radius AND ulna; without graft (eg, compression technique)
25420	Repair of nonunion or malunion, radius AND ulna; with autograft (includes obtaining graft)
25430	Insertion of vascular pedicle into carpal bone (eg, Hori procedure)
25431	Repair of nonunion of carpal bone (excluding carpal scaphoid (navicular)) (includes obtaining graft and necessary fixation), each bone
25440	Repair of nonunion, scaphoid carpal (navicular) bone, with or without radial styloidectomy (includes obtaining graft and necessary fixation)
25441	Arthroplasty with prosthetic replacement; distal radius
25442	Arthroplasty with prosthetic replacement; distal ulna
25443	Arthroplasty with prosthetic replacement; scaphoid carpal (navicular)
25444	Arthroplasty with prosthetic replacement; lunate
25445	Arthroplasty with prosthetic replacement; trapezium
25446	Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)
25447	Arthroplasty, interposition, intercarpal or carpometacarpal joints
25449	Revision of arthroplasty, including removal of implant, wrist joint
25450	Epiphyseal arrest by epiphysiodesis or stapling; distal radius OR ulna
25455	Epiphyseal arrest by epiphysiodesis or stapling; distal radius AND ulna
25800	Arthrodesis, wrist; complete, without bone graft (includes radiocarpal and/or intercarpal and/or carpometacarpal joints)
25805	Arthrodesis, wrist; with sliding graft
25810	Arthrodesis, wrist; with iliac or other autograft (includes obtaining graft)
25820	Arthrodesis, wrist; limited, without bone graft (eg, intercarpal or radiocarpal)
25825	Arthrodesis, wrist; with autograft (includes obtaining graft)
25830	Arthrodesis, distal radioulnar joint with segmental resection of ulna, with or without bone graft (eg, Sauve-Kapandji procedure)
26010	Drainage of finger abscess; simple
26011	Drainage of finger abscess; complicated (e.g., felon)
26020	Drainage of tendon sheath, digit and/or palm, each
26040	Fasciotomy, palmar (eg, Dupuytren's contracture); percutaneous
26045	Fasciotomy, palmar (e.g., Dupuytren's contracture); open, partial

Back to Top

26055	Tendon sheath incision (eg, for trigger finger)
26070	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; carpometacarpal joint
26075	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; metacarpophalangeal joint, each
26080	Arthrotomy, with exploration, drainage, or removal of loose or foreign body; interphalangeal joint, each
26100	Arthrotomy with biopsy; carpometacarpal joint, each
26105	Arthrotomy with biopsy; metacarpophalangeal joint, each
26110	Arthrotomy with biopsy; interphalangeal joint, each
26111	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; 1.5 cm or greater
26113	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (e.g., intramuscular); 1.5 cm or greater
26115	Excision, tumor or vascular malformation, soft tissue of hand or finger, subcutaneous; less than 1.5 cm
26116	Excision, tumor, soft tissue, or vascular malformation, of hand or finger, subfascial (e.g., intramuscular); less than 1.5 cm
26117	Radical resection of tumor (eg, sarcoma), soft tissue of hand or finger; less than 3 cm
26118	Radical resection of tumor (eg, sarcoma), soft tissue of hand or finger; 3 cm or greater
26121	Fasciectomy, palm only, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26123	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26125	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft); each additional digit (List separately in addition to code for primary procedure)
26160	Excision of lesion of tendon sheath or joint capsule (eg, cyst, mucous cyst, or ganglion), hand or finger
26170	Excision of tendon, palm, flexor or extensor, single, each tendon
26180	Excision of tendon, finger, flexor or extensor, each tendon
26200	Excision or curettage of bone cyst or benign tumor of metacarpal
26205	Excision or curettage of bone cyst or benign tumor of metacarpal; with autograft (includes obtaining graft)
26210	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger
26215	Excision or curettage of bone cyst or benign tumor of proximal, middle, or distal phalanx of finger; with autograft (includes obtaining graft)
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis); metacarpal
26235	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis); proximal or middle phalanx of finger
26236	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); distal phalanx of finger
26320	Removal of implant from finger or hand
26350	Repair or advancement, flexor tendon, not in zone 2 digital flexor tendon sheath (eg, no man's land); primary or secondary without free graft, each tendon
26352	Repair or advancement, flexor tendon, not in zone 2 digital flexor tendon sheath (eg, no man's land); secondary with free graft (includes obtaining graft), each tendon
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); primary, without free graft, each tendon
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); secondary, without free graft, each tendon
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (eg, no man's land); secondary, with free graft (includes obtaining graft), each tendon
26370	Repair or advancement of profundus tendon, with intact superficialis tendon; primary, each tendon
26372	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary with free graft (includes obtaining graft), each tendon

Back to Top

26373	Repair or advancement of profundus tendon, with intact superficialis tendon; secondary without free graft, each tendon
26392	Removal of synthetic rod and insertion of flexor tendon graft, hand or finger (includes obtaining graft), each rod
26410	Repair, extensor tendon, hand, primary or secondary; without free graft, each tendon
26412	Repair, extensor tendon, hand, primary or secondary; with free graft (includes obtaining graft), each tendon
26418	Repair, extensor tendon, finger, primary or secondary; without free graft, each tendon
26420	Repair, extensor tendon, finger, primary or secondary; with free graft (includes obtaining graft) each tendon
26426	Repair of extensor tendon, central slip, secondary (e.g., boutonniere deformity); using local tissue(s), including lateral band(s), each finger
26428	Repair of extensor tendon, central slip, secondary (eg, boutonniere deformity); with free graft (includes obtaining graft), each finger
26432	Closed treatment of distal extensor tendon insertion, with or without percutaneous pinning (e.g., mallet finger)
26433	Repair of extensor tendon, distal insertion, primary or secondary; without graft (e.g., mallet finger)
26434	Repair of extensor tendon, distal insertion, primary or secondary; with free graft (includes obtaining graft)
26437	Realignment of extensor tendon, hand, each tendon
26440	Tenolysis, flexor tendon; palm or finger, each tendon
26442	Tenolysis, flexor tendon; palm and finger, each tendon
26445	Tenolysis, extensor tendon, hand or finger, each tendon
26449	Tenolysis, complex, extensor tendon, finger, including forearm, each tendon
26450	Tenotomy, flexor, palm, open, each tendon
26455	Tenotomy, flexor, finger, open, each tendon
26460	Tenotomy, extensor, hand or finger, open, each tendon
26480	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; without free graft, each tendon
26483	Transfer or transplant of tendon, carpometacarpal area or dorsum of hand; with free tendon graft (includes obtaining graft), each tendon
26485	Transfer or transplant of tendon, palmar; without free tendon graft, each tendon
26489	Transfer or transplant of tendon, palmar; with free tendon graft (includes obtaining graft), each tendon
26500	Reconstruction of tendon pulley, each tendon; with local tissues (separate procedure)
26502	Reconstruction of tendon pulley, each tendon; with tendon or fascial graft (includes obtaining graft) (separate procedure)
26516	Capsulodesis, metacarpophalangeal joint; single digit
26517	Capsulodesis, metacarpophalangeal joint; 2 digits
26518	Capsulodesis, metacarpophalangeal joint; 3 or 4 digits
26520	Capsulectomy or capsulotomy; metacarpophalangeal joint, each joint
26525	Capsulectomy or capsulotomy; interphalangeal joint, each joint
26540	Repair of collateral ligament, metacarpophalangeal or interphalangeal joint
26541	Reconstruction, collateral ligament, metacarpophalangeal joint, single; with tendon or fascial graft (includes obtaining graft)
26542	Reconstruction, collateral ligament, metacarpophalangeal joint, single; with local tissue (e.g., adductor advancement)
26545	Reconstruction, collateral ligament, interphalangeal joint, single, including graft, each joint
26565	Osteotomy; metacarpal, each
26567	Osteotomy; phalanx of finger, each
26587	Reconstruction of polydactylous digit, soft tissue and bone
26590	Repair macrodactylia, each digit
26591	Repair, intrinsic muscles of hand, each muscle
26593	Release, intrinsic muscles of hand, each muscle
26596	Excision of constricting ring of finger, with multiple Z-plasties

Back to Top

26600	Closed treatment of metacarpal fracture, single; without manipulation, each bone
26605	Closed treatment of metacarpal fracture, single; with manipulation, each bone
26607	Closed treatment of metacarpal fracture, with manipulation, with external fixation, each bone
26608	Percutaneous skeletal fixation of metacarpal fracture, each bone
26615	Open treatment of metacarpal fracture, single, includes internal fixation, when performed, each bone
26641	Closed treatment of carpometacarpal dislocation, thumb, with manipulation
26645	Closed treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation
26650	Percutaneous skeletal fixation of carpometacarpal fracture dislocation, thumb (Bennett fracture), with manipulation
26665	Open treatment of carpometacarpal fracture dislocation, thumb (Bennett fracture), includes internal fixation, when performed
26670	Closed treatment of carpometacarpal dislocation, other than thumb, with manipulation, each joint; without anesthesia
26675	Closed treatment of carpometacarpal dislocation, other than thumb, with manipulation, each joint; requiring anesthesia
26676	Percutaneous skeletal fixation of carpometacarpal dislocation, other than thumb, with manipulation, each joint
26685	Open treatment of carpometacarpal dislocation, other than thumb; includes internal fixation, when performed, each joint
26686	Open treatment of carpometacarpal dislocation, other than thumb; complex, multiple, or delayed reduction
26700	Closed treatment of metacarpophalangeal dislocation, single, with manipulation; without anesthesia
26705	Closed treatment of metacarpophalangeal dislocation, single, with manipulation; requiring anesthesia
26706	Percutaneous skeletal fixation of metacarpophalangeal dislocation, single, with manipulation
26715	Open treatment of metacarpophalangeal dislocation, single, includes internal fixation, when performed
26720	Closed treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb; without manipulation, each
26725	Closed treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb; with manipulation, with or without skin or skeletal traction, each
26727	Percutaneous skeletal fixation of unstable phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, with manipulation, each
26735	Open treatment of phalangeal shaft fracture, proximal or middle phalanx, finger or thumb, includes internal fixation, when performed, each
26740	Closed treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint; without manipulation, each
26742	Closed treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint; with manipulation, each
26746	Open treatment of articular fracture, involving metacarpophalangeal or interphalangeal joint, includes internal fixation, when performed, each
26750	Closed treatment of distal phalangeal fracture, finger or thumb; without manipulation, each
26755	Closed treatment of distal phalangeal fracture, finger or thumb; with manipulation, each
26756	Percutaneous skeletal fixation of distal phalangeal fracture, finger or thumb, each
26765	Open treatment of distal phalangeal fracture, finger or thumb, includes internal fixation, when performed, each
26770	Closed treatment of interphalangeal joint dislocation, single, with manipulation; without anesthesia
26775	Closed treatment of interphalangeal joint dislocation, single, with manipulation; requiring anesthesia
26776	Percutaneous skeletal fixation of interphalangeal joint dislocation, single, with manipulation
26785	Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed, single
26841	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation

Back to Top

26842	Arthrodesis, carpometacarpal joint, thumb, with or without internal fixation; with autograft (includes obtaining graft)
26843	Arthrodesis, carpometacarpal joint, digit, other than thumb, each;
26844	Arthrodesis, carpometacarpal joint, digit, other than thumb, each; with autograft (includes obtaining graft)
26850	Arthrodesis, metacarpophalangeal joint, with or without internal fixation
26852	Arthrodesis, metacarpophalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)
26860	Arthrodesis, interphalangeal joint, with or without internal fixation
26861	Arthrodesis, interphalangeal joint, with or without internal fixation; each additional interphalangeal joint (List separately in addition to code for primary procedure)
26862	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft)
26863	Arthrodesis, interphalangeal joint, with or without internal fixation; with autograft (includes obtaining graft), each additional joint (List separately in addition to code for primary procedure)
26910	Amputation, metacarpal, with finger or thumb (ray amputation), single, with or without interosseous transfer
26951	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with direct closure
26952	Amputation, finger or thumb, primary or secondary, any joint or phalanx, single, including neurectomies; with local advancement flaps (V-Y, hood)
27301	Incision and drainage, deep abscess, bursa, or hematoma, thigh or knee region
27310	Arthrotomy, knee, with exploration, drainage, or removal of foreign body (e.g., infection)
27323	Biopsy, soft tissue of thigh or knee area; superficial
27324	Biopsy, soft tissue of thigh or knee area; deep (subfascial or intramuscular)
27330	Arthrotomy, knee; with synovial biopsy only
27331	Arthrotomy, knee; including joint exploration, biopsy, or removal of loose or foreign bodies
27332	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial or lateral
27333	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial AND lateral
27334	Arthrotomy, with synovectomy, knee; anterior or posterior
27335	Arthrotomy, with synovectomy, knee; anterior and posterior including popliteal area
27340	Excision, prepatellar bursa
27345	Excision of synovial cyst of popliteal space (e.g., Baker's cyst)
27347	Excision of lesion of meniscus or capsule (e.g., cyst, ganglion), knee
27350	Patellectomy or hemipatellectomy
27372	Removal of foreign body, deep, thigh region or knee area
27380	Suture of infrapatellar tendon; primary
27381	Suture of infrapatellar tendon; secondary reconstruction, including fascial or tendon graft
27385	Suture of quadriceps or hamstring muscle rupture; primary
27386	Suture of quadriceps or hamstring muscle rupture; secondary reconstruction, including fascial or tendon graft
27403	Arthrotomy with meniscus repair, knee
27405	Repair, primary, torn ligament and/or capsule, knee; collateral
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate
27409	Repair, primary, torn ligament and/or capsule, knee; collateral and cruciate ligaments
27418	Anterior tibial tubercleplasty (e.g., Maquet type procedure)
27420	Reconstruction of dislocating patella; (eg, Hauser type procedure)
27422	Reconstruction of dislocating patella; with extensor realignment and/or muscle advancement or release (eg, Campbell, Goldwaite type procedure)
27424	Reconstruction of dislocating patella; with patellectomy
27427	Ligamentous reconstruction (augmentation), knee; extra-articular
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular
27570	Manipulation of knee joint under general anesthesia (includes application of traction or other

Back to Top

	fixation devices)
27605	Tenotomy, percutaneous, Achilles tendon (separate procedure); local anesthesia
27606	Tenotomy, percutaneous, Achilles tendon (separate procedure); general anesthesia
27610	Arthrotomy, ankle, including exploration, drainage, or removal of foreign body
27612	Arthrotomy, posterior capsular release, ankle, with or without Achilles tendon lengthening
27620	Arthrotomy, ankle, with joint exploration, with or without biopsy, with or without removal of loose or foreign body
27625	Arthrotomy, with synovectomy, ankle;
27626	Arthrotomy, with synovectomy, ankle; including tenosynovectomy
27630	Excision of lesion of tendon sheath or capsule (eg, cyst or ganglion), leg and/or ankle
27650	Repair, primary, open or percutaneous, ruptured Achilles tendon;
27652	Repair, primary, open or percutaneous, ruptured Achilles tendon; with graft (includes obtaining graft)
27654	Repair, secondary, Achilles tendon, with or without graft
27656	Repair, fascial defect of leg
27658	Repair, flexor tendon, leg; primary, without graft, each tendon
27659	Repair, flexor tendon, leg; secondary, with or without graft, each tendon
27664	Repair, extensor tendon, leg; primary, without graft, each tendon
27665	Repair, extensor tendon, leg; secondary, with or without graft, each tendon
27675	Repair, dislocating peroneal tendons; without fibular osteotomy
27676	Repair, dislocating peroneal tendons; with fibular osteotomy
27680	Tenolysis, flexor or extensor tendon, leg and/or ankle; single, each tendon
27681	Tenolysis, flexor or extensor tendon, leg and/or ankle; multiple tendons (through separate incision[s])
27685	Lengthening or shortening of tendon, leg or ankle; single tendon (separate procedure)
27686	Lengthening or shortening of tendon, leg or ankle; multiple tendons (through same incision), each
27687	Gastrocnemius recession (eg, Strayer procedure)
27690	Transfer or transplant of single tendon (with muscle redirection or rerouting); superficial (eg, anterior tibial extensors into midfoot)
27691	Transfer or transplant of single tendon (with muscle redirection or rerouting); deep (eg, anterior tibial or posterior tibial through interosseous space, flexor digitorum longus, flexor hallucis longus, or peroneal tendon to midfoot or hindfoot)
27692	Transfer or transplant of single tendon (with muscle redirection or rerouting); each additional tendon (List separately in addition to code for primary procedure)
27695	Repair, primary, disrupted ligament, ankle; collateral
27696	Repair, primary, disrupted ligament, ankle; both collateral ligaments
27698	Repair, secondary, disrupted ligament, ankle, collateral (eg, Watson-Jones procedure)
27705	Osteotomy; tibia
27707	Osteotomy; fibula
27709	Osteotomy; tibia and fibula
27720	Repair of nonunion or malunion, tibia; without graft, (e.g., compression technique)
27722	Repair of nonunion or malunion, tibia; with sliding graft
27726	Repair of fibula nonunion and/or malunion with internal fixation
27756	Percutaneous skeletal fixation of tibial shaft fracture (with or without fibular fracture) (e.g., pins or screws)
27792	Open treatment of distal fibular fracture (lateral malleolus), includes internal fixation, when performed
27814	Open treatment of bimalleolar ankle fracture (eg, lateral and medial malleoli, or lateral and posterior malleoli, or medial and posterior malleoli), includes internal fixation, when performed
27822	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; without fixation of posterior lip
27823	Open treatment of trimalleolar ankle fracture, includes internal fixation, when performed, medial and/or lateral malleolus; with fixation of posterior lip
27870	Arthrodesis, ankle, open

Back to Top

27871	Arthrodesis, tibiofibular joint, proximal or distal
28001	Incision and drainage, bursa, foot
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space
28003	Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot
28008	Fasciotomy, foot and/or toe
28010	Tenotomy, percutaneous, toe; single tendon
28011	Tenotomy, percutaneous, toe; multiple tendons
28020	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; intertarsal or tarsometatarsal joint
28022	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; metatarsophalangeal joint
28024	Arthrotomy, including exploration, drainage, or removal of loose or foreign body; interphalangeal joint
28035	Release, tarsal tunnel (posterior tibial nerve decompression)
28039	Excision, tumor, soft tissue of foot or toe, subcutaneous; 1.5 cm or greater
28041	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); 1.5 cm or greater
28043	Excision, tumor, soft tissue of foot or toe, subcutaneous; less than 1.5 cm
28045	Excision, tumor, soft tissue of foot or toe, subfascial (e.g., intramuscular); less than 1.5 cm
28046	Radical resection of tumor (eg, sarcoma), soft tissue of foot or toe; less than 3 cm
28047	Radical resection of tumor (e.g., sarcoma), soft tissue of foot or toe; 3 cm or greater
28055	Neurectomy, intrinsic musculature of foot
28060	Fasciectomy, plantar fascia; partial (separate procedure)
28062	Fasciectomy, plantar fascia; radical (separate procedure)
28070	Synovectomy; intertarsal or tarsometatarsal joint, each
28072	Synovectomy; metatarsophalangeal joint, each
28080	Excision, interdigital (Morton) neuroma, single, each
28086	Synovectomy, tendon sheath, foot; flexor
28088	Synovectomy, tendon sheath, foot; extensor
28090	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (eg, cyst or ganglion); foot
28092	Excision of lesion, tendon, tendon sheath, or capsule (including synovectomy) (e.g., cyst or ganglion); toe(s), each
28100	Excision or curettage of bone cyst or benign tumor, talus or calcaneus
28102	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with iliac or other autograft (includes obtaining graft)
28103	Excision or curettage of bone cyst or benign tumor, talus or calcaneus; with allograft
28104	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus
28106	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with iliac or other autograft (includes obtaining graft)
28107	Excision or curettage of bone cyst or benign tumor, tarsal or metatarsal, except talus or calcaneus; with allograft
28108	Excision or curettage of bone cyst or benign tumor, phalanges of foot
28110	Ostectomy, partial excision, fifth metatarsal head (bunionette) (separate procedure)
28111	Ostectomy, complete excision; first metatarsal head
28112	Ostectomy, complete excision; other metatarsal head (second, third or fourth)
28113	Ostectomy, complete excision; fifth metatarsal head
28114	Ostectomy, complete excision; all metatarsal heads, with partial proximal phalangectomy, excluding first metatarsal (eg, Clayton type procedure)
28116	Ostectomy, excision of tarsal coalition
28118	Ostectomy, calcaneus
28119	Ostectomy, calcaneus; for spur, with or without plantar fascial release
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g.,

Back to Top

	osteomyelitis or bossing); talus or calcaneus
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (eg, osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus
28124	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); phalanx of toe
28126	Resection, partial or complete, phalangeal base, each toe
28130	Talectomy (astragalectomy)
28140	Metatarsectomy
28150	Phalangectomy, toe, each toe
28153	Resection, condyle(s), distal end of phalanx, each toe
28160	Hemi phalangectomy or interphalangeal joint excision, toe, proximal end of phalanx, each
28190	Removal of foreign body, foot; subcutaneous
28192	Removal of foreign body, foot; deep
28193	Removal of foreign body, foot; complicated
28200	Repair, tendon, flexor, foot; primary or secondary, without free graft, each tendon
28202	Repair, tendon, flexor, foot; secondary with free graft, each tendon (includes obtaining graft)
28208	Repair, tendon, extensor, foot; primary or secondary, each tendon
28210	Repair, tendon, extensor, foot; secondary with free graft, each tendon (includes obtaining graft)
28220	Tenolysis, flexor, foot; single tendon
28222	Tenolysis, flexor, foot; multiple tendons
28225	Tenolysis, extensor, foot; single tendon
28226	Tenolysis, extensor, foot; multiple tendons
28230	Tenotomy, open, tendon flexor; foot, single or multiple tendon(s) (separate procedure)
28232	Tenotomy, open, tendon flexor; toe, single tendon (separate procedure)
28234	Tenotomy, open, extensor, foot or toe, each tendon
28238	Reconstruction (advancement), posterior tibial tendon with excision of accessory tarsal navicular bone (eg, Kidner type procedure)
28250	Division of plantar fascia and muscle (e.g., Steindler stripping) (separate procedure)
28260	Capsulotomy, midfoot; medial release only (separate procedure)
28261	Capsulotomy, midfoot; with tendon lengthening
28262	Capsulotomy, midfoot; extensive, including posterior talotibial capsulotomy and tendon(s) lengthening (eg, resistant clubfoot deformity)
28264	Capsulotomy, midtarsal (eg, Heyman type procedure)
28270	Capsulotomy; metatarsophalangeal joint, with or without tenorrhaphy, each joint (separate procedure)
28272	Capsulotomy; interphalangeal joint, each joint (separate procedure)
28280	Syndactylization, toes (e.g., webbing or Kelikian type procedure)
28285	Correction, hammertoe (eg, interphalangeal fusion, partial or total phalangectomy)
28286	Correction, cock-up fifth toe, with plastic skin closure (e.g., Ruiz-Mora type procedure)
28288	Ostectomy, partial, exostectomy or condylectomy, metatarsal head, each metatarsal head
28289	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant
28291	Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; with implant
28292	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with resection of proximal phalanx base, when performed, any method
28295	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal metatarsal osteotomy, any method
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method
28297	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
28298	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with proximal phalanx osteotomy, any method

Back to Top

28299	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with double osteotomy, any method
28300	Osteotomy; calcaneus (eg, Dwyer or Chambers type procedure), with or without internal fixation
28302	Osteotomy; talus
28304	Osteotomy, tarsal bones, other than calcaneus or talus;
28305	Osteotomy, tarsal bones, other than calcaneus or talus; with autograft (includes obtaining graft) (eg, Fowler type)
28306	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal
28307	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal with autograft (other than first toe)
28308	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; other than first metatarsal, each
28309	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; multiple (eg, Swanson type cavus foot procedure)
28310	Osteotomy, shortening, angular or rotational correction; proximal phalanx, first toe (separate procedure)
28312	Osteotomy, shortening, angular or rotational correction; other phalanges, any toe
28313	Reconstruction, angular deformity of toe, soft tissue procedures only (e.g., overlapping second toe, fifth toe, curly toes)
28315	Sesamoidectomy, first toe (separate procedure)
28320	Repair, nonunion or malunion; tarsal bones
28322	Repair, nonunion or malunion; metatarsal, with or without bone graft (includes obtaining graft)
28470	Closed treatment of metatarsal fracture; without manipulation, each
28476	Percutaneous skeletal fixation of metatarsal fracture, with manipulation, each
28485	Open treatment of metatarsal fracture, includes internal fixation, when performed, each
28496	Percutaneous skeletal fixation of fracture great toe, phalanx or phalanges, with manipulation
28525	Open treatment of fracture, phalanx or phalanges, other than great toe, includes internal fixation, when performed, each
28666	Percutaneous skeletal fixation of interphalangeal joint dislocation, with manipulation
28675	Open treatment of interphalangeal joint dislocation, includes internal fixation, when performed
28705	Arthrodesis; pantalar
28715	Arthrodesis; triple
28725	Arthrodesis; subtalar
28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse
28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (eg, flatfoot correction)
28737	Arthrodesis, with tendon lengthening and advancement, midtarsal, tarsal navicular-cuneiform (eg, Miller type procedure)
28740	Arthrodesis, midtarsal or tarsometatarsal, single joint
28750	Arthrodesis, great toe; metatarsophalangeal joint
28755	Arthrodesis, great toe; interphalangeal joint
28760	Arthrodesis, with extensor hallucis longus transfer to first metatarsal neck, great toe, interphalangeal joint (e.g., Jones type procedure)
28810	Amputation, metatarsal, with toe, single
28820	Amputation, toe; metatarsophalangeal joint
28825	Amputation, toe; interphalangeal joint
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)
29806	Arthroscopy, shoulder, surgical; capsulorrhaphy
29807	Arthroscopy, shoulder, surgical; repair of SLAP lesion
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (eg, humeral

Back to Top

	bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (Mumford procedure)
29825	Arthroscopy, shoulder, surgical; with lysis and resection of adhesions, with or without manipulation
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (ie, arch) release, when performed (List separately in addition to code for primary procedure)
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair
29828	Arthroscopy, shoulder, surgical; biceps tenodesis
29830	Arthroscopy, elbow, diagnostic, with or without synovial biopsy (separate procedure)
29835	Arthroscopy, elbow, surgical; synovectomy, partial
29836	Arthroscopy, elbow, surgical; synovectomy, complete
29837	Arthroscopy, elbow, surgical; debridement, limited
29838	Arthroscopy, elbow, surgical; debridement, extensive
29840	Arthroscopy, wrist, diagnostic, with or without synovial biopsy (separate procedure)
29843	Arthroscopy, wrist, surgical; for infection, lavage and drainage
29844	Arthroscopy, wrist, surgical; synovectomy, partial
29845	Arthroscopy, wrist, surgical; synovectomy, complete
29846	Arthroscopy, wrist, surgical; excision and/or repair of triangular fibrocartilage and/or joint debridement
29847	Arthroscopy, wrist, surgical; internal fixation for fracture or instability
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
29870	Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29871	Arthroscopy, knee, surgical; for infection, lavage and drainage
29873	Arthroscopy, knee, surgical; with lateral release
29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
29875	Arthroscopy, knee, surgical; synovectomy, limited (eg, plica or shelf resection) (separate procedure)
29876	Arthroscopy, knee, surgical; synovectomy, major, 2 or more compartments (eg, medial or lateral)
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29880	Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed
29881	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29882	Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)
29883	Arthroscopy, knee, surgical; with meniscus repair (medial AND lateral)
29884	Arthroscopy, knee, surgical; with lysis of adhesions, with or without manipulation (separate procedure)
29885	Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
29886	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion
29887	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion with internal fixation
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction
29891	Arthroscopy, ankle, surgical, excision of osteochondral defect of talus and/or tibia, including

Back to Top

	drilling of the defect
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
29893	Endoscopic plantar fasciotomy
29894	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; with removal of loose body or foreign body
29895	Arthroscopy, ankle (tibiotalar and fibulotalar joints), surgical; synovectomy, partial
29900	Arthroscopy, metacarpophalangeal joint, diagnostic, includes synovial biopsy
29901	Arthroscopy, metacarpophalangeal joint, surgical; with debridement
29902	Arthroscopy, metacarpophalangeal joint, surgical; with reduction of displaced ulnar collateral ligament (eg, Stenar lesion)
29906	Arthroscopy, subtalar joint, surgical; with debridement
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
02/25/2021	03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	05/02/2023

[MPC] Medical Policy Committee

Revision History	Description
03/02/2021	MPC approved criteria for Ambulatory Surgery Center Site of Care. Requires 60-day notice; effective July 1, 2021.
04/13/2021	Updated policy effective date to August 1, 2021 with phased approach
05/12/2021	Updated 'site of service' terminology to 'site of care' throughout the policy.
07/27/2021	Updated policy effective date to September 1, 2021 with phased approach
12/15/2022	Moved the ASC list of codes to this criteria page for consolidation.
03/06/2023	Updated applicable codes to include new CPT codes effective 1/1/2023: 49591, 49593, 49595, 49613, 49615, 49617, 49621, 49623
05/02/2023	MPC approved an expansion of the ASC criteria and adoption of SOC restriction for Gastroenterology procedures. GI procedures is applicable to the following counties: **King and Thurston (new counties) and existing counties. This requires a 60-day notice, effective October 1, 2023.

Back to Top

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bone Anchored Hearing System (BAHA)

- BONEBRIDGE Bone Conduction Implant
- Osia®
- Vibrant Soundbridge
- Softband
- Adhear

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 16, section 100 – "Hearing Aids and Auditory Implants" and section 180 – "Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare."
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Effective until September 1, 2023

Kaiser Permanente has elected to use the Bone Anchored Hearing System (BAHS) (KP-0564 v2) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective September 1, 2023

Kaiser Permanente has elected to use the Bone Anchored Hearing System (BAHS) (KP-0564 09012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

Service	Criteria Used
Vibrant Soundbridge	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting these services, please send the following documentation to support medical necessity:

- Most recent audiogram/hearing test
- Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)

Back to Top

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Vibrant Soundbridge System

The Vibrant Soundbridge System is an implantable alternative to standard hearing aids. It is intended for use in adults with moderate to severe sensorineural hearing loss, who desire an alternative to an acoustic hearing aid. Common limitations of conventional hearing aids are acoustic feedback, sound and voice distortion, and need for frequent servicing and maintenance (FDA documents, Sterkers et al., 2003; Luetje, 2002).

The Soundbridge system consists of a middle-ear implant known as the Vibrating Ossicular Prosthesis (VORP) and an external portion, the amplification system called the Audio Processor. The Audio Processor is about 1.2 inches in diameter and designed to be worn behind or above the ear. It contains a microphone that converts environmental sound to electrical signals. These signals are delivered to the VORP, causing the Floating Mass Transducer (FMT), one of its components, to vibrate. The vibration manually stimulates the auditory ossicles and is perceived by the patient as sound (manufacturer's documents).

Potential adverse effects of the Vibrant Soundbridge include the usual risks of major ear surgery and a possible decrease in residual hearing (FDA documents).

The Vibrant Soundbridge has been available commercially since February 1998 in Europe and received FDA approval in the US in August 2000. The FDA recommends that patients have experience with appropriately fitting conventional hearing aids before using the Vibrant Soundbridge.

Bone Anchored Hearing Aid (BAHA) (Entific Medical Systems)

The BAHA is an alternative device for hearing-impaired patients who are unable to wear traditional hearing aids. According to the manufacturer, the BAHA can be beneficial to individuals with chronic inflammation or infection of the ear canal, an incomplete ear canal e.g. congenital ear malformation and single-sided hearing loss. The BAHA is based on bone conduction technology, sound transmission without involvement of the skin and soft tissue and thus can be used by individuals with an impaired or diseased external or middle ear (Tjellstrom & Hakansson, 1995).

The BAHA device consists of an implant and an external sound processor attached to a subcutaneous abutment. The implant, a titanium fixture, is implanted behind the ear where it "osseointegrates" or bonds with the living bone. After healing from surgery, a percutaneous abutment is attached to the fixture. The sound processor "snaps" into the abutment. The sound processor, which transmits sound directly via the bone to the inner ear can be connected and disconnected at will (FDA and manufacturer's documents)

The BAHA was developed in Sweden in the 1980s. It was approved by the FDA in August 1996 and was introduced in the US market in January 1997. There are several different models, all of which were considered by the FDA to be Class II devices, substantially equivalent to air conduction hearing aids with digital sound processing.

Medical Technology Assessment Committee (MTAC)

Vibrant Soundbridge

06/06/2005: MTAC REVIEW

Evidence Conclusion: There are studies with pre- and post-implantation data, but no controlled studies on the efficacy of either the Vibrant Soundbridge or the BAHA. Data from case series suggest that patients who meet eligibility requirements may experience improvement and hearing from the Vibrant Soundbridge and BAHA. Lack of blinding and lack of a control group limit the validity of case series. The publications are further limited by small sample sizes and/or missing data.

Articles: *Vibrant Soundbridge*: Only case series were identified. Most were conducted in Europe where there is longer experience with the device compared to the U.S. Two studies were selected for review: The largest case series, a French study (n=125), and the strongest US study (n=54). The US study was the one used by the FDA to grant approval. *BAHA*: Only case series were identified, all with sample sizes <100. The two best-case series

Back to Top

were reviewed. They were selected based on sample size and length of follow-up. There were two publications on one of the studies, so a total of three articles were reviewed. *The studies that were critically appraised are*: Sterkers O, Boucarra D, Labassi S. A middle ear implant, the Symphonix Vibrant Soundbridge: Retrospective study of the first 125 patients implanted in France. *Otol Neurotol* 2003; 24: 427-436. See Evidence Table Luetje CM, Brackman D, Balkany TJ et al. Phase III clinical trial results with the Vibrant Soundbridge implantable middle ear hearing device: A prospective controlled multicenter study. See Evidence Table Mylanus EA, van der Pouw KC, Snik AFM et al. Intraindividual comparison of the bone-anchored hearing aid and air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 1998; 124: 271-276**.** See Evidence Table Hol MKS, Snik AFM, Mylanus EAM et al. Long-term results of bone-anchored hearing aid recipients who had previously used air-conduction hearing aids. *Arch Otolaryngol Head Neck Surg* 2005; 131: 321-325. See Evidence Table Lustig LR, Arts A. Brackmann DE. Hearing rehabilitation using the BAHA bone-anchored hearing aid: Results in 40 patients. *Otol Neurotol* 2001; 22: 328-334. See Evidence Table

The use of Vibrant Soundbridge or the BAHA in the treatment of hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Bone anchored or transcutaneous bone-conduction hearing systems

Medicare –

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69719	Revision or replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69726	Removal, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator,

Back to Top

	replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Considered Not Medically Necessary:

CPT® Codes	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor
69717	Replacement (including removal of existing device), osseointegrated implant, skull; with percutaneous attachment to external speech processor
69718	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
HCPC Codes	**Description**
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only

Vibrant Soundbridge - Considered Not Medically Necessary:

Back to Top

HCPC Codes	Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear
V5095	Semi-implantable middle ear hearing prosthesis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Review Dates	Date Last Revised
06/06/2005	09/07/2010[MDCRPC], 07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC],10/01/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	04/04/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/9/2018	Added Adhear to non-coverage statement
04/21/2020	Added applicable CPT codes: 69714, 69715, 69717, 69718
08/04/2020	MPC approved to adopt updates for Non-Medicare, adding clinical indications for BONEBRIDGE (MCG* KP-0564-see KP-0564 v2 eff 01.01.2021). Requires 60-day notice, effective date 01/01/2021.
12/08/2022	Added New CPT Codes applicable for MA and Non-MA.
04/04/2023	MPC approved modification to criteria to include OSIA and clarification to hearing thresholds.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Balloon Dilation of the Eustachian Tube

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Balloon Dilation of the Eustachian Tube*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Eustachian Tube Dilation

Unilateral or bilateral Eustachian tube balloon dilation (ETBD) is considered medically necessary once per lifetime for the treatment of chronic obstructive Eustachian tube dysfunction when **ALL** of the following criteria are met:

- Age 18 years or older
- Patient has had any of the following symptoms continuously for at least 12 months:
  - aural fullness
  - aural pressure
  - otalgia
  - hearing loss
  - autophony
- History of chronic ear disease or intolerance to barometric changes greater than 12 months
- The patient does not have any other causes of aural fullness such as:
  - Temporomandibular joint disorders
  - Extrinsic obstruction of the eustachian tube
  - Superior semicircular canal dehiscence
  - Endolymphatic hydrops
- Prior evaluation of the eustachian tube with nasal endoscopy
- Abnormal result of **BOTH** of the following prior to ETBD:
  - Tympanogram (Type B or C)
  - Tympanic membrane (i.e., retracted membrane, effusion, perforation) on exam
- If applicable, failure to respond to appropriate medical management of potential co-occurring conditions, such as:
  - Allergic rhinitis, rhinosinusitis - 4-6 weeks of a nasal steroid spray, if indicated
  - Laryngopharyngeal reflux - Proton pump inhibitor or antacid treatment

Back to Top

- If patient has a history of tympanostomy tube placement, symptoms of Eustachian tube obstruction improved while tubes were patent, or the patient underwent myringotomy without tube placement with symptom relief

Eustachian tube balloon dilation (ETBD) is considered experimental, investigational or unproven for all other indications.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Eustachian Tube Role, ETD, & Prevalence, & Risk factors: (Anand et al., 2019; Fischer et al., 2020; Juszczak, Aubin-Pouliot, Sharon, & Loftus, 2019; Magro et al., 2021; Shan et al., 2019)
The eustachian tube (ET) is a ciliated epithelial-lined tube that covers the anterior wall of the middle ear and the nasopharynx. The ET has several roles including maintenance of middle ear physiology and function, pressure equalization across the tympanic membrane, clearance of secretions from the middle ear, and protection from pathogens and secretions from the oropharynx. An alteration of the opening or closing of the ET leads to ET dysfunction (ETD).
Categories of ETD vary from obstructive dysfunction to patulous dysfunction. Obstructive dysfunction is an insufficient opening of the ET. Patulous dysfunction is characterized by a patent valve (resulting in equalization of pressure between the middle ear and the nasopharynx).
The prevalence of ETD is estimated at 4.6% among adults in the United States and over 5% in the elderly population. Sinonasal risk factors include self-reported allergic rhinitis and persistent cold/flu.

Presentation & Treatment of ETD: (Swain, Janardan, & Mohanty, 2020)
Signs and symptoms of Eustachian tube dysfunctions consist of fullness of the ear, hearing difficulty, ear pain, tinnitus and vertigo. The medical treatments of ET dysfunction consist of antihistamines, nasal decongestants and oral or nasal steroids. If ETD is recalcitrant, Eustachian tuboplasty may be done. Balloon dilation of the Eustachian tube is a new surgical technique that has garnered interest.

Rationale
Existing treatments are not efficacious.

Description of the procedure (Magro et al., 2021; Meyer et al., 2018; Swain et al., 2020)
Balloon dilation of the ET (BDET) is a minimally invasive endoscopic procedure for ETD resistant to conservative treatment, in which a balloon is inflated into the Eustachian tube (ET). The procedure is generally performed under general anesthesia. Nevertheless, it can be done in office setting under local anesthesia. It can be unilateral or bilateral.
A balloon catheter is inserted, through the nose, into the ET under nasal endoscopy. The balloon is then inflated by filling in it up with saline to a pressure of 10 to 12 bars. The pressure is maintained for 2 minutes. Once the ET is dilated, the balloon is deflated and removed. The goal of the procedure is to dilate the cartilaginous portion of the ET without causing damage.

Medical Technology Assessment Committee (MTAC)

Balloon Dilation of the Eustachian Tube
Date: 10/11/2021
Evidence Conclusion:

- Low-quality evidence suggests that eustachian tube balloon dilation is more effective than medical treatment, on the short and long-term, in adult patients with eustachian tube dilation refractory to medical management.

Back to Top

The procedure may be safe as no serious device-related complications are reported. However, more RCTs with longer follow-up are still needed.
- The evidence is insufficient to compare ETBD and tympanoplasty in patients with otitis media and severe ETD.

Articles: See Evidence Table

The use of Balloon Dilation of the Eustachian Tube does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPCS Codes	Description
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/27/2022	02/01/2022[MPC], 02/07/2023[MPC],	

[MPC] Medical Policy Committee

Revision History	Description
02/01/2022	MPC approved to adopt MTAC's recommendation of coverage and the clinical review criteria for this medical procedure. Requires 60-day notice, effective date 07/01/2022.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bariatric Surgery

- Adjustable gastric banding, Laparoscopic or Open (Lap Band)
- Biliopancreatic Diversion with Duodenal Switch (Scopinaro Procedure)
- EndoGastric Solutions StomaphyX™ Endoluminal Fastener
- Endoscopic Sleeve Gastrecomy (ESG)
- Gastric Bypass for GERD
- Gastric Electrical Stimulator
- Intragastric Balloons
- Mini-Gastric Bypass
- Roux-en-Y Gastric Bypass (RYGB)
- Single Anastomosis Duodeno-Ileal Bypass w/ Sleeve gastrectomy (SADI-S)
- Vertical Banded Gastroplasty (VBG)
- Vertical Sleeve Gastrectomy (VSG)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)—Requires Medical Necessity review AND Level of Care Review
Local Coverage Determinations (LCD)	None
Local Coverage Article	Billing and Coding: Bariatric Surgery Coverage (A53028)

For Non-Medicare Members (Adult & Pediatric/Adolescent)

Procedure	Criteria
Adjustable gastric banding, Laparoscopic or Open (Lap Band) -Not covered for Federal Plans Laparoscopic Vertical Sleeve Gastrectomy (VSG) as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity Roux-en-Y Gastric Bypass (RYGB) Biliopancreatic Diversion with Duodenal Switch* Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)*	Requires Level of Care Review **AND** medical necessity review using Bariatric Surgery (KP-516 01012024) MCG*. *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access **If requesting this service, please send the following documentation to support medical necessity:** • Last 2 years of gastroenterology notes • Most recent clinical note from requesting provider

Back to Top

Procedure	Criteria
*reserved for patients with a BMI >50	• Documentation of patient height, weight & comorbid conditions
EndoGastric Solutions StomaphyX™ Endoluminal Fastener Endoscopic Sleeve Gastroplasty (ESG) Gastric Bypass for GERD Gastric Electrical Stimulation (GES) for Obesity Transoral Outlet Reduction (TORe)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist
Intragastric Balloon Device	MCG* A-0970 This is not covered per MCG **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

The following procedures are not covered (benefits are varied and need to be verified): Distal gastric bypass, Mini-gastric bypass

The vertical banded gastroplasty (VBG) is no longer a standard of care and is therefore considered not medically necessary and not covered.

CDC Adult Body Mass Index (BMI) Calculator View Chart
https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html
Percent of Excess Body Weight Loss Formula
(Initial Weight – Postop Weight)/ (Initial weight – Ideal Weight*) Ideal weight is defined by the weight corresponding to a BMI of 25 for the person in question.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

EndoGastric Solutions
Gastric Bypass for GERD
Gastric Electrical Stimulator for Obesity
Intragastric Balloons
Laparoscopic Sleeve Gastrectomy

Back to Top

Vertical Sleeve Gastrectomy (VSG)

Background

The NIH has defined overweight as a BMI between 25 kg/m2 and 29.9 kg/m2, and obesity as a BMI of > 30 kg/m2. According to national survey data, an estimated one-third of adults in the United States are overweight. Overweight and obesity are associated with an increased risk of mortality. Individuals with a BMI > 30 have a 50-100% increased risk of premature death compared to individuals with a BMI between 20 and 25. In addition, overweight and obesity are associated with an increased risk of coronary heart disease, type 2 diabetes, hypertension, certain cancers and musculoskeletal disorders such as knee osteoarthritis (Surgeon General report: USPSTF).

Lifestyle changes, including diet, exercise, and behavior modification, are generally considered first-line therapy for overweight and obesity. Pharmacotherapy can be used as an adjunctive therapy when lifestyle changes alone are ineffective. Medical management of obesity has been found to be less effective with individuals who are morbidly obese (BMI > 35) than for those with lower BMI, particularly in terms of sustained weight loss. The NIH has stated that bariatric surgery is an option for patients with a BMI > 40 or a BMI > 35 with comorbid conditions, who have failed medical treatment (Fisher and Schauer, 2002; NIH, 1998).

There are two main strategies for surgically inducing weight loss, gastric restriction and intestinal malabsorption. Restrictive procedures mechanically reduce the size of the stomach. This limits the amount of food a patient can consume at a single meal and causes early satiety. Substantial dietary compliance is required, because individuals are still able to consume high-calorie liquids or soft foods. Malabsorption procedures involve bypassing a portion of the intestines which decreases the proportion of nutrients that are absorbed from food. Some types of surgeries use elements of both strategies (Fisher and Schauer, 2002; Southern California-RAND EBPC 2004).

Two currently accepted bariatric surgery methods are Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB). VBG is a restrictive procedure that uses staples to create a narrow gastric inlet or pouch and a non-adjustable band is placed around the new inlet to prevent enlargement. RYGB includes both restrictive and malabsorptive elements. The stomach is reduced to a small gastric pouch, and this pouch is connected to a segment of the jejunum, bypassing the duodenum and proximal small intestine. RYGB can be performed as open surgery or laparoscopically.

Adjustable gastric banding is a restrictive technique, using the Lap-Band System® (Inamed). A small gastric pouch is formed by laparoscopically placing a silicone ring (the Lap-Band) around the upper part of the stomach just below the gastro-esophageal junction. The band is connected via tubing to an access port that is secured beneath the skin of the abdomen. The band has a reservoir that is accessed percutaneously and filled with saline. The size of the band can be adjusted by adding or removing saline. The Lap-Band is removable, either laparoscopically or via an open procedure. In the clinical study presented by the manufacturer to the FDA, 60% of the band removal procedures were laparoscopic. The Lap-Band has been used in Europe and Australia since early 1990s and was approved by FDA in June 2001 (manufacturer's Web site).

Medical Technology Assessment Committee (MTAC)

Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)

2/10/1999: MTAC REVIEW

Evidence Conclusion: The published scientific evidence consists of several large case series and one randomized controlled trial from multiple institutions published over a 10-year period of time. Vertical Banded Gastroplasty (VBG) Data from 4 case series and 1 RCT totaling 403 patients undergoing VBG with 75-100% follow up at 3 years demonstrates between 15 and 31% weight loss. Reoperation or revisional surgery was required in 3% of patients in one series and 36% in another series. Mortality was 1-3% overall. Roux-en-Y (REY)-Data from 2 case series and 1 RCT totaling 532 patients in the REY groups with 60-86% follow up at 3 years demonstrates that Roux-en-Y gastric restrictive surgery results in between 33 and 35% weight loss. Reoperation or revisional surgery was required in 6% of patients in one series and not reported in the other series. Mortality was 1% overall.

Articles: MacLean, LD et al. *Surgery*, 1993;113:380-388. See Evidence Table. Sugerman, HJ, et al. 1989: *Am J Surg.*;157 93-100. See Evidence Table.

Sjostrom CD, Peltonen M, Wedel H, Sjostrom L. Differentiated long-term effects of intentional weight loss on diabetes and hypertension. *Hypertension* 2000; 36: 20-25. See Evidence Table.

Back to Top

The use of gastric restrictive surgery (VBG or REY) meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/8/2006: MTAC REVIEW
Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)
Evidence Conclusion: There is some evidence that Lap-Band surgery is more effective than optimal non-surgical management for patients with BMI between 30-35 kg/m2 with co-morbidities. This evidence is not conclusive due to the size of the single RCT, and its limitations. Evidence from non-randomized studies suggests that gastric bypass surgery is more effective for weight loss than the Lap-Band technique for patients who meet standard eligibility criteria for bariatric surgery (BMI > 40 kg/m2 or > 35 kg/m2 with co-morbidities) and for the sub-set of patients with BMI > 50 kg/m2. Gastric surgery was not associated with more complications than the Lap-Band procedure, and studies generally found a higher reoperation rate after Lap-Band surgery. There may be residual confounding in the non-randomized studies. There are no randomized controlled trials comparing the safety and effectiveness of Lap-Band surgery to either gastric bypass or optimal non-surgical management for adults with BMI > 35 kg/m2. There is evidence from one randomized controlled trial that Lap-Band surgery is more effective for weight loss than a non-surgical intervention (i.e. supervised dieting, pharmacotherapy) for patients with BMI between 30-35 kg/m2 with co-morbidities (O'Brien et al., 2005). However, in the two years of follow-up 4 of the 39 patients who received the Lap-Band experienced prolapse of the posterior gastric wall. In addition, limitations of the study were that it was not blinded, follow-up was only two years, and the nonsurgical intervention was not well described beyond 6 months. The best evidence comparing the Lap-Band and Roux-en-Y gastric bypass comes from two non-randomized comparative studies (Weber et al., 2004; Cottam et al. 2006). Both matched patients who did and did not receive the Lap-Band according to age, sex and BMI. The Weber study included patients with BMI > 40 kg/m2 or BMI > 35 kg/m2 who had co-morbidities and the Cottam study did not specify eligibility criteria, but mean BMI was 47 kg/m2. Both studies found significantly more weight loss at 2-3 years and fewer co-morbidities in the group that underwent gastric bypass. In the Weber et al. study, the rate of reoperation was somewhat higher in the gastric bypass group than the Lap-Band group during the first 30 days (n=7 vs. n=1), but after 30 days the rate was higher in the Lap-Band group (n=26) than the gastric bypass group (n=4). The Cottam et al. study found a slightly higher rate of major reoperation in the gastric bypass group compared to the Lap-Band group (8% vs. 5%), but this difference was not statistically significant. A third non-randomized study compared the Lap-Band and laparoscopic Roux-en-Y gastric bypass in super morbidly obese patients (BMI > 50 kg/m2). Similar to the studies of patients with lower mean BMI, there was greater reduction in BMI and a higher proportion of excess weight loss in patients who received gastric bypass compared to the Lap-Band. There appeared to be a greater reduction in co-morbidities and fewer complications in the gastric bypass group, but numbers were too small to accurately compare the groups in these areas. Reoperations were necessary in 15% of the Lap-Band group and 6.5% of the gastric bypass group. In all of the non-randomized studies, there may be confounding variables, differences between groups that affect the outcome (such as differences in commitment to losing weight). A large case series conducted in Italy (n=1893) provides additional information on the safety of the Lap-Band technique. Reported post-operative mortality was 1 out of 200 procedures (0.5%) and was restricted to patients with preoperative cardiovascular complications. The most common post-operative complications were gastric pouch dilation (5%) and tube port complications (4%). The ideal study would be a randomized controlled trial comparing long-term outcomes of gastric surgery with the Lap-Band and commonly accepted bariatric surgery procedures or optimal non-surgical management. One randomized controlled trial was identified and critically appraised. It compared the Lap-Band to non-surgical treatment. Five non-randomized comparative studies were identified comparing the Lap-Band to gastric bypass. One study conducted in Sweden was excluded because it compared two case series of patients treated at different institutions. A second study was excluded because only preliminary findings were reported: there was 60% follow-up at 1 year and 15% at 2 years. The other three studies were critically appraised. A large case series from Italy (n=1863) was also reviewed to evaluate the long-term safety of Lap-Band surgery.
Articles: *Evidence tables were created for the following studies:* O'Brien PE, Dixon JB, Laurie C et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program. *Ann Intern Med* 2005; 144: 625-633. See Evidence Table. Weber M, Miller MK, Bucher T. Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. *Ann Surg* 2004; 240: 975-983. See Evidence Table. Cottam DR, Atkinson J, Anderson A et al. A case-controlled matched-pair cohort study of laparoscopic Roux-en-Y gastric bypass and Lap-Band patients in a single US center with three-year follow-up. *Obesity Surg* 2006; 16: 534-540. See Evidence Table. Browne WB, Julliard K, Castro AE et al. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients. *Arch Surg* 2006; 141: 683-689. See Evidence Table. Angrisani L, Furbette F, Doldi SB et al. Lap-Band adjustable gastric banding system: The Italian experience with 1863 patients operated on over 6 years. *Surg Endosc* 2003; 17: 409-412. See Evidence Table.

Back to Top

The use of adjustable gastric banding and lap-band in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/15/2014: MTAC REVIEW
Vertical Banded Gastroplasty (VBG) and Roux-en-Y gastric bypass (RYGB)
Evidence Conclusion: There is a lack of good quality RCTs with long-term follow-up that compared laparoscopic gastric banding versus Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy. The few published RCTs were small, with short follow-up duration, and methodological limitations. Colquitt and colleagues' 2014 systematic review and meta-analysis on surgery for morbid obesity was the last published update of previous Cochrane reviews and updates on that topic conducted by the same group of authors over the last decade. This last August 2014 update (Evidence table 1) included RCTs on bariatric surgery published through December 2013. The meta-analysis included 15 trials (N=1,180 participants) that compared different bariatric surgery procedures used for weight loss (seven additional trials compared surgery to non-surgical weight loss therapies). The meta-analysis had valid methodology and analysis, but the majority of the studies included had uncertain or high risk of bias. The overall results for the comparisons made among the three most commonly performed procedures were as follows: Laparoscopic gastric bypass (LRYGB) vs. laparoscopic adjustable gastric banding (LAGB)
The review found moderate quality evidence from 3 RCTs with uncertain risk of bias that LRYGB achieved significantly greater weight loss and BMI reductions up to 5 years after surgery vs. LAGB. Two trials reported longer duration of hospitalization with LRYGB, and one study showed that it was associated with larger number of late major complications vs. LAGB. On the other hand, one study showed that a large proportion of those undergoing LAGB required reoperation for band removal (the authors warned against generalizability of results of this study due to high drop-out rates). The evidence on QoL and co-morbidities was of very low quality. LAGB vs laparoscopic sleeve gastrectomy (LSG) One relatively small study (Himpens et al, 2006) with methodological limitations (reviewed earlier by MTAC) showed that reductions in weight and BMI were statistically significantly higher with LSG vs LABG. The study also showed that symptoms of GERD were resolved in a higher proportion among patients in the LSG group vs. LAGB (no tests of significance were provided). Open or LRYGB vs. LSG
The RCTs included showed no statistically significant differences between the two procedures in the reductions in weight or BMI. Serious adverse events were reported in one trial and were higher in the LRYGB group. There were no statistically significant differences between the 2 procedures in their effect on comorbidities and complications except for one study that showed significantly more improvement in diabetes mellitus with LRYGB. The authors of the review concluded that the outcomes were similar between RYGB and LSG and that both procedures had better outcomes than LAGB. There was no good evidence from RCTs to determine whether any procedure was more effective than another in controlling comorbidities. The studies had relatively short-term follow-up durations, which was insufficient to study the long-term effects of the surgical procedures.
Wang et al, 2013 (Evidence table 2) conducted a meta-analysis of 11 randomised and non-randomized controlled studies (N=1,004 participants) that compared LAGB with LSG. The pooled results suggest that LSG is associated with greater excess with loss (EWL% mean difference -12.55 [95% CI, -15.66, -9.43] at 6 months and -4.97 [95% CI, -7.58, -2.36] at 12 months). LSG was also associated with better improvement in type 2 DM than LAGB (pooled OR of 0.34; 95 % CI 0.16-0.73). The meta-analysis combined the results of a small number of randomized and non-randomized studies with small sample sizes and short-term follow-up durations. The authors concluded that larger RCTs with long-term follow-up are needed to compare the efficacy of LSG, LAGB, and LRYGB.
Dogan and colleagues (2014) compared the safety and effectiveness of LAGB, LRYGB, and LSG in a matched retrospective cohort study involving 735 patients who underwent the procedures in two centers in the Netherlands between 2007 and 2010. The results showed that LRYGB was associated with a significantly higher excess weight loss compared to LSG in the first year after which there was no significant difference in weight loss between the two procedures. After 3 years of follow-up LAGB had a higher complication rate compared to the other two procedures. Revision surgery was needed in 21% of LAGB, and 9% of LSG underwent conversion to RYGB. The authors concluded that LRYGB is a safe and effective treatment in morbidly obese patients with good long-term outcomes. LSG was comparable to LRYGB regarding weight loss and complication rate; and that LAGB was inferior to both LRYGB and LSG. Arterburn, et al (2014) compared the short and long-term outcomes of LRYGB and LAGB in a retrospective cohort study of 7,457 adult patients who underwent laparoscopic bariatric surgery from January 2005 through December 2009 in 10 health care systems (including Kaiser Permanente) in the US. 1,507 underwent LAGB and 5,950 underwent RYGB. The primary outcomes were change in BMI, composite of 30-day rate of major adverse outcomes, subsequent hospitalization, and subsequent intervention. The results indicate that RYGB led to a significantly greater loss in BMI than LAGB (14.8 loss with RYGB vs. 8.0 LAGB, p<0.001). RYGB was associated with a higher rate of short-term complication, and long-term subsequent

Back to Top

hospitalization. LAGB on the other hand was associated with a higher risk of long-term subsequent interventions procedures. The study was large and included a diverse group of patients but was retrospective and not randomized. Data were obtained from records which did not included all required information, and the subsequent interventions and hospitalizations may have been due to causes unrelated to the bariatric procedures. Trastulli et al (2013) conducted a systematic review to evaluate the safety and effectiveness of LSG in terms of weight loss, comorbidity remission, and efficacy for the management of patients with type 2 diabetes mellitus. The review included 15 RCTs, 6 of which compared LSG with LGB and 2 vs. LAGB. Three of these studies were judged by the authors to have good quality and the rest were of fair quality. The authors could not perform a meta-analysis due to the heterogeneity of the studies but performed some cumulative analyses when suitable. The results of these analyses indicate that the complication rate was 12.1% (range 10-32%) with LSG vs. a mean of 20.9% (range 10-26.4%) with LGB. Only two trials compared LSG with LAGB, one reported 0% hospital morbidity for both procedures, and the other (Himpens 2006) a total of 7 (17.5%) complications with LAGB (all were late) vs. 2 (5%) complications with SLG (all were postoperative). The percentage of excess weight loss (%EWL) ranged from 49% to 81% in the LSG group, 62.1% to 94.4% in the LGB group, and 28.7%-48% in the LAGB group) in a follow-up duration ranging from 3 months to 3 years. Type 2 DM remission ranged from 26.5% to 75% with LSG and 42%-93% with LGB. Buchwald and colleagues (2009) performed a systematic review and meta-analysis of 621 experimental and observational studies (N=136,134 participants) on bariatric surgery that were published in English between 1990- 2006, and that reported on the resolution of type 2 diabetes. Nineteen studies with 43 treatment arms and 11,175 patients reported on both weight loss and diabetes resolution separately for diabetic patients (N=4,070). The analysis indicated that overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion/duodenal switch, followed by gastric bypass, and least for banding procedures. Insulin levels declined significantly postoperatively, as did hemoglobin A1C and fasting glucose values. Conclusion: The limited published evidence comparing LAGB to LRYGB or LSG suggest that LAGB is not the most effective surgical procedure for the morbidly obese patients. The literature indicates that LAGB may have shorter operative time, shorter length of hospital stays, and lower rate of early complications; but it is also associated with higher rates of late complications and risk of surgical interventions compared to other bariatric surgery procedures. There is no good published quality evidence to date, to determine the comparative effectiveness of LAGB to LSG or LRYGB on the resolution of co-morbidities and improvement of health-related quality of life.

Articles: The literature search for studies published after the 2006 MTAC review, revealed over 500 publications, many of which were unrelated to the current review. Very few small randomized controlled trials compared the effects of one surgical bariatric procedure versus another. The search identified a recently updated Cochrane review (Colquitt et al, 2014) on surgery for weight loss in adults; a meta-analysis that compared LAGB with LSG (Wang et al, 2013), a multicenter retrospective matched cohort study (Dogan et al, 2014) that compared gastric bypass, LAGB and LSG in morbidly obese patients; three systematic reviews with no meta-analyses of RCTs on bariatric surgeries; a comparative effectiveness study of laparoscopic adjustable gastric banding vs. laparoscopic gastric bypass; as well as several cohort studies with no control or comparison groups that reported on short and long-term outcomes of gastric banding and LSG procedures. The two most recent meta-analyses were selected for critical appraisal.

Colquitt JL, Pickett K, Loveman E, et al. Surgery for weight loss in adults. Cochrane Database Syst Rev. 2014 Aug 8;8:CD003641. DOI: 10.1002/14651858.CD003641.pub 4. See Evidence Table 1

Wang S, Li P, Sun XF, et al. Comparison between laparoscopic sleeve gastrectomy and laparoscopic adjustable gastric banding for morbid obesity: a meta-analysis. Obes Surg. 2013 Jul; 23(7):980-986. See Evidence Table 2

The use of LAGB in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener

BACKGROUND

Obesity Surgery the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system is a sterile, single-use device for use in transoral tissue approximation and ligation in the GI tract. The system consists of an ergonomic, flexible fastener delivery device and sterile polypropylene fastener implants. The device is introduced into the body through the mouth under endoscopic visualization. Once inside the stomach, the stomach wall is suctioned into the tissue port on the StomaphyX™ creating a large plication. Non-resorbable polypropylene fasteners are then deployed across the fold to hold the tissue in place. Typically, 10 to 20 folds are required depending on the patient's anatomy. The pleats created in the stomach will reduce its size, which would potentially lead to early satiety and weight loss. According to the manufacturer, the StomaphyX™ procedure is incisionless, adjustable, and revisable. It is usually performed as an outpatient procedure, and is intended for

Back to Top

individuals who want an alternative to invasive weight loss surgery, or those who have had previous gastric bypass surgery and are regaining weight. The EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system was cleared for marketing by the FDA in February 2007 for use in endoluminal trans-oral tissue approximation and ligation in the GI tract. The InScope™ Tissue Apposition System is a sterile, single patient used disposable suture system for approximating and securing soft tissue within the gastrointestinal tract. It is intended to perform suturing in conjunction with endoscopes having a working channel of 2.8 mm or larger. The system can be used to treat variety of defects endoscopically including ulcers and perforations (FDA Web site). The InScope™ Tissue Apposition System was cleared by the FDA for marketing in January 2007 to be used for the placement of sutures and approximation of soft tissue. GERD According to the Montreal Consensus, gastroesophageal reflux disease (GERD) is defined as a condition which develops when the reflux of stomach contents cause troublesome symptoms and/or complications. GERD is a mechanical disorder that is caused by a defective lower esophageal sphincter, a gastric emptying disorder, or failed esophageal peristalsis. Typical symptoms of GERD include heartburn and regurgitation; however, overtime reflux can cause ulceration, Barrett's esophagus, airway disease, and esophageal cancer. It is estimated that 40% of individuals in the United States suffer from GERD on a monthly basis. Current treatment options for GERD include long-term use of acid suppression medications or surgical intervention. While treatment with acid suppressing medications such as proton pump inhibitors and histamine 2-receptor blockers are effective, they do not treat the underlying mechanical disorder. Additionally, not all patients respond to these therapies (Zagol 2011, Stefanidid 2010). Surgery is another treatment option for patients with GERD. According to the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), surgical therapy should be considered in patients with a diagnosis of reflux who (Stefanidid 2010): Have failed medical management (due to inadequate symptom control, severe regurgitation not controlled with acid suppression, or medication side-effects). Opt for surgery despite medical management (due to quality-of-life considerations, lifelong need for medication intake, expense of the medication, etc.). Have complications of GERD (e.g., Barrett's esophagus, peptic stricture). Have extra-esophageal manifestations (asthma, hoarseness, cough, chest pains, aspiration). There are a variety of surgical procedures used for the treatment of GERD. Currently, there is no consensus on the best procedure for all patients. The choice of procedure is often based on anatomic considerations and expertise; however, the laparoscopic Nissen fundoplication has emerged as one of the most widely used techniques. With fundoplication, the gastric fundus is wrapped around the lower end of the esophagus to reduce gastric reflux. The fundal wrap can be either total (360°) or partial (less than 360°). Studies suggest that approximately 90% of patients who undergo Nissen fundoplication achieve symptom relief. Side effects of this procedure include dysphagia, hyperflatulence, inability to belch, bloating, and postsurgery bowel symptoms (AGA 2008, Stefanidid 2010). Transoral incisionless fundoplication using the EsophyX device (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. This procedure attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. The EsophyX device is inserted transorally, under direct endoscopic visualization, into the stomach and is positioned at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The result is an omega shaped valve 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are less than 2 cm in size through the use of a built-in vacuum invaginator. As this procedure is incisionless and can often be performed on an outpatient basis it is an attractive alternative to conventional surgical procedures (Jafri 2009, Louis 2010). The EsophyX system had been cleared by the FDA for use in transoral tissue approximation, full-thickness plication and ligation in the gastrointestinal tract for the treatment of GERD in patients with symptomatic chronic GERD who require and respond to pharmacological therapy. This device may also be used to narrow the gastroesophageal junction and reduce hiatal hernia ≤2 cm in size in patients with symptomatic chronic GERD. The EsophyX system has not been previously reviewed by the Medical Technology Assessment Committee and is being review based on request from bariatric surgery and a member appeal.

04/09/2008: MTAC REVIEW
EndoGastric Solutions Stomaphy X™ Endoluminal Fastener
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.
Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer's Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Vertical Sleeve Gastrectomy (VSG)

BACKGROUND

Obesity is a rapidly growing health problem in the United States and worldwide. According to data from the National Health and Nutrition Examination Survey (NHANES), over two thirds of the adults in the US are overweight or obese. Overweight is defined as Body Mass Index [BMI] between 25 and 29 kg/m2, and obesity is defined as BMI of 30.0 kg/m2 or higher. Obesity can be further subdivided into class 1: (BMI 30 to less than 35), class 2: (BMI 35 to less than 40), class 3: severe or morbid obesity (BMI of 40 or higher), and class IV: super obese or super morbid (BMI >50 kg/m2). Obesity leads to substantial morbidity, lower social functioning and quality of life, as well as premature mortality. It is associated with development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis (Duval 2006, Ogden 2006, Sturm 2007, Flegal 2012). Diet, behavioral modification, and exercise are the primary recommended treatments for obesity, but were found to have limited success among the morbidly obese. Drug therapy may be indicated for some, but has its side effects, and the majority regain the lost weight over time. Bariatric surgery is considered as an alternative therapy for morbidly obese individuals. Studies showed that bariatric surgery was more effective than behavioral and medical therapy, had long-term control of obesity, and improved comorbidities as type 2 diabetes. There are several surgical techniques for weight loss, but the Roux-en-Y gastric bypass (RYGB) and the adjustable gastric banding (AGB) are the two most commonly performed procedures across the world. However, surgery is a major intervention and may be associated with risk of complications and perioperative mortality. The morbidly obese individuals usually have a higher incidence of co-existing medical problems and are more likely to develop short and long-term complications after bariatric surgery (Karamanakos 2008, Almogy 2004, Fuks 2009). Sleeve gastrectomy (SG), also known as vertical sleeve gastrectomy (VSG), vertical gastrectomy (VG), greater curvature gastrectomy, parietal gastrectomy or vertical gastroplasty, was initially described in the late 1980s, as a first step procedure performed before RYGB or biliopancreatic diversion-duodenal switch in the super obese patients with severe comorbidities. It was intended to achieve a significant weight loss prior to performing a more restrictive and malabsorption operation among those at high surgical or anesthesiologic risk. After a period of initial weight loss, the surgical risk would be reduced, and the second definitive surgery could be performed. More recently, SG have been increasingly used as stand-alone operation for the morbidly obese patients due to its technical simplicity and short-term outcomes in weight loss (Lee 2007, Rubin 2008, Akkary 2008, Mellissas 2008, Keuper 2008, Kehagias 2011). Sleeve gastrectomy is a purely restrictive operation with no malabsorptive effects. It involves removing the fundus and greater curvature portion of the stomach leaving a narrow tubular stomach that is approximately the size and shape of a banana. It preserves the integrity of the pylorus and does not include intestinal bypass as part of the technique. The technique is simple, but some components of the surgery can result in serious complications if not performed correctly (Peterli 2009, Gill 2010, Brethauer 2011). There are several mechanisms contributing to the weight loss with SG; removing 80-90% of the stomach and leaving behind only a sleeve restricts the amount of the food that can be ingested and gives the sensation of fullness with minimal oral intake. Hormonal change represented by the decrease in the ghrelin level due to resection of the fundus may be another factor for the weight loss, as well as the accelerated gastric emptying, and the behavioral modification of the patients. The exact underlying mechanism is still unknown, and the long-term effects of the surgery are still under investigation (Rubin 2008, Akkary 2008, Moy 2008, Karamanakos 2008, Brethauer 2011). Sleeve gastrectomy has many potential advantages. Preservation of gastric function including the pylorus eliminates dumping, and being purely restrictive, SG does not result in malabsorption. Moreover, it can be performed laparoscopically (laparoscopic sleeve gastrectomy or LSG) even in the super-obese patients. SG does not require implantation of any artificial device or adjustments as the laparoscopic adjustable gastric band. It can also be performed in patients with disorders which preclude intestinal bypass e.g. anemia or Crohn’s disease. However, the procedure is irreversible and has potential complications associated with the relatively long staple line such as bleeding and leakage. Leakage is the most concerning complication after SG and may result from the placement of the final staple line across the gastroesophageal junction or distal esophagus resulting in a staple line disruption. It may also result from mid-sleeve stenosis due to stenosis in the lumen or twisting or kinking of the sleeve at the incisura. Other reported complications associated with the sleeve gastrectomy include pulmonary embolism, subphrenic abscess, liver failure, stricture, wound infection, and need for reoperation. On the long-term, sleeve gastrectomy may potentially lead to gastroesophageal reflux disease due to an increase in the gastric pressure associated with the procedure (Moy 2008, Fuks 2009, Brethauer 2011). The First Report form the American College of Surgeons Bariatric Surgery Center Network indicates that obesity is a life-long disease, and thus short-term safety and efficacy of bariatric surgery should not be the deciding factor for selection of the procedure, and long-term follow-up beyond 1 year is needed; more importantly 5 years or longer. The

Back to Top

report also notes that specifically longer-term assessment of the sleeve gastrectomy is critical as the gastric pouch enlargement over time may limit its ultimate effectiveness (Hutter 2011).

04/06/2009: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)
Evidence Conclusion: The evidence consists of two RCTs (Himpens et al 2006, and Karamanakos et al (2008), and several case series. Himpens and colleagues compared laparoscopic sleeve gastrectomy to gastric banding in 80 patients with a median BMI 38 kg/m2 and Karamanakos and colleagues compared it with laparoscopic Roux-en-Y gastric bypass in 32 patients with mean BMI of 46 kg/m2. The longest follow-up duration reported was 3 years in Himpen's study. The two trials were randomized and controlled but had their limitations. The authors did not discuss specific inclusion criteria e.g. the BMI threshold and other characteristics. In addition, there was no standardized technique for performing sleeve gastrectomy, no standardized size or design for the gastric sleeve, and no optimal dilator size to create the lesser curvature conduit. All these variables could affect weight loss and make it difficult to compare sleeve gastrectomy with other established bariatric procedure. Himpen and colleagues found that the weight loss after 1 and 3 years was more significant with sleeve gastrectomy vs. gastric banding. However, the late weight loss after the two procedures was insufficient; it ranged from 1 to 48 kg with sleeve (median 29.5 kg), and 0 to 40 kg with gastric banding (median 17 kg). The number of reported adverse events associated with sleeve gastrectomy was small. However, some events were severe and required re-operations as intraperitoneal bleed, ischemia of the sleeve, anastomosis leak, and insufficient weight loss. Other reported complications of SG included pulmonary embolism, GERD, gastric erosion, gastric pain, vomiting, and others. Karamanakos and colleagues' trial showed no significant difference in the weight loss at 12 months between the two procedures. However, the study was too small, and had insufficient power to detect significant differences between the two study groups. In conclusion, there is insufficient published scientific literature to date to determine the long-term efficacy, safety, and durability of the weight loss associated with sleeve gastrectomy procedure as a stand-alone treatment option for obese patients. There is also insufficient evidence to determine the optimum BMI threshold where SG would be recommended or encouraged.
Articles: The search yielded over 130 articles. Many were reviews and opinion pieces. There were three randomized controlled trials; one compared SG with adjustable gastric banding, another compared it with Roux-en-Y gastric bypass, and the third compared two different techniques for sleeve gastrectomy. There were also a number of case series with different population sizes and follow-up durations. Only four were relatively large with sample sizes over 100, one was conducted in the US and three were conducted overseas. The US series (Lee et al 2007) had the largest sample size, longest follow-up duration, and non-randomized comparison groups.
The two RCTs that compared SG with alternative bariatric surgeries were selected for critical appraisal as well as the Lee et al's case series. The citations for the critically appraised studies are:
Himpens J, Dapri G, Cadiere GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy. Results after 1 and 3 years. Obesity Surgery 2006; 16:1450-1456. See Evidence Table Karamanakos SN, Vagenas K, Kalfarentzos F, et al. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide –YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy. A prospective, double blind study. Ann Surg 2008; 247:401-410. See Evidence Table
Lee CM, Cirangle PT, Jossart GH. Vertical gastrectomy for morbid obesity in 216 patients: Report of two-year results. Surg Endosc 2007; 21:1810-1816. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

2/11/2013: MTAC REVIEW
Vertical Sleeve Gastrectomy (VSG)
Evidence Conclusion: There is some evidence from very few small RCTs, and non-randomized prospective studies that laparoscopic sleeve gastrectomy performed as a stand-alone surgery, leads to short to mid-term significant weight loss, and improvement in comorbidities in obese patients. However, there is insufficient evidence to determine whether the weight loss and resolution of comorbidities will be sustained long-term. There is insufficient evidence to determine the long-term comparative effectiveness and safety of sleeve gastrectomy and Rou-en-Y gastric bypass or adjustable gastric banding for the treatment of obesity and obesity-related comorbidities. There is insufficient evidence to determine the long-term net health outcomes of laparoscopic sleeve gastrectomy. The studies that reported on long-term outcomes were small case series with no comparison or control group. Himpens and colleagues (2010) reported on the results of 6 years follow-up of 53 patients who underwent laparoscopic SG (different population from that in the RCT published by the same group of investigators in 2006). The results showed that after the sixth postoperative year weight gain was observed in 31 cases (75.6%). The mean BMI in this group of patients was 39.9± 5.9 at baseline, 26.6 ± 4.3 at 3 years, and 31.1

Back to Top

± 6.2 at 6 years. New gastroesophageal reflux symptoms were also reported after 6 years; 18% of the patients in the stand-alone SG group reported occasional vomiting, and 23% reported frequent episodes of GERD. In another follow-up of a case series, D'Hondt and colleagues (2012) also reported a trend towards decrease in weight loss by time (median % excess weight loss [EWL] was 78.5% at 12 months, 72% at 24 months, and 54.4% at 72 months). When % EWL above 50% was considered, the total success rate of SG was 92.9% at 1 year, 89.5%, 87%, 85.7%, 64.3% and 54.5% after 2, 3, 4, 5, and 6 years respectively. There is also insufficient evidence to establish criteria for patient selection or an optimum BMI threshold where SG is recommended or encouraged.

Articles: The search for studies published after the 2009 MTAC review revealed one RCT comparing laparoscopic sleeve gastrectomy versus laparoscopic Roux-en-Y gastric bypass in patients with BMI <50 kg/m2, another very small RCT that compared the effects of the two procedures on the glucose metabolism, two non-randomized prospective comparative studies, and one case control study that compared the outcomes of SG to one or more other bariatric surgery. The literature search also revealed one network meta-analysis and two systematic reviews without meta-analyses that evaluated the different procedures for bariatric surgery, as well as a number of prospective and retrospective case series with or without comparison groups.

The two RCTs and two prospective comparative studies were selected for critical appraisal. The network meta-analysis was not selected for further critical appraisal as it compared changes of BMI levels with different bariatric surgeries vs. standard care and included only two earlier studies on SG. The following studies were critically appraised: Peterli R, Wölnerhanssen B, Peters T, et al. Improvement in glucose metabolism after bariatric surgery: comparison of laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy: a prospective randomized trial. Ann Surg. 2009; 50:234-241. See Evidence Table Kehagias I, Karamanakos SN, Argentou M, et al. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the management of patients with BMI<50 kg/m2.Obes Surg. 2011;21:1650-1656. See Evidence Table Leyba JL, Aulestia N, Llopis SN. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the treatment of morbid obesity. A prospective study of 117 patients. Obes Surg 2011; 21:212-216. See Evidence Table Varela JE. Laparoscopic sleeve gastrectomy versus laparoscopic adjustable gastric banding for the treatment severe obesity in high risk patients. JSLS 2011; 15:486-491. See Evidence Table

The use of Vertical Sleeve Gastrectomy for the treatment of obesity does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity

BACKGROUND

Individuals with BMI >60 are considered to be "super obese." Super obesity is associated with an increased risk of multiple health problems including arthritis, breathing problems, cancer, depression, diabetes, heart disease, hypertension, venous disorders and death. In addition, surgical treatment for obesity, such as a Roux-en-Y gastric bypass, is believed to be more dangerous in super obese than less obese patients, particularly for individuals who carry their weight in the belly area. Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that involves the laparoscopic removal of 70-80% of the left side of the stomach. This results in a stomach that is approximately the size and shape of a banana. LSG is technically simpler than other bariatric procedures including gastric bypass surgery, since it does not require re-routing of the intestines. In addition, the procedure does not require implantation of any artificial device as with other obesity treatments such as the Lap-Band. LSG is most commonly used as the first stage in a two-stage procedure. Patients may be able to lose 80 or more pounds after an LSG, reducing their BMI to the point that a Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch can be done more safely. The second operation is generally performed 8-12 months after the LSG. LSG is sometimes performed as a stand-alone procedure, but this application is not yet recognized by the American Society for Bariatric Surgery (ASDS). LSG has not been reviewed previously by MTAC.

04/02/2007: MTAC REVIEW

Laparoscopic Sleeve Gastrectomy as Initial Procedure in a Planned Two-Stage Operation for Patients with Severe Morbid Obesity

Evidence Conclusion: There is insufficient evidence on the safety and efficacy of laparoscopic sleeve gastrectomy for obesity. Only case series were available; there are no randomized controlled trials or cohort studies. The case series were generally small, and the largest series (Cottam et al., 2006) was compromised by a low follow-up rate. Follow-up data 12 months after the stage-one LSG were available for fewer than half of the treated patients. Mean weight loss in 46% of patients with follow-up data was 45± 17%.

Articles: The search yielded 6 case series; all but one included fewer than 50 patients. The only published case series with a sample size of >100 patients was critically appraised for MTAC: Cottam D, Qureshi FG, Mattar G et

Back to Top

al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc 2006; 20: 859-863.

The use of laparoscopic sleeve gastrectomy in the treatment of severe morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Electrical Stimulator for Obesity

BACKGROUND

Gastric electric stimulation is a new technique that has been proposed as a treatment for obesity. It involves the application of a small electrical current to the stomach through leads that are implanted in the muscular layer of the gastric wall. Although the exact mechanism of action is not fully understood, it is thought that electrical stimulation of the stomach wall can induce early satiety and reduce appetite. It may also have an effect on hormones related to satiety and/or appetite (Mizrahi 2012, Stamin 2012, Verdam 2012). Currently, no gastric electric stimulation devices are FDA approved for the treatment of obesity. This technology was previously reviewed by the Medical Technology Assessment Committee (MTAC) in 2001 for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. It did not meet MTAC criteria for this indication. It has not been previously reviewed for the treatment of obesity. It is being reviewed based on a request from Kaiser Permanente Bariatric Surgery.

2/11/2013: MTAC REVIEW

Gastric Electrical Stimulator for Obesity

Evidence Conclusion: A recent RCT that included 190 obese subjects evaluated the effects of gastric electric stimulation on weight loss. All patients underwent implantation with the gastric electric stimulator. Patients were instructed to consume a diet with a 500 kcal per day deficit and were required to attend monthly support group meetings. Patients in the treatment group had their devices activated. The devices for patients in the control group were kept inactive. After 12 months, there was no significant difference in the percent of excess weight lost between the treatment and the control group. The mean percent of excess weight loss was 11.7 in the treatment group and 11.8 in the control group (P=0.71). Adverse events included: endoscopy-detected gastric lumen lead penetration during the 2-lead implantation procedure (N=26), low battery between month 10 and month 12 (N=22), lead dislodgement (N=2), and pocket infection (N=1). There were no deaths or major complications. Medtronic/Transeuronix sponsored the study (Shikora 2009). An earlier study conducted by the same author also found no significant difference in the percent of excess weight loss between treatment (device on) and control (device off) subjects at 6 months; however, due to methodological limitations results from this study should be interpreted with caution (Shikora 2004). Conclusion: Evidence from a RCT suggests that there is no significant difference in the percent of excess weight lost between patients who received treatment with gastric electric stimulation plus a lifestyle intervention and patients who were treatment with lifestyle intervention alone.
Articles: The literature search revealed several small, case-series and two randomized controlled trials (RCTs) that evaluated the safety and efficacy of gastric electric stimulation for the treatment of obesity. The RCTs were selected for review. The following studies were selected for review: Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surg Obes Relat Dis 2009; 5:31-7. See Evidence Table Shikora SA. "What are the yanks doing?" the U.S. experience with implantable gastric stimulation (IGS) for the treatment of obesity - update on the ongoing clinical trials. Obes Surg 2004;14 Suppl 1: S40-8. See Evidence Table

The use of Gastric Electric Stimulation for the Treatment of Obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Bypass for GERD

BACKGROUND

Obesity is a rapidly growing health problem in the United States and worldwide. According to the National Health and Nutrition Examination Survey (NHANES), more than one third of the adults and almost 17% of the youths in the US are obese defined as Body Mass Index [BMI] 30.0 kg/m2 or higher. It is estimated that at least 5% of the total population are morbidly obese (i.e. with BMI >40 kg/m2). Obesity is associated with the development and /or aggravation of many chronic conditions including cardiovascular diseases, hypertension, type 2 diabetes mellitus, sleep apnea, some forms of cancer, depression, and osteoarthritis. Obesity may also be a predisposing factor for gastroesophageal reflux disease (GERD); obese patients are nearly three times as likely to experience GERD symptoms as those with normal BMI. However, researchers have found that the prevalence of GERD, even in the setting of severe obesity is <50%, which suggests that severe obesity itself is not sufficient to cause GERD. The mechanism by which obesity may increase gastroesophageal reflux is not fully understood, but several pathophysiologic mechanisms have been proposed to explain the association between the two conditions. Obese

Back to Top

individuals may experience extrinsic gastric compression by surrounding adipose tissue leading to the increase in intragastric pressure and subsequent relaxation of the lower esophageal sphincter (LES), as well as anatomical disruption of the gastroesophageal junction. The latter may result in the formation of hiatal hernia which was found to be more prevalent in obese individuals than in those with normal weight (Ortega 2004, Nelson 2005, Duval 2006, Ogden 2012, Sturm 2007, Tai 2009, Prachand 2010, Flegal 2012).
The initial treatment of GERD symptoms involves lifestyle and dietary modification, which are often combined with acid inhibiting therapy. These generally alleviate GERD symptoms, but are usually unsuccessful in morbidly obese patients. If conservative measures fail, surgery is often considered as an alternative approach. Laparoscopic Nissen fundoplication has been the standard operation for these cases with medically refractory GERD. However, its use is controversial among obese patients due to conflicting results concerning its long-term effectiveness and sustainability. Fundoplication affects only the LES and lower gastroesophageal junction without addressing weight. Bariatric operations, which are intended primarily to induce weight loss in the morbidly obese, are considered as a potential alternative approach for treating GERD in obese patients. The success of these surgeries depends on the technique used. Restrictive techniques such as laparoscopic adjustable gastric banding and sleeve gastrectomy result in weight reduction by reducing the stomach volume leading to early satiety. However, some patients reported persistence or worsening acid reflux symptoms after these surgeries. Malabsorptive techniques such as jejuno-ileal bypass and biliopancreatic diversion result in weight reduction by functional shortening of the digestive tract and /or by diverting gastric juices. The Roux-en-Y gastric bypass (RYGB), a more technically complex operation, has both restrictive and malabsorptive properties and is described by some as a reliable procedure for treating severe GERD in obese individuals. It does not directly affect the cardio-esophageal competence but may prevent GERD through weight loss and physically altering the anatomy of the gastrointestinal tract and preventing acid reflux into the esophagus (Nelson 2005, El-Serag 2008, Ikramuddin 2008, De Groot 2009, Prachand 2010, Reavis 201).

2/11/2013: MTAC REVIEW
Gastric Bypass for GERD
Evidence Conclusion: There is insufficient published evidence from randomized controlled trials to determine the comparative effectiveness and safety of Roux-en-Y gastric bypass (RYGB) surgery and Nissen fundoplication for the treatment of GERD in obese patients. The methodological quality of the published studies is low due to non-randomization of the patients, small population sizes, differences in definitions of obesity and evaluation of GERD symptoms, lack of objective outcome assessment, as well as other inherent limitations of observational studies. In a non-randomized trial, Braghetto and colleagues (2012) evaluated postoperative results after fundoplication, RYGB, or a combination of the two procedures for the treatment of 139 obese patients with GERD and Barrett's esophagus. The authors did not explain why and how they selected the patients for each operation, and patients were not equally distributed among the different procedures. They noted however, that those with BMI >35 kg/m2 were selected for RYGB. Compared to the other two groups, patients in the RYGB had significantly higher BMI and weight. Patients underwent careful clinical assessment of symptoms and endoscopic/histological studies at baseline, and at 3-5 years after surgery. Manometric studies and 24-intra-esophageal pH studies were performed in all patients at baseline and among 116 (83%) after surgery. Overall the results of the study showed that the reflux symptoms and erosive esophagitis improved after all three surgeries compared to baseline. The improvement observed was significantly higher in the two approaches that included gastric bypass versus fundoplication alone. The gastric bypass surgery alone did not modify the lower esophageal sphincter (LES) pressure but led to the highest reduction in body weight and BMI. In an earlier very small (N=12) study with data obtained from a prospectively maintained database, Patterson and colleagues (2003) also showed that laparoscopic Roux-en-Y gastric bypass and laparoscopic Nissen Fundoplication were both effective in treating heartburn symptoms and acid reflux in obese patients. The LES resting pressure increased significantly after the fundoplication but not after the RYGB surgeries. Results from a number of other case series show that RYGB resulted in weight loss, improvement of GERD symptoms, regression of esophagitis, and reduction of number of antireflux medications used in obese patients with GERD. The studies did not evaluate the effect of lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term benefits of gastric bypass in these obese patients with GERD.
Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients. There was one non-randomized prospective study that compared outcomes of three different laparoscopic procedures for the treatment of obese patients with GERD and Barrette's esophagus, a very small study that compared bypass surgery to fundoplication, and another small study that compared vertical banded gastroplasty vs. Roux-en-Y gastric bypass in patients with GERD and morbid obesity. Other published studies on bypass surgery for GERD were all case series with population sizes ranging from less than ten to just over 200 patients. The study that included fundoplication as a comparative surgery as well as 4 relatively large and/or more recent case series

Back to Top

were selected for critical appraisal. Braghetto I, Korn O, Csendes A, et al. Laparoscopic treatment of obese patients with gastroesophageal reflux disease and Barrett's esophagus: a prospective study. Obes Surg 2012; 22:764-772. See Evidence Table Frezza EE, Ikramuddin S, Gourash W, et al. Symptomatic improvement in gastroesophageal reflux disease (GERD) following laparoscopic Roux-en-Y gastric bypass. Surg Endosc 2002; 16:1027-1031. See Evidence Table Nelson LG, Gonzalez R, Haines K, et al. Amelioration of gastroesophageal reflux symptoms following Roux-en-Y gastric bypass for clinically significant obesity. Am Surg 2005; 71:950-953. See Evidence Table Ortega J, Escudero MD, Mora F, yet al. Outcome of esophageal function and 24-houir esophageal pH monitoring after vertical banded gastroplasty and Roux-en-Y gastric bypass. Obes Surg 2004; 14:1086-1094. See Evidence Table Tai CM, Lee YC, Wu MS, et al. The effect of Roux-en-Y gastric bypass on gastroesophageal reflux disease in morbidly obese Chinese patients. Obes Surg 2009; 19:565-570. See Evidence Table

The use of gastric bypass surgery for treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW
Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
Evidence Conclusion: The literature search did not identify any published randomized controlled trials to date, that compared gastric bypass surgery to Nissen fundoplication, or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients. The studies published after the last MTAC reviews were all case series, and retrospective analyses of registered data in a database with no control or comparison groups. Due to their inherent biases, particularly selection bias; and lack of control groups, case series represent a level IV of evidence in the hierarchy of evidence. Case series cannot prove a cause and effect relationship but may only generate hypotheses for future research. Overall, the results the published case series suggest that gastric bypass leads to significant weight loss in obese patients, and is associated with improvement in GERD symptoms, and/or reduction of number of anti-reflux medications used by obese patients with severe GERD. These series generally relied on subjective outcomes, did not evaluate the effect of confounding factors, lifestyle and dietary habits of the patients after the surgery, and do not provide sufficient evidence to determine the long-term durability of the observed outcomes. Madalosso and colleagues, 2016 (Evidence table 1), recently published 3-years results of a prospective case series to assess the impact of Roux-en-Y gastric bypass (RYGB) on gastroesophageal reflux disease (GERD) in morbidly obese patients. The study did not compare gastric bypass to Nissen fundoplication, sham procedure, or any other surgical or medical therapy. In addition, the 39 months follow-up data were available for only 53 of the 94 (56%) patients recruited. The authors compared the postoperative outcomes to the baseline values and had the advantage of including objective measures. The overall results of the analysis suggest that RYGB surgery was associated with a significant weight loss, reduction in GERD symptoms, and decrease in esophageal acid exposure. These results have to interpreted with caution due to the nature of the study, potential selection bias, confounding, lack of a control group, and high dropout rate. Dupree, et al (2014) retrospectively analyzed data from the Bariatric Outcomes Longitudinal Database (BOLD)*, focusing on patients with pre-existing GERD. 33,876 patients underwent LRYGB, and 4,832 underwent LSG from 2007-2010. The results of the analysis showed that LRYGB was associated with complete resolution of GERD symptoms in 62.8% of the patients (symptoms were stable in 17.6% and worse in 2.2 %). For those who underwent LSG, 84.1% continued to have GERD symptoms, and 9.0% reported worsening of symptoms. Pallati and colleagues (2014) also used the same database (BOLD) to compare the efficacy of various bariatric procedures on the improvement of GERD symptoms, 36,938 patients out of 116,136 registered in the database from 2007–2009), had evidence of GERD before undergoing a bariatric surgery. After excluding patients undergoing concomitant hernia repair or fundoplication, 22,870 patients with 6 months follow-up were included in the analysis. 14,078 of these patients underwent RYGB, 8,207 LAGB, and 585 underwent LSG procedures. The analysis showed that GERD symptom score was significantly improved with the three surgeries, with the highest improvement reported with RYGB (56.5%) followed by AGB (46%) and SG (41%). Worsening of symptoms occurred in 2% of patients undergoing RYGB (4.6% with SG, and 1.2% with LAGB). The remainder of patients had no change in their GERD status. The study did not show any objective measure of GERD improvement. The results of Dupree et al and Pallati et al's analyses of data obtained from the Bariatric Outcomes Longitudinal Database should be interpreted cautiously. These were retrospective analyses influenced by the quality of the database and the extent of variables/patient characteristics it includes, such as alcohol consumption, cigarette smoking and other factors that have a potential impact on GERD. In addition, according to the authors the documented data on GERD was only based on the use of acid suppression medication with no objective data to confirm the gastroesophageal reflux e.g. 24-hour pH monitoring. Varban and colleagues (2015), retrospectively analyzed data from the Michigan Bariatric Surgery Collaborative (MBSC)

Back to Top

registry to assess the use of acid-reducing medication (ARM) at one year after bariatric surgery in morbidly obese patients. Approximately 50% of the patients were reported to have GERD at baseline. 51% of those who underwent RYGB had GERD, and 40.6% of them were using an ARM at baseline, compared to 29.2% at 1-year after surgery. It was also reported that 19.2% of the patients not using ARM at baseline started using one after RYGB.

Conclusion:

- Due to the nature of the published studies, lack of comparison groups and objective outcome assessment, it is hard to determine whether the observed improvement of GERD symptoms were due to a direct effect of gastric bypass and reduction of abdominal pressure, or due to a placebo effect, masking of GERD by the change in diet after surgery, or undervaluation of the disease due to satisfaction with weight loss.
- There is insufficient published evidence to determine the comparative effectiveness and safety of gastric bypass surgery to Nissen fundoplication or other standard medical or endoscopic procedures used for the treatment of severe GERD in morbidly obese patients.
- There is insufficient published evidence to determine the long-term safety and efficacy of gastric bypass surgery in reducing GERD symptoms morbidly obese patients.
- There is insufficient published evidence to determine the effect gastric bypass surgery on the progression or regression of Barrett's esophagus in morbidly obese patients with GERD

Articles: The literature search did not reveal any randomized controlled trial that compared gastric bypass surgery to other standard medical or surgical treatment for severe GERD in obese patients with or without Barrett's esophagus. The empirical studies on gastric bypass surgery for patients with GERD were all observational studies that assessed the impact of RGYB on GERD in morbidly obese patients that underwent the surgery either as an initial operation or after a failed fundoplication surgery. The search also identified an analysis using a prospective database (Bariatric Outcomes Longitudinal Database) for patients who underwent bariatric surgery by a participant in the American Society of Metabolic and Bariatric surgery center of Excellence program; a recent meta-analysis that compared RYGB versus laparoscopic sleeve gastrectomy to treat morbid obesity-related comorbidities including GERD; and a number case series on the role of RYGB for failed antireflux surgery. The use of bypass surgery for a failed fundoplication as well as the comparison of different bariatric surgeries were outside the scope of the current review. The largest observational study with the longer follow-up duration was selected for critical appraisal. Madalosso CA, Gurski RR, Callegari-Jacques SM, et al. The Impact of Gastric Bypass Gastroesophageal Reflux Disease in Morbidly Obese Patients. Ann Surg. 2016 Jan; 263(1):110-116. See Evidence Table 1.

The use of Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intragastric balloons for the treatment of obesity or morbid obesity

BACKGROUND

Obesity is a chronic disease that is strongly associated with numerous conditions including cardiovascular disease (heart failure, stroke, hypertension), diabetes mellitus, sleep apnea, cancers, osteoarthritis and disability [1]. The prevalence of obesity has been increasing and it is projected that, by the year of 2030, 20% of the world's adult population will be obese [1]. Obesity can be categorized based on body mass index (BMI). A body mass index (BMI) between 25 kg/m2 and 29 kg/m2 is considered overweight while obesity is defined as BMI greater than 30 kg/m2 [1]. Moderate and morbid obesity are defined as BMI between 30 to 39.9 kg/m2 and BMI >40 kg/m2 respectively [2]. The cause of obesity is multifactorial [3]. First, the chronic imbalance between energy intake and energy expense leads to obesity. Second, interactions between genetic, behaviors, social and environmental factors play a crucial role in the pathogenesis of obesity[3].

Management of obesity includes conservative therapy such as diet modification, physical exercise, psychosocial interventions, pharmacotherapy such as orlistat and bariatric surgery[4]. A study investigating the effect of diet on weight loss [5] showed that hypocaloric diet and exercise alone led to a non-sustainable weight reduction (5%). Similarly, pharmacotherapy results in additional benefits. Bariatric surgery seems to be an alternative method for long term management [6] but can be associated with adverse events. Despite the benefits of these approaches, some patients might not be able to lose weight or sustain weight loss.

For patients who have failed weight reduction with diet and exercise alone, intragastric balloon (IGB) may be an alternative. Performed for the first time in 1980s [7], IGB is a minimally invasive procedure that diminishes the capacity of the stomach resulting in premature satiation and prolonged satiety and subsequently induces weight loss; Other mechanism resides in the regulation of hormone-mediated signal transduction [4, 8]. IGB insertion is a restrictive procedure in which a spherical, saline-filled balloon is endoscopically positioned in the stomach under

Back to Top

mild sedation and left inflated for six months [9]. One or two balloons can be inserted and different fill volumes (400-700ml) and fill media have been described. These include air, fluid, combination of air and fluid. Some balloons can be swallowed and do not need to be endoscopically inserted.

Early designs were removed from the market due to severe complication such as migration resulting in intestinal obstruction but the introduction of the dual-balloon from ReShape Medical (San Clemente, CA) is believed to reduce the risks of obstruction and perforation. The ReShape Integrated Dual Balloon System (Reshape Dual Balloon) and ORBERA Intragastric Balloon System were approved by the Food and Drug Administration (FDA) in 2015.

03/21/2016: MTAC REVIEW
Intragastric balloons for the treatment of obesity or morbid obesity
Evidence Conclusion: Zheng et al., 2015 [4]: Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis (Evidence table 1) This meta-analysis aimed to confirm the safety and efficacy of intragastric balloon (IGB). The outcomes measured were weight loss, BMI, percent excess weight loss and safety. 11 RCTs were included after searching MEDLINE, EMBASE, CENTRAL plus other sources through December 2014. The quality of included studies was assessed, and weighted mean differences were determined from the analysis. Modest efficacy for intragastric balloon as a conjunction therapy to conservative therapy was achieved in six months group (SMG). The incidences of the adverse events were higher in the intervention group (IGB plus conservative therapy). The authors concluded that short-term efficacy for 6 months treatment of intragastric balloon in association with conservative therapy is clinically significant. However, the findings should be interpreted with cautious due to several limitations. Ponce et al., 2015 [10] The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity (Evidence table 2): This is a RCT, multicenter, sham controlled which aimed to investigate the safety and effectiveness of a dual balloon system plus diet and exercise in the treatment of obesity compared to diet and exercise alone. The study measured the percent excess weight loss (%EWL), the proportion of DUO patients achieving at Least a 25% EWL as primary outcomes. 326 patients were randomized to dual gastric balloon plus diet and exercise (Duo) or Sham endoscopy plus diet and exercise (Diet) and followed up for 48 weeks. The %EWL was greater in Duo arm compared to Diet arm. The response rate among DUO was 48.8 in the intention to Treat ($p<0.0001$). Improvements in comorbid conditions were observed. The authors concluded that the reshape duo balloon had an excellent safety profile and was significantly more effective than diet and exercise. However, the results should be interpreted with cautious due to many limitations. Other small sample size RCTs [11-14] with short follow-up duration and meta-analysis [15], suggested that IGB may be safe and effective on the short term. Conclusion: The results indicate that intragastric balloon in combination with diet and exercise may have a short-term effect in reducing weight in obese patients. The findings also indicate that intragastric balloon may be temporarily more effective than diet and exercise. However, the follow-up duration was insufficient to determine the safety and durability of the outcomes. There is insufficient data to determine whether intragastric balloon is safer and more effective than standard weight loss surgeries or pharmacotherapy. Intragastric balloon was reviewed by Interregional New Technology Committee (INTC) which concluded that “based on low-quality evidence of benefit as compared to conventional weight-loss management and lack of long-term evidence regarding safety and efficacy, it could not be concluded whether or not the benefit of intragastric balloon outweigh the harms at this time”.
Articles: The search identified a meta-analysis [4] and RCTs comparing IGB to diet and exercise and or sham balloon. However, the search did not identify RCTs making direct comparison between IGB and standard weight loss surgeries or pharmacotherapy. The following studies were selected for critical appraisal: Zheng, Y., M. Wang, et al. (2015). "Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis." Journal of translational medicine 13(1): 1-9. See Evidence Table 1. Ponce, J., G. Woodman, et al. (2015). "The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity." Surgery for Obesity and Related Diseases 11(4): 874-881. See Evidence Table 2.

The use of Intragastric balloons for the treatment of obesity or morbid obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

01/09/2023: MTAC REVIEW
Bariatric surgery in patients with obesity related medical problems in patients with BMI 35-40
Evidence Conclusion:

- Dyslipidemia: Low to moderate quality evidence suggest that bariatric surgery may improve dyslipidemia in patients with BMI 35-40 kg/m2.

Back to Top

- Gastroesophageal reflux disease (GERD): Low to moderate evidence suggest that RYGB and SG may be effective in treating GERD in patients with obesity (BMI range 27- ≥60 kg/m2), with RYGB showing a better effect.
- Fatty liver or Nonalcoholic fatty liver disease (NAFLD): There is insufficient evidence to draw a firm conclusion for or against the efficacy of bariatric surgery in obese patients (BMI 35-40 kg/m2) with NAFLD.

Articles: PubMed was searched from 2017 to November 2022. Search terms include bariatric surgery AND obesity AND (GERD OR gastroesophageal reflux disease OR hyperlipidemia OR dyslipidemia OR fatty liver OR comorbidities). Filters: study design (systematic review, meta-analysis, RCTs). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications.PubMed search was also performed for nonalcoholic fatty liver disease from 2010 to 2022. Search terms include non-alcoholic fatty liver disease and bariatric surgery. The search was filtered by systematic review & meta-analysis. Thirty-four articles were yielded, and 10 were selected based on title screening.

01/09/2023: MTAC REVIEW
Bariatric Surgery in patients with BMI 30-35 kg/m2 with Type 2 Diabetes mellitus
Evidence Conclusion:
Moderate quality evidence from RCTs suggest that bariatric surgeries including Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding may be safe and effective in adult patients with BMI 30-35 kg/m2 and type 2 diabetes mellitus over the short and mid-term.
Articles: PubMed was searched through 2017 to November 2022. Search terms include (metabolic surgery OR bariatric surgery OR gastric bypass OR Roux-en-Y OR sleeve gastrectomy OR gastric sleeve OR adjustable gastric banding OR adjustable gastric band) AND (obesity OR BMI <35 OR BMI 30 - 35 OR class I obesity OR nonsevere obesity OR nonmorbidly obese OR nonmorbid obesity) AND (type 2 diabetes mellitus OR T2DM OR T2D). Other search terms include obesity AND diabetes AND bariatric surgery. Filters include publication year (2018 to November 2022), age (19 years and above), and study design (systematic review, meta-analysis, RCTs). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications.

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Intragastric Balloons for Treatment of Obesity. Lansdale, PA: Hayes, Inc; 3/2018

Applicable Codes

Adjustable Gastric Banding--

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® /HCPC Codes	Description
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only

Back to Top

43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Biliopancreatic Diversion with Duodenal Switch (Scorpinaro Procedure)—
Single Anastomosis Duodeno-Ileal Bypass with sleeve gastrectomy (SADI-S)
reserved for patients with BMI >50

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)

Vertical Banded Gastroplasty (VBG)--

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty

Endoscopic Sleeve Gastroplasty--

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

Vertical Sleeve Gastrectomy (VSG)--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty

Lap Band Port Revision--

Medicare – Considered Not Medically Necessary

Back to Top

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

Roux-en-Y Gastric Bypass (RYGB)

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

Transoral Outlet Reduction (TORe)—

Medicare – Considered Not Medically Necessary
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

Gastric Electrical Stimulation (GES) for Obesity--

Considered Not Medically Necessary:

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation,

Back to Top

	cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Intragastric Balloon--

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)

Gastric Bypass for GERD--

Considered Not Medically Necessary:

CPT® Codes	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

EndoGastric Solutions StomaphyX™ Endoluminal Fastener—

Considered Not Medically Necessary:

CPT® Codes	Description
No Specific Codes – *often submitted as 43289 or 43499*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/01/1999	07/06/2010[MDCRPC], 05/03/2011[MDCRPC], 03/06/2012[MDCRPC], 01/08/2013[MDCRPC], 03/5/2013[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC] 01/06/2015 [MPC], 05/05/2015 [MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC]	03/16/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Back to Top

Revision History	Description
05/05/2015	KP-516: Medical policy has been revised to highlight treatment for bariatric complications and repeat bariatric surgical procedure criteria.
09/01/2015	Revised Laparoscopic Sleeve Gastrectomy L34166 and L34157
04/05/2016	Added MTAC Review for Intragastric Balloons
06/20/2016	Added MTAC Review for Roux-en-Y Gastric Bypass (RYGB) Surgery for Obese Patients with Severe Gastroesophageal Reflux Disease (GERD)
09/28/2017	Added Gastric Electrical Stimulation codes
11/02/2017	PEBB criteria updated
02/14/2017	Added non-covered procedures from CWQI
03/27/2018	Added LCA A53028
04/17/2018	Added Hayes review – Intragastric Balloons for Treatment of Obesity
10/06/2020	MPC approved the MCG 24th ed. guideline for Intragastric Balloon Device: A-0970
06/01/2021	MPC approved the updated recommendations to the current hybrid criteria for Bariatric Surgery to lower the qualifying age from 20 to 18 years or older. Requires 60-day notice, effective date 11/01/2021.
08/19/2021	Noted that PEBB is adopting Kaiser Permanente Commercial clinical review criteria for bariatric surgery procedures effective 01/01/2022.
09/07/2021	Removed reference to retired Noridian LCD L34157 as its content was added to LCA A53028 in 2016.
10/05/2021	MPC approved the removal of Vertical Banded Gastroplasty (VBG) from covered procedures. Requires 60-day notice, effective date 03/01/2022.
01/07/2022	Removed PEBB criteria from the commercial plan. PEBB will be using KP criteria effective 01/01/2022.
10/04/2022	MPC approved to adopt Adolescent indications for Bariatric Surgery. 60-day notice required. MPC approved coverage for Biliopancreatic Diversion with Duodenal Switch and Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S). 60-day notice required.
03/16/2023	Added MTAC review for Bariatric Surgery in patients with BMI 30-35 kg/m2 with Type 2 Diabetes mellitus and Bariatric surgery in patients with obesity related medical problems in patients with BMI 35-40.
8/01/2023	MPC approved to adopt added Coronary Artery Disease (CAD) indication for bariatric surgery. Requires 60-day notice, effective date 01/01/2024.
10/20/2023	Updated coding with new codes C9784 and C9785 (effective 7/1/2023)
12/04/2023	Effective 12/05/2023 Lumbar Spinal Fusion will require Level of Care review when procedure is performed as an elective procedure

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Basivertebral Nerve Ablation

- Intracept® Intraosseous Nerve Ablation System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Intraosseous Basivertebral Nerve Ablation (L39644)
Local Coverage Article (LCA)	Billing and Coding: Intraosseous Basivertebral Nerve Ablation (A59468)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Basivertebral nerve ablation (BVN), such as with the Intracept System (Relievant Medsystems Inc.), is intended to relieve chronic low back pain (CLBP) thought to be due to vertebrogenic causes by inhibiting the transmission of pain signals (Freburger et al., 2009).

The Intracept Procedure is a treatment option for patients who have not had adequate pain relief with conservative therapy. The minimally invasive procedure can be performed in the outpatient setting. Treatment-refractory CLBP and magnetic resonance imaging–detected Modic 1 or Modic 2 changes are listed as key indications by the manufacturer and were inclusion criteria in the identified studies. In the reviewed clinical studies, patients with symptomatic spinal stenosis, radiculopathy, disk protrusion, or spondylolisthesis were excluded.

The Intracept System consists of the Intracept Introducer Cannula, the Intracept Curved Cannula, the Intracept Radiofrequency Probe, and the Intracept Radiofrequency Generator. According to Relievant Medsystems Inc., the cannula is inserted via minimally invasive procedure under fluoroscopic guidance through the pedicle using a transpedicular approach. The Curved Cannula is then passed through the Introducer to create a channel to the trunk of the BVN. Next, the Radiofrequency Probe is inserted via the Curved Cannula and placed at the BVN.

Back to Top

Bipolar radiofrequency (RF) energy is provided using the Radiofrequency Generator to accomplish the thermal ablation of the BVN. The RF destruction of the BVN is intended to stop the transmission of pain.

Insights

Clinical studies consistently indicate benefits in patient-oriented outcomes after the Intracept System was used to treat chronic low back pain (CLBP) believed to be due to vertebrogenic origin; however, a randomized controlled trial (RCT) did not convincingly indicate advantages over sham. A second RCT did find short-term treatment advantages over continued standard care; however, given the placebo response observed in the sham-controlled RCT, the findings of this open-label study should be interpreted carefully. Although 1 spine specialty society noted Intracept may be considered, no other guidance documents were identified and payer policies are generally unfavorable, possibly due to the lack of comparative research convincingly demonstrating advantages over treatment alternatives.

Reference

Hayes. Hayes Evolving Evidence Review. Intracept Intraosseous Nerve Ablation System (Relievant Medsystems) for Treatment of Adults with Low Back Pain. Dallas, TX: Hayes; July 9, 2020. Retrieved April 20, 2021 from https://evidence.hayesinc.com/report/eer.intraceptlbp4481.

Medical Technology Assessment Committee (MTAC)

Intraosseous Radiofrequency Basivertebral Nerve Ablation for the Treatment of Adults with Chronic Vertebrogenic Low Back Pain

06/24/2022: INTC Review

Evidence Conclusion: Low-certainty evidence from two RCTs, two open-label extensions, two prospective case series, and one post-hoc RCT analysis (Total N = 429 patients; 330 patients received Intracept and had data analyzed) demonstrate that the Intracept procedure improved function, pain, and QOL in adults with CLBP (≥6 months) with some patients showing durable and sustained improvements up to 5 years post-procedure. However, these improvements were not significantly different (either statistically or clinically) when compared to sham procedure at 3 months and up to 12 months. Statistically and clinically important differences in these outcomes favoring Intracept were found in one open-label RCT comparing Intracept June 24, 2022 | SCPMG Evidence-Based Medicine Services Page 3 of 35 KAISER PERMANENTE CONFIDENTIAL INFORMATION – internal use only, do not distribute outside of KP to standard care up to 3 months but given the context of no significant differences between Intracept and sham procedure at this timepoint, the results of this RCT must be interpreted with caution. Intracept appears to be relatively safe as no serious adverse events occurred during these clinical trials, but adverse events were not uncommon, with complication rates ranging from 2.7% to 25% among Intracepttreated patients across studies. Complications rates were similar between treatment and control arms in comparative RCTs. One of the most common AEs was postoperative leg pain due to a pedicle breach, often at levels L5 or S1. As with all interventional procedures, the experience of the operator and accurate patient selection will correlate with the safety of the procedure. More rigorous RCTs not funded and/or affiliated with the manufacturer and with longer-term comparative data are needed to validate any findings of benefit of the Intracept procedure over sham or standard care. Additionally, trials evaluating the comparative effectiveness of Intracept compared to other minimally invasive procedures are needed to determine its role among several available interventions for CLBP.

Articles: The Medical Technology Assessment Team (MTAT) reviewed the evidence on intraosseous radiofrequency basivertebral nerve ablation (i.e., Intracept®) for the treatment of chronic low back pain on June 24, 2022. Based on 2 RCTs of two different comparisons, 2 follow-up open-label extensions of these RCTs, 2 prospective case series, and 1 post-hoc RCT analysis, conclusions are limited by the overall low quantity and quality of the body of evidence.

Applicable Codes

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Considered Not Medically Necessary

CPT® or HCPC Codes	Description

Back to Top

64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/21/2021	05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	01/16/2024

[MPC] Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved adoption of non-coverage policy for Basivertebral nerve ablation. Requires 60-day notice, effective October 1, 2021.
01/16/2024	Updated Medicare LCD and Billing coding article for NEW coverage policies for Basivertebral Nerve Ablation Effective 1/28/2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Eating Disorders – Anorexia Nervosa

Criteria

Inpatient Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa, Adult: Inpatient Care (B-001-IP) and Anorexia Nervosa, Child or Adolescent: Inpatient Care (B-016-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Partial Hospitalization Program (B-KP-001-PHP v2 eff 12.01.2021) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Intensive Outpatient Program (B-KP-001-IOP v2 eff 12.01.2021) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Outpatient Care (B-KP-001-AOP v2 eff 12.01.2021) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Anorexia Nervosa: Residential Care (B-KP-001-RES v2 eff 12.01.2021) for medical necessity determinations.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional

Back to Top

impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."
Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
6/30/2010	7/6/2010 MDCRPC, 5/3/2011 MDCRPC, 3/6/2012MDCRPC,1/08/2013MDCRPC, 11/05/2013MPC, 2/04/2014MPC, 12/02/2014MPC, 10/06/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC , 06/07/2022MPC , 06/06/2023MPC	07/06/2021

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/01/2015	Revised criteria to reflect GHC hybrid policy
03/31/2016	Removed 60-day notice
02/07/2017	MPC approved to adopt MCG 20th Ed. guidelines for Inpatient & Acute Outpatient Care; MPC approved to adopt hybrid (GHC/MCG) guidelines for Residential, Partial Hospital and Intensive Outpatient
09/05/2017	MPC approved to adopt KP-MCG hybrid criteria for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Anorexia Nervosa, Adult: Inpatient Care (B-001-IP) and Anorexia Nervosa, Child or Adolescent: Inpatient Care (B-016-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Anorexia Nervosa: Partial Hospitalization Program (B-KP-001-PHP), Anorexia Nervosa: Intensive Outpatient Program (B-KP-001-IOP), Anorexia Nervosa: Outpatient Care (B-KP-001-AOP) and Anorexia Nervosa: Residential Care (B-KP-001-RES). Requires 60-day notice, effective date 12/01/2021.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Eating Disorder - Binge, Bulimia and Specified Eating Disorders

Criteria

Inpatient Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Adult: Inpatient Care (B-005-IP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Child or Adolescent: Inpatient Care (B-021-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Partial Hospital Program (B-KP-005-PHP) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Intensive Outpatient Program (B-KP-005-IOP) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Outpatient Care (B-KP-005-AOP) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Residential Care (B-KP-005-RES) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

Definitions
Binge Eating
According to DSM 5:
An episode of binge eating is characterized by both of the following

Back to Top

1. Eating, in a discrete period of time (e.g. usually less than a 2-hour period), an amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances.
2. A sense of lack of control over eating during the episode (e.g. a feeling that one cannot stop eating or control what or how much one is eating).

The binge-eating episodes are associated with 3 (or more) of the following:

1. Eating much more rapidly than normal
2. Eating until feeling uncomfortably full
3. Eating large amounts of food when not feeling physically hungry
4. Eating alone because of feeling embarrassed by how much one is eating.
5. Feeling disgusted with oneself, depressed, or very guilty afterward.
   There is marked distress regarding binge eating.

The binging occurs, on average, at least once a week for 3 months, and is not associated with recurrent use of inappropriate compensatory behavior and does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

Overeating

According to DSM 5 - In Overeating, there is a consumption of excess food, with no engagement in inappropriate compensatory behavior and no excessive concern with body shape and weight characteristics that are seen in bulimia nervosa.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."
Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	07/06/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

Back to Top

MPC Medical Policy Committee

Revision History	Description
03/31/2016	Removed 60 day hold notice
02/07/2017	MPC approved to adopt hybrid (MCG/GHC) guidelines for all levels of care
12/05/2017	MPC approved to adopt hybrid (MCG/KP) guidelines for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Adult: Inpatient Care (B-005-IP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders, Child or Adolescent: Inpatient Care (B-021-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Partial Hospital Program (B-KP-005-PHP), Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Intensive Outpatient Program (B-KP-005-IOP), Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Outpatient Care (B-KP-005-AOP) and Bulimia Nervosa, Binge-Eating Disorder, and Other Specified Feeding or Eating Disorders: Residential Care (B-KP-005-RES). Requires 60-day notice, effective date 12/01/2021.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Eating Disorder – Unspecified

Criteria

Inpatient Behavioral Health Level of Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders: Inpatient Behavioral Health Level of Care, Adult (B-904-IP) and Eating Disorders: Inpatient Behavioral Health Level of Care, Child or Adolescent (B-913-IP) for medical necessity determinations.

Partial Hospitalization
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Partial Hospital Behavioral Health Level of Care, Adult (B-KP-904-PHP) and Eating Disorders, Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-913-PHP) for medical necessity determinations.

Intensive Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-904-IOP) and Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-913-IOP) for medical necessity determinations.

Acute Outpatient
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Outpatient Behavioral Health Level of Care, Adult (B-KP-904-AOP) and Eating Disorders, Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-913-AOP) for medical necessity determinations.

Residential Care
Kaiser Permanente has elected to use the MCG* Care Guideline: Eating Disorders, Residential Behavioral Health Level of Care, Adult (B-KP-904-RES) and Eating Disorders, Residential Behavioral Health Level of Care, Child or Adolescent (B-KP-913-RES) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

Definitions
Binge Eating
According to DSM 5:
An episode of binge eating is characterized by both of the following:

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

1. Eating, in a discrete period of time (e.g. usually less than a 2-hour period), an amount of food that is definitely larger than what most people would eat in a similar period of time under similar circumstances.
2. A sense of lack of control over-eating during the episode (e.g. a feeling that one cannot stop eating or control what or how much one is eating).

The binge-eating episodes are associated with 3 (or more) of the following:

1. Eating much more rapidly than normal
2. Eating until feeling uncomfortably full
3. Eating large amounts of food when not feeling physically hungry
4. Eating alone because of feeling embarrassed by how much one is eating.
5. Feeling disgusted with oneself, depressed, or very guilty afterward.

There is marked distress regarding binge eating.
The binging occurs, on average, at least once a week for 3 months, and is not associated with recurrent use of inappropriate compensatory behavior and does not occur exclusively during the course of bulimia nervosa or anorexia nervosa.

Overeating
According to DSM 5 - In Overeating, there is a consumption of excess food, with no engagement in inappropriate compensatory behavior and no excessive concern with body shape and weight characteristics that are seen in bulimia nervosa.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG (formerly Milliman) Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Care Guidelines are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."
Inpatient anorexia nervosa services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient anorexia nervosa treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
6/30/2010	7/6/2010 MDCRPC, 5/3/2011 MDCRPC, 3/6/2012MDCRPC,1/08/2013MDCRPC , 11/05/2013MPC , 2/04/2014MPC, 12/02/2014MPC, 10/06/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC, 06/07/2022MPC ,	07/06/2021

Back to Top

	06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/02/2015	Changed documentation of GHC hybrid to MCG
12/01/2015	Revised criteria to reflect approval of MCG 19th Ed.
02/07/2017	MPC approved to adopt hybrid (MCG/GHC) guidelines for all levels of care
12/05/2017	MPC approved to adopt hybrid (MCG/KP) guidelines for all levels of care
06/02/2020	Removed diagnosis codes
07/06/2021	MPC approved to adopt MCG 25th Edition for Eating Disorders: Inpatient Behavioral Health Level of Care, Adult (B-904-IP) and Eating Disorders: Inpatient Behavioral Health Level of Care, Child or Adolescent (B-913-IP). MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Eating Disorders, Partial Hospital Behavioral Health Level of Care, Adult (B-KP-904-PHP) and Eating Disorders, Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-913-PHP), Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-904-IOP) and Eating Disorders, Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-913-IOP), Eating Disorders, Outpatient Behavioral Health Level of Care, Adult (B-KP-904-AOP) and Eating Disorders, Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-913-AOP) and Eating Disorders, Residential Behavioral Health Level of Care, Adult (B-KP-904-RES) and Eating Disorders, Residential Behavioral Health Level of Care, Child or Adolescent (B-KP-913-RES). Requires 60-day notice, effective date 12/01/2021.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Mental Health – Inpatient Services

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Inpatient Behavioral Health Level of Care, Adult

Kaiser Permanente has elected to use the MCG* Inpatient Behavioral Health Level of Care, Adult (B-KP-901-IP) for medical necessity determinations.

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Behavioral Health Department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health Unit for more information regarding the case under review.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2006, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Inpatient Psychiatric services are provided or authorized with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively in a less restrictive and disruptive level of care. Under specific circumstances (e.g. initiation of ECT), the inpatient level of care may be required for safe administration of certain treatments.

Inpatient psychiatric treatment is utilized when it is the most effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Guidelines for inpatient mental health treatment. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Date Created	Date Reviewed	Date Last Revised
08/01/2006	05/07/2013[MPC] ,03/04/2014 [MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MPC] Medical Policy Committee

Revision History	Description
01/06/2016	MPC approved to adopt 19th Edition MCG guidelines
09/06/2016	MPC approved to adopt 20th Edition MCG guidelines
07/11/2017	MPC approved to adopt 21st Edition MCG guidelines

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Mental Health Services – Intensive Outpatient Services

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 – Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the following MCG* guidelines for medical necessity determinations:

- Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-901-IOP v2 eff 12.01.2021)
- Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-902-IOP v2 eff 12.01.2021)

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated annually.

Mental health outpatient services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. Also Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on

Back to Top

an individual's social, medical, and/or occupational functioning."

Service authorization decisions also based on the member's contractually covered services and MCG Care Guidelines Behavioral Health criteria.

Applicable Codes

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
11/01/2016	11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/011/2023[MPC]	07/06/2021

[MPC] Medical Policy Committee

Revision History	Description
09/05/2017	MPC approved to adopt KP hybrid criteria
07/06/2021	MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Intensive Outpatient Program Behavioral Health Level of Care, Adult (B-KP-901-IOP) and Intensive Outpatient Program Behavioral Health Level of Care, Child or Adolescent (B-KP-902-IOP). Requires 60-day notice, effective date 12/01/2021.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Neuropsychological Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 of the coverage manual, 80.2 - Psychological Tests and Neuropsychological Tests.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Neuropsychological Testing (B-805-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions

Neuropsychological testing will not be authorized for any of the exclusions found in the member's contract, including learning disabilities.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of PCP or specialty notes that describe the members cognitive deficits

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning." The MCG Care Guidelines do not include any criteria regarding neuropsychological testing thus the need to develop these criteria. These criteria are based upon literature from the American Psychological Association as well as the Clinical Neuropsychological Society regarding standards for psychological testing.

Explanation to Differentiate Psychological and Neuropsychological Testing

Psychological Testing

Psychological tests assess a range of mental abilities and attributes, including achievement, personality, cognitive, and behavioral functioning. They are used to address a variety of questions about people's functioning, diagnostic classification, co-morbidity, and choice of treatment approach. For example, personality tests and inventories evaluate the thoughts, emotions, attitudes, and behavioral traits that contribute to an individual's interpersonal functioning. The results of these tests determine an individual's personality strengths and weaknesses, and may identify certain disturbances in personality, or psychopathology. Basic assessment of memory and intellectual functioning is also part of psychological testing.

Psychological Testing is indicated in the following circumstances:

- Differential diagnosis of behavioral or psychiatric conditions when the member's history and symptomatology are not readily attributable to a particular psychiatric diagnosis and the questions to be answered by testing could not be resolved by a psychiatric/diagnostic interview, observation in therapy, or an assessment for level of care at a mental health or substance abuse facility; or
- Develop treatment recommendations after the member has been tried on various medications and/or psychotherapy, has not progressed in treatment, and continues to be symptomatic.
- A patient has had a recent mild traumatic brain injury (i.e. concussion) and a screening of his/her cognitive status is desired early on after the injury to answer more immediate questions about cognitive and emotional functioning as well as ability to return to accustomed life's activities at that time.
- There has been a recent change in patient's memory (i.e. within past six months) or changes in memory have been present for extended period of time and it is not significant or complex. Psychological testing can clarify /determine extent of memory and cognitive change and impact on functioning.
- Majority of Pre-surgical evaluations (spinal cord stimulator, complex spine surgery, bariatric surgery)

Neuropsychological Testing

Neuropsychological testing is a sub classification of psychological testing and is a well-established method for evaluating patients who demonstrate complex cognitive or behavioral abnormalities Areas of brain functioning that are typically assessed are basic motor and sensory-perceptual functions; attention, concentration, speed and efficiency of information processing; learning and memory functions; language and verbal intellectual functions; spatial, perceptual and nonverbal intellectual functions; reasoning and complex problem solving functions; and executive regulatory and monitoring functions. A Neuropsychological evaluation is both a neuro-diagnostic procedure, as well as the most in-depth and comprehensive way of identifying in individual's cognitive strengths and limitations.

Neuropsychological testing is indicated when:

- There is the presence of a significant cognitive deficit, mental status abnormality, behavioral change, or memory loss that requires quantification, monitoring of change, diagnostic clarification, differentiation of cause (e.g., organic cognitive vs. psychiatric disease) and determination of the patient's ability to function.
- There is the presence of a known neurological disease or condition (i.e. dementia, CVA, traumatic brain injury, multiple sclerosis, Parkinson's, etc.) and testing is needed to determine the impact of the disease or condition on brain functioning and the patient's ability to function in his or her personal situation. Patients with mild traumatic brain injury (TBI) should not be referred prior to 3 months post injury as the majority of mild TBI patients recover essentially back to baseline over the initial 3 months post injury period.
- There is a medically complex, not well understood case with memory and cognitive deficits as significant presenting concerns and/or barriers to effective functioning.
- Further assessment of a patient with persisting cognitive symptoms or complaints is needed where a range of previous workups including but not limited to a Neurology consult, brain imaging, Mini-mental State Examination (MMSE), a previous Clinical Psychological evaluation and so forth have been negative or non-contributory.
- As part of pre and post procedure evaluation for deep brain stimulation procedure for Parkinson's Disease

Summary

When to refer for psychological testing as compared to neuropsychological testing:

Back to Top

- If the primary concern is differential diagnosis (is it bipolar. is it psychosis, is there a personality disorder present), refer for psychological testing
- Majority of pre-surgical evaluation refer for psychological testing.
- There is the presence of cognitive and/or memory concerns and it has not been present for extended period of time (i.e. greater than six months), and there is not the presence of other complicated medical conditions, refer for psychological testing.
- If cognitive, memory and behavioral concerns have been present for extended period of time, there are significant medical complications, and/or previous assessments (psychological evaluation, neurology consult) have been unable to clarify diagnosis or functioning status of patient, refer for neuropsychological testing.
- Pre-surgical evaluation for deep brain stimulation for Parkinson's Disease is referred for neuropsychological testing

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
96125	Standardized cognitive performance testing (eg, Ross Information Processing Assessment) per hour of a qualified health care professional's time, both face-to-face time administering tests to the patient and time interpreting these test results and preparing the report
96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96146	Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Back to Top

Date Created	Date Reviewed	Date Last Revised
09/07/2006	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC]	09/01/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/02/2016	Removed LCD
04/05/2016	Adopted MCG 19th Edition
11/07/2017	Adopted MCG 21st Edition
09/04/2018	Adopted MCG 22nd Edition
07/31/2020	Added CPT code 96121
09/01/2020	Removed deleted CPT codes 96118-96120 and G0505; Added CPT codes 96136-96139 and 96146

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Mental Health Services – Acute Outpatient

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 – Covered Medical and Other Health Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare members

Kaiser Permanente has elected to use the following MCG* guidelines for medical necessity determinations:

- Outpatient Behavioral Health Level of Care, Adult (B-KP-901-AOP v2 eff 12.01.2021)
- Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-902-AOP v2 eff 12.01.2021)

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

The MCG guidelines will be used for determination of Initial Authorization of Service, Continued Authorization of Service, and for Discontinuation of Service.

Exclusions:
Outpatient mental health services may not be authorized or reimbursed if any of the contract exclusions are met.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated annually.

Date Sent: 4/29/24

Mental health outpatient services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. Also, Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Service authorization decisions also based on the member's contractually covered services and MCG Care Guidelines Behavioral Health criteria.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
012/15/2006	09/04/2012[MPC],07/02/2013[MPC],05/06/2014[MPC],03/03/2015[MPC],01/05/2016[MPC], 11/01/2016[MPC], 07/10/2018 [MPC] ,07/09/2019 [MPC],07/07/2020 [MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC]	07/06/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Date of Revision	Revision History
11/01/2016	MPC approved to adopt MCG 20th Ed.: Acute Outpatient Behavioral Health Level of Care, Adult (B-901-AOP) and Acute Outpatient Behavioral Health Level of Care, Child or Adolescent (B-902- AOP)
09/05/2017	MPC approved to adopt KP hybrid criteria
07/06/2021	MPC approved to adopt MCG 25th Edition with modifications (hybrid) for Outpatient Behavioral Health Level of Care, Adult (B-KP-901-AOP) and Outpatient Behavioral Health Level of Care, Child or Adolescent (B-KP-902-AOP). Requires 60-day notice, effective date 12/01/2021.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Mental Health – Partial Hospitalization & Day Treatment

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Partial Hospital Behavioral Health Level of Care, Adult (B-KP-901-PHP) for medical necessity determinations.

Kaiser Permanente has elected to use the MCG* Partial Hospital Behavioral Health Level of Care, Child or Adolescent (B-KP-902-PHP) for medical necessity determinations.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions:
Partial hospital mental health services will not be authorized if any of the exclusion criteria are met as referenced in the member's coverage contract.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***The MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Behavioral Health department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health unit for more information regarding the case under review.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente Behavioral Health Service adopted and integrated into its clinical review criteria, the MCG for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG Criteria are updated annually.

Mental health partial hospital services are provided or authorized with the overall goals of assessing and improving the member's symptoms and function. In addition, Kaiser Permanente Behavioral Health Services

Back to Top

operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Partial hospitalization designates a structured, intensive, multidisciplinary treatment program that provides psychiatric, medical, and nursing care which meets the standards for licensure as a partial hospital program. The program is usually offered in an inpatient setting, but the patient goes home in the evening and on weekends. The program delivers a highly structured environment and 20 or more hours of treatment per week. Patients are expected to participate 5 to 7 days per week. Patient must be medically stable and live near treatment setting.

Service authorization decisions are also based on the member's contractually covered services and MCG Guidelines Behavioral Health criteria.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/14/06	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 02/04/2014[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopted MCG 19th Ed. guidelines
07/11/2017	Adopted MCG 21st Ed. guidelines

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Mental Health – Residential Care

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 2 and Chapter 4.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

These criteria apply to members whose contract includes coverage for residential care.

Medical Necessity Criteria for Coverage of Admission:
Inpatient Mental Health Residential Admission for a mental health clinical disorder is medically necessary when MCG* Guidelines, current edition, Admission Guidelines for Residential Acute Behavioral Health Level of Care are met.
Residential Acute Behavioral Health Level of Care, Adult ORG: B-KP-901-RES (BHG)
Residential Acute Behavioral Health Level of Care, Child or Adolescent ORG: B-KP-902-RES (BHG)

Medical Necessity Criteria for Coverage of Continued Stay:
Continued Inpatient Mental Health Residential Stay for a mental health clinical disorder is medically necessary when MCG* Guidelines, current edition, Continued Care Guidelines for Residential Acute Behavioral Health Level of Care are met.
Residential Acute Behavioral Health Level of Care, Adult ORG: B-KP-901-RES (BHG)
Residential Acute Behavioral Health Level of Care, Child or Adolescent ORG: B-KP-902-RES (BHG)

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Exclusions:
Residential psychiatric services will not be authorized for any exclusion criteria referenced in a member's contract.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

***The MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our Behavioral Health department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health Unit for more information regarding the case under review.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Date Sent: 4/29/24

Background

Residential care is intended for patients who need around-the-clock behavioral care but do not need the high level of physical security and frequency of psychiatric and nursing intervention that are available on an inpatient unit. Patients admitted to residential care are unlikely to need physical restraint or extensive nursing care. Psychiatrists typically round less often and nurses are generally on site for fewer hours each day than on an inpatient unit. However, the treatment team is generally composed of a similar mix of professionals as on an inpatient unit. Although it is sometimes assumed that residential care implies a longer length of stay than inpatient care, randomized controlled trials (RCTs) have shown that residential care is an efficacious short-term alternative to inpatient care for voluntary patients with urgent behavioral health conditions.

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. These criteria are independently developed and based on a review of the scientific literature, expert input, and clinical practice. In addition, the MCG criteria are updated yearly. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Mental health, acute residential treatment is utilized when it is the most appropriate and effective level of care that can safely be provided for the member's immediate condition. Service authorization is based on the member's contract and the MCG Care Guidelines for mental health acute residential treatment, and with the overall goals of assessing and stabilizing the member's acute symptoms, in order that treatment can be continued effectively and safely in a less restrictive and disruptive level of care. When treating children or adolescents, the parents or guardians must be included in both the evaluation and treatment planning processes, except for children age 13 or older who refuse to have a parental figure involved.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
09/11/2008	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	07/11/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopt MCG 19th Ed. guidelines
07/11/2017	Adopt MCG 21st Ed. guidelines

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Psychological Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Chapter 15 of the coverage manual, 80.2 - Psychological Tests and Neuropsychological Tests
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Psychological Testing (B-807-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 2007, Kaiser Permanente adopted and integrated into its clinical review criteria, the MCG Care Guidelines for determining appropriate levels of care based on symptoms and functional impairment. Kaiser Permanente Behavioral Health Services operationally defines clinically indicated services as "services for mental health conditions that are having a clinically significant impact on an individual's social, medical, and/or occupational functioning."

Explanation to Differentiate Psychological and Neuropsychological Testing

Psychological Testing

Psychological tests assess a range of mental abilities and attributes, including achievement, personality, cognitive, and behavioral functioning. They are used to address a variety of questions about people's functioning, diagnostic classification, co-morbidity, and choice of treatment approach. For example, personality tests and inventories evaluate the thoughts, emotions, attitudes, and behavioral traits that contribute to an individual's interpersonal functioning. The results of these tests determine an individual's personality strengths and

Date Sent: 4/29/24

weaknesses, and may identify certain disturbances in personality, or psychopathology. Basic assessment of memory and intellectual functioning is also part of psychological testing.

Psychological Testing is indicated in the following circumstances:

- Differential diagnosis of behavioral or psychiatric conditions when the member's history and symptomatology are not readily attributable to a particular psychiatric diagnosis and the questions to be answered by testing could not be resolved by a psychiatric/diagnostic interview, observation in therapy, or an assessment for level of care at a mental health or substance abuse facility; or
- Develop treatment recommendations after the member has been tried on various medications and/or psychotherapy, has not progressed in treatment, and continues to be symptomatic.
- A patient has had a recent mild traumatic brain injury (i.e. concussion) and a screening of his/her cognitive status is desired early on after the injury to answer more immediate questions about cognitive and emotional functioning as well as ability to return to accustomed life's activities at that time.
- There has been a recent change in patient's memory (i.e. within past six months) or changes in memory have been present for extended period of time and it is not significant or complex. Psychological testing can clarify /determine extent of memory and cognitive change and impact on functioning.
- Majority of Pre surgical evaluations (spinal cord stimulator, complex spine surgery, bariatric surgery)

Neuropsychological Testing

Neuropsychological testing is a sub classification of psychological testing and is a well-established method for evaluating patients who demonstrate complex cognitive or behavioral abnormalities Areas of brain functioning that are typically assessed are basic motor and sensory-perceptual functions; attention, concentration, speed and efficiency of information processing; learning and memory functions; language and verbal intellectual functions; spatial, perceptual and nonverbal intellectual functions; reasoning and complex problem solving functions; and executive regulatory and monitoring functions. A Neuropsychological evaluation is both a neuro-diagnostic procedure, as well as the most in-depth and comprehensive way of identifying in individual's cognitive strengths and limitations.

Neuropsychological testing is indicated when:

- There is the presence of a significant cognitive deficit, mental status abnormality, behavioral change, or memory loss that requires quantification, monitoring of change, diagnostic clarification, differentiation of cause (e.g., organic cognitive vs. psychiatric disease) and determination of the patient's ability to function.
- There is the presence of a known neurological disease or condition (i.e. dementia, CVA, traumatic brain injury, multiple sclerosis, Parkinson's, etc.) and testing is needed to determine the impact of the disease or condition on brain functioning and the patient's ability to function in his or her personal situation. Patients with mild traumatic brain injury (TBI) should not be referred prior to 3 months post injury as the majority of mild TBI patients recover essentially back to baseline over the initial 3 months post injury period.
- There is a medically complex, not well understood case with memory and cognitive deficits as significant presenting concerns and/or barriers to effective functioning.
- Further assessment of a patient with persisting cognitive symptoms or complaints is needed where a range of previous workups including but not limited to a Neurology consult, brain imaging, Mini-mental State Examination (MMSE), a previous Clinical Psychological evaluation and so forth have been negative or non-contributory.
- As part of pre and post procedure evaluation for deep brain stimulation procedure for Parkinson's Disease

Summary

When to refer for psychological testing as compared to neuropsychological testing:

- If the primary concern is differential diagnosis (is it bipolar. is it psychosis, is there a personality disorder present), refer for psychological testing.
- Majority of pre surgical evaluation, refer for psychological testing.
- There is the presence of cognitive and/or memory concerns and it has not been present for extended period of time (i.e. greater than six months), and there is not the presence of other complicated medical conditions, refer for psychological testing.
- If cognitive, memory and behavioral concerns have been present for extended period of time, there are significant medical complications, and/or previous assessments (psychological evaluation, neurology consult) have been unable to clarify diagnosis or functioning status of patient, refer for neuropsychological testing.
- Pre surgical evaluation for deep brain stimulation for Parkinson's Disease is referred for neuropsychological testing

Back to Top

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
09/26/2006	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
02/02/2016	Adopted MCG 19th Ed. guidelines
12/06/2016	Adopted MCG 20th Ed. guidelines
10/03/2017	Adopted MCG 21st Ed. guidelines
08/07/2018	Adopted MCG 22nd Ed. guidelines
08/04/2020	Added CPT code 96130

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Biofeedback

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Biofeedback Therapy (30.1).
Local Coverage Determinations (LCD)	3/14/2007 Noridian retired ***LCD Biofeedback Therapy Policy (L14443)***. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L14443 for determining medical necessity.
Local Coverage Article	None

For FEHB plans: See the member's contract for specific coverage details

For Non-Medicare Members

I. Biofeedback is covered for **ONE of the following**:
   A. Fecal Incontinence
   B. Tension or migraine headache if pharmacologic treatment inadequate or not indicated, by **1 or more** of the following:
      - Breast-feeding patient
      - History of long-term, frequent, or excessive use of analgesic or medications that can aggravate headache
      - Insufficient or no response to multiple pharmacologic treatment attempts
      - Intolerance of multiple pharmacologic treatment attempts
      - Patient attempting to become pregnant
      - Pregnant patient

II. The following indications for biofeedback are not medically necessary. There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
   - Abdominal pain, recurrent
   - Anxiety disorders
   - Arthritis
   - Asthma
   - Autism
   - Back pain

Back to Top

- Bell's palsy
- Bruxism and sleep bruxism
- Cardiovascular disorders
- Chronic fatigue
- Chronic pain
- Chronic obstructive pulmonary disease (COPD)
- Depression
- Epilepsy
- Facial palsy
- Fibromyalgia
- Hand hemiplegia
- Insomnia
- Knee pain
- Low back pain
- Low vision
- Lupus [systemic lupus erythematosus (SLE)]
- Motor function after stroke, injury, or lower limb surgery
- Movement disorders
- Myalgia or muscle pain
- Neck pain
- Orthostatic hypotension in patients with a spinal cord injury
- Post-traumatic stress disorder (PTSD)
- Raynaud's disease
- Side effects of cancer chemotherapy
- Temporomandibular joint disorders
- Tinnitus
- Vesicoureteral reflux
- Voiding dysfunction
- Vestibulodynia, vulvodynia, vulvar vestibulitis

Biofeedback for the Treatment of Urinary Incontinence
See the Treatment of Urinary Incontinence criteria document

Neurofeedback for ADHD (EEG Biofeedback)
See the Neurofeedback criteria document

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Biofeedback is a technique designed to help individuals self-regulate certain physiological processes that are not normally considered to be under voluntary control or responses that are ordinarily easily regulated, but for which regulation has broken down due to trauma or disease. This is achieved through conveying audio and visual information about physiological processes such as blood pressure, heart rate, skin temperature, galvanic skin response (sweating), or muscle tension in real-time to raise awareness of physiological activities and train patients to control them. The goal of biofeedback is that eventually the patient will learn to control physiologic response without the aid of monitors (Kaiser 2011, Roditi 2011).

Different types of biofeedback include (Kaiser 2011, Magnusson 2008, Kapitza 2010):
- Electroencephalography (EEG) biofeedback, which monitors the activity of brain waves linked to different mental states.
- Electrocardiography (EKG) biofeedback, which tracks the patient's heart rate.
- Electromyography (EMG) biofeedback, which uses sensors to measure tension in specific muscles.

Back to Top

- Galvanic skin response biofeedback, which uses sensors to signal anxiety based on the activity of a person's sweat glands and the amount of perspiration on the skin.
- Skin temperature biofeedback, which involves attaching sensors to the fingers or feet to indicate stress when the temperature is low.
- Respiratory biofeedback, which uses sensors to measure breathing.
- Postural biofeedback, which uses sensors to measure body motion.

Biofeedback has been used to treat a variety of medical conditions such as urinary incontinence, ADHD, headaches, anxiety, and back pain.

Evidence and Source Documents

Biofeedback for Anxiety Disorders
Biofeedback for Back Pain
Biofeedback for Migraine and Tension Headaches
Biofeedback for Treatment of Urinary Incontinence

Medical Technology Assessment Committee (MTAC)

Biofeedback for Anxiety Disorders

02/13/2012: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

Articles: The literature search revealed several studies evaluating biofeedback for the treatment of generalized anxiety disorder. All of the studies had small sample sizes and the majority were published more than 20 years ago. The newest study was a randomized controlled trial that evaluated the efficacy of a biofeedback enhanced virtual reality system. This study was not selected for review as the treatment group contained only 4 subjects (Gorini, 2010). Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of generalized anxiety disorders.

The use of biofeedback for anxiety disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Biofeedback for Chronic Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: The Kaiser review included four randomized controlled trials that ranged in size from 42 to 128 patients. Findings from these trials suggest that pain and disability improved with biofeedback, cognitive behavioral therapy (CBT), biofeedback plus CBT, placebo biofeedback, and rehabilitation; however, no significant differences were found between biofeedback and the other treatments. The body of evidence was limited by heterogeneity in the patient population, biofeedback protocols, and comparator treatments. Additionally, the studies were small with short follow-up periods. Biofeedback vs. CBT alone vs. waitlisted controls (Newton-John 1995) • N=44 • Type of biofeedback: Electromyography biofeedback (EMG). • Both the biofeedback and the CBT groups showed improvement in pain intensity, pain belief, and depression; however, there no significant differences between the two groups. There was no improvement in the waitlisted control group. Biofeedback plus CBT vs. CBT alone vs. waitlisted controls (Glombiewski 2010) • N=128 • Type of biofeedback: EMG • Both the combined group and the CBT alone group showed improvement in pain intensity compared to waitlisted control; however, there no significant differences between the two groups. Active biofeedback vs. placebo biofeedback (Kapitza 2010) • N=42 • Type of biofeedback: Respiratory biofeedback. • There was no significant difference in pain reduction between the two groups. Biofeedback plus rehabilitation vs. rehabilitation alone (Magnusson 2008) • N=47 • Type of biofeedback: Postural biofeedback. • Although the combined group showed improvements in pain, range of motion, and quality of life, the study did not report if they were statistically significantly different from the rehabilitation alone group. Conclusion: There is insufficient evidence to determine the safety and efficacy of biofeedback for the treatment of chronic back pain.

Articles: The 2007 American College of Physicians and the American Pain Society (ACP/APS) guideline evaluated the evidence on biofeedback for chronic back pain. The studies evaluating this treatment were of poor quality and therefore they were unable to evaluate the net benefits of biofeedback. The conclusions of the ACP/APS guideline were supported by a 2009 BMJ clinical evidence review (Chou 2009). In 2011, the Kaiser Permanente Medical Technology Assessment Team (MTAT) also reviewed biofeedback for the treatment of chronic back pain. No additional studies were identified after the Kaiser review. The following technology assessments were selected for review: Kaiser Permanente TPMG New Medical Technologies. Biofeedback for chronic neck and low back pain. May 2011.

Back to Top

The use of biofeedback for back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Biofeedback for Migraine and Tension Type Headaches

02/13/2012: MTAC Review

Evidence Conclusion: A recent meta-analysis that included 94 RCTs and quasi-experimental studies evaluate the efficacy of different types of biofeedback for the treatment of migraine and tension-type headaches. Results from this analysis suggest that biofeedback was more effective than no treatment for headache reduction in patients with migraine headache (small effect size); however, there was no significant difference between biofeedback and placebo or relaxation. For patients with tension-type headache, biofeedback was significantly more effective than no treatment, placebo, and relaxation for headache reduction (small to medium effect size). There was no significant difference between biofeedback treatment modalities for the reduction of migraine headache pain (Nestouric 2008). A meta-analysis is only as good as the studies that it includes. The studies included in the meta-analysis had several limitations. • The majority of the studies included in the meta-analysis were small. The mean number of subjects per study was 40 for migraine studies and 45 for tension-type headache studies. • The type and number of sessions of biofeedback varied. • Several studies failed to describe basic treatment and patient characteristics. • Several studies used unstructured diagnostic systems. Conclusion: Migraine • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, but not placebo or relaxation for headache reduction. Tension-type headaches • Results from a recent meta-analysis suggest that biofeedback may be more effective than no treatment, placebo, and relaxation for headache reduction. • Another recent BMJ Clinical Evidence review found insufficient evidence to determine whether EMG biofeedback is effective for treating chronic tension-type headaches (Krishnan 2009).

Articles: Several meta-analyses and randomized controlled trials (RCTs) were identified that evaluated the efficacy of biofeedback for the treatment of migraine and tension-type headaches. The most recent meta-analysis was selected for review. An RCT published after the meta-analysis was also identified that evaluated the efficacy of a pain program that included education and training in pain theory plus EMG and temperature biofeedback compared to the pain program alone. This study was not selected for review due to methodological limitations (i.e., small sample size, high loss to follow-up, power not addressed, and baseline characteristics were not presented) (Mullally 2009). The following study was selected for review: Nestoriuc Y, Martin A, Rief W, Andrasik F. Biofeedback treatment for headache disorders: a comprehensive efficacy review. Appl Psychophysiology Biofeedback. 2008; 33:125-140. See Evidence Table.

The use of biofeedback for Migraine and Tension-type Headaches does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
E0746	Electromyography (EMG), biofeedback device

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

Back to Top

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
03/06/2012	03/06/2012[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 05/02/2017[MPC], 02/06/2018[MPC], 08/07/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	03/12/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Added indication to cover migraine headaches
07/18/2018	Added FEHB language
06/23/2020	Removed deleted CPT code 90911; Added CPT codes 90912 and 90913
12/02/2022	Added Retired LCD L14443
03/12/2024	Removed urinary conditions from the exclusions list

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bioimpedance Spectroscopy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Bioimpedance Spectroscopy***, for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Bioimpedance Spectroscopy (A-0667) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lymphedema is a chronic progressive disorder of the lymphatic system characterized by interstitial accumulation of protein rich fluid. This occurs when lymphatic transport is reduced causing lymphatic stasis and subsequent protein accumulation within tissues. Accumulation of protein and fluid in the tissues triggers an inflammatory response and swelling that eventually leads to fibrosis. Primary lymphedema is rare and results from congenital anatomic abnormalities of the lymphatic system such as lymphatic hypoplasia or dysfunction of lymphatic valves. Secondary lymphedema on the other hand, is more common and may result from disease, trauma, surgery, or radiation therapy. In the United States, the most common cause of secondary lymphedema is malignancy and its related treatment, particularly in breast cancer patients treated with axillary surgery and/or

Back to Top

radiation therapy (Warren 2007).

The proportion of women who develop breast cancer-related lymphedema (BCRL) is estimated to range from 3-15% for women who had sentinel node biopsy and up to 49% among those who underwent axillary lymph node dissection. This big variation in reported incidence of lymphedema is due to lack of a standardized assessment and differences in diagnostic criteria. Lymphedema may cause limb swelling, heaviness, pain, pitting of the skin, tightness, inflammation, reduced mobility, and impaired limb function (Taylor 2006, Smoot 2011).

Accurate assessment of lymphedema may facilitate earlier diagnosis and monitoring of treatment response. Physical assessment of BCRL is performed by comparing the affected versus the unaffected arm, or by comparing postoperative with preoperative measurements. Physical measurements used include limb circumferential assessment with a tape measure, and limb volume measurement using water displacement or optoelectrical perometry (also known as infrared volumetry). Circumferential measurement is the most common clinical assessment measure used. Limb circumference is used to calculate volume by assuming either cylindrical or truncated cone geometry. It thus indirectly measures the limb volume and may be confounded by changes in muscle and fat mass. In addition, it may be hard to use for the hand due to its irregular shape. Water volumetry or displacement, in which the limb is lowered in a water tank, has been considered by many as the reference method for determining limb volume. It is a reliable method and provides a way of including volumetric measurements of the hand or foot in the total limb volume measurements. However, water displacement cannot distinguish changes due to fat or muscle from extracellular fluid accumulation. The Perometer is an opto-electrical device that has a square frame in which the extended extremity is placed. The frame emits infrared light and slides up and down scanning the patient's extremity and recording cross sectional information every 3 mm. Limb volume is then calculated based on the assumption that the cross-section is an ellipse or circle. Many investigators consider perometry the modern gold standard for the assessment of limb volume. It is however, bulky in size, not available in most clinics, and cannot be used for bed- ridden patients. In more challenging cases radiologic imaging studies as lymphoscintigraphy, magnetic resonance imaging, or computerized tomography may be necessary to diagnose lymphedema (Sander 2002, Warren 2007, Jain 2010, Czerniec 2010, Smoot 2011).

While circumference and volume measures are reliable measures for changes in limb volume, they are not specific to lymphedema. Bioimpedance analysis (BIA) or bioimpedance spectroscopy (BIS) has been proposed as an alternate method to differentiate the extracellular fluid compartment from the total limb volume. It attempts at measuring lymph volume directly and detecting early increase in the extracellular fluid at a subclinical stage of lymphedema before it is manifests as a change limb volume.

BIS is a noninvasive procedure that uses skin electrodes to pass a low-level alternating current through the limb and measures the opposition or impedance to the flow of this current. Current flows along the path of least resistance through the body and thus follows tissues with the highest water content. Tissues as fat and bone act as insulators, while electrolyte body fluids conduct electrical current and as the fluid increases, impedance to current flow decreases, i.e. changes in impedance are inversely proportional to the volume of the extracellular fluid in the extremity the level of impedance is not only a function of the type of tissue, but also the frequency of the current. At low frequencies, cell membranes are non-conductive and current passes only through the extracellular fluid, while at high frequencies, the current passes through cell membranes in addition to the extra-and intracellular fluids. BIS thus gives a measure of electrical impedance and not volume (Warren 2007, Jain 2010, Czerniec 2010).

Medical Technology Assessment Committee (MTAC)

Bioimpedance Lymph Analysis

06/20/2011: MTAC REVIEW

Evidence Conclusion: The 2010 report prepared for the AHRQ assessed the diagnosis and treatment of secondary lymphedema in general, not specifically for cancer breast-related lymphedema. However, the reviewers indicated that most of the diagnostic studies involved patients with breast cancer. They noted that based on the evidence from the studied reviewed, there does not appear to be a gold standard for grading or measuring the severity of lymphedema. However, based on the extent of use and consistent evidence for reliability and validity, the reviewers of the AHRQ report recommend that measures of limb volume or circumference be considered the gold standard for diagnosing secondary lymphedema. They indicated that

Back to Top

there was very little evidence to allow making conclusions about the reliability of bioimpedance lymph analysis (BIA) which was listed among other tests. BIA was found to have good validity when compared with tape measured circumference or perometry, but lower correlation coefficients than those for the circumference-displacement comparisons. The AHRQ report also indicated that the diagnostic testing studies do not provide sufficient evidence to determine whether any of the test methods would influence the choice of lymphedema treatment or patient outcome. Two more recent studies published after the AHRQ report and critically appraised for this MTAC review do not provide any additional evidence on the accuracy, validity or reliability of BIA, or on its impact on patient management or outcome.

Articles: The search revealed a recent comprehensive review on the diagnosis and treatment of secondary lymphedema prepared for the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment (TA) Program in May 2010. The literature search for this AHRQ report was made through January 2010. Two more recent studies that compared the accuracy and/or reliability of BIS to other physical measures used for the assessment of breast cancer-related lymphedema were critically appraised. Czerniec SA, Ward LC, Refshauge KM, et al Assessment of breast cancer-related arm lymphedema--comparison of physical measurement methods and self-report. *Cancer Invest.* 2010; 28:54-62. See Evidence Table. Smoot BJ, Wong JF, Dodd MJ. Comparison of diagnostic accuracy of clinical measures of breast cancer-related lymphedema: Area under the curve. *Arch Phys Med Rehabil*. 2011; 92:603-610. See Evidence Table.

The use of bioimpedance lymph analysis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0358T	Bioelectrical impedance analysis whole body composition assessment, with interpretation and report
93702	Bioimpedance spectroscopy (BIS), extracellular fluid analysis for lymphedema assessment(s)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/05/2011	07/05/2011[MPC], 05/01/2012[MPC], 03/05/2013[MPC], 01/07/201[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	01/07/2014

[MPC] Medical Policy Committee

Review History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Blepharoplasty

- Blepharoptosis
- Brow Lift

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Blepharoplasty, Eyelid Surgery, and Brow Lift (L36286)
Local Coverage Article	Billing and Coding: Blepharoplasty, Eyelid Surgery, and Brow Lift (A57191)

For Non-Medicare Members

Blepharoplasty, blepharoptosis repair, or brow ptosis repair will be considered medically necessary when **ONE of the** following are met:

I. **Upper eyelid reconstructive blepharoplasty** is considered medically necessary and NOT cosmetic when **ONE of the following** is met:

A. Blepharoplasty for the following diagnoses may be considered medically necessary for an affected upper or lower lid without meeting visual loss criteria:
   1. Trichiasis
   2. Ectropion
   3. Entropion
   4. Exposure keratitis
   5. Painful blepharospasm refractory to medical management

B. In the absence of one of the conditions listed above **unilateral or bilateral upper lid** may be considered medically necessary for reconstructive purposes when the operative eye **meets ALL of the following** criteria:
   1. Visual field less than 20° above central fixation – (untaped eye) OR limited to 10 to 15 degrees (untaped eye) laterally
   2. Frontal or lateral photograph demonstrates visual field limitation consistent with the visual field examination, AND
   3. Does not have unstable myasthenia gravis or a thyroid condition (No concerns about stability raised by Neurology for myasthenia gravis patients and normal thyroid lab if patient has pre-existing thyroid disease)
   4. **ALL of following** information must be submitted:
      - Visual fields, including physician interpretation
      - MRD1 (marginal reflex distance) measurement
      - Documentation of clinically decreased vision
      - Lateral and full-face photographs

II. **Upper eyelid ptosis (blepharoptosis) repair** may be considered medically necessary for reconstructive purposes when the operative eye meets **ALL of the following** criteria:

Date Sent: 4/29/24

A. Documented complaints of interference with vision or visual field-related activities causing significant functional impairment (difficulty reading or driving due to eyelid position
B. Photographs demonstrate the eyelid at or below the upper edge of the pupil
C. Visual field less than 20° above central fixation
D. MRD1 (marginal reflex distance from pupil center to upper eyelid) of 2.0mm or less
E. Does not have unstable myasthenia gravis or a thyroid condition
F. **ALL of the following** information must be submitted
   - Visual fields, including physician interpretation
   - MRD1 (marginal reflex distance) measurement
   - Documentation of clinical decreased vision
   - Lateral and full-face photographs

III. **Brow ptosis repair** may be considered medically necessary for reconstructive purposes when **ALL of the following** criteria are met:
A. Photographs demonstrate the eyebrow is below the super orbital rim
B. Visual field less than 20° above central fixation
C. MRD1 of 2.0 mm or less
D. Cannot be corrected by upper lid blepharoplasty alone
E. Frontal or lateral photograph demonstrates visual field limitation consistent with the visual field examination, AND
F. Does not have unstable myasthenia gravis or a thyroid condition
G. **ALL of the following** information must be submitted:
   - Visual fields, including physician interpretation
   - MRD1 (marginal reflex distance) measurement
   - Documentation of clinically decreased vision
   - Lateral and full-face photographs

IV. **Blepharoplasty in anophthalmia** is considered medically necessary when the upper eyelid position interferes with the fit of eye prosthesis in the socket.

V. Blepharoplasty of the lower lids for excessive skin that does not correct a functional issue is considered **cosmetic** under the member benefit.

If requesting this service, please send the following documentation to support medical necessity:

- Signed clinical notes supporting a decrease in peripheral vision and/or upper field vision and excessive upper/lower lid skin
- Supporting pre-op lateral and full-face photographs
- Documented subjective patient complaints which justify functional surgery (vision, ptosis, etc.)
- Visual fields, including physician interpretation and recommendations (when applicable)
- MRD1 (marginal reflex distance) measurement (for blepharoptosis or brow ptosis repair)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

This service is covered when it is medically indicated and determined not to be for cosmetic. The Medicare coverage language includes the identification of how to determine medical necessity. This is the language that has been adopted by Kaiser Permanente.

In order to determine coverage, the clinical history submitted by the requesting physician should include the reason for the surgery and the identification of the procedure to be done.

Evidence and Source Documents

References:
Kaiser Permanente Coverage Contract Language
Medicare Coverage Manual /PROW Criteria

Medicare Part B News 180, March 2000, topic 1143 entry #5782, applicable to Washington State. And effective in March 2000 as of publish date.

Applicable Codes

Blepharoplasty – Medicare – Considered Not Medically Necessary:

CPT® Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad

Blepharoplasty – Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Blepharoplasty – Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Blepharoptosis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
67909	Reduction of overcorrection of ptosis

Repair of Brow ptosis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description

67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/30/1998	05/04/2010[MDCRPC], 03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/27/2015	Added new LCD L35536
09/08/2015	Revised LCD to L36281, L34886, L35008
10/04/2016	Added indication: OR limited to 10 to 15 degrees (untapped eye) laterally
06/15/2019	Added indication: Does not have unstable myasthenia gravis or a thyroid condition (No concerns about stability raised by Neurology for myasthenia gravis patients and normal thyroid lab if patient has pre-existing thyroid disease)
07/07/2020	Added Medicare LCA (A57191)
08/04/2020	Added Medicare LCA (A57642); MPC approved to adopt updates to clinical criteria for non-Medicare, separating indications for blepharoplasty and blepharoptosis repair.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Bone Lengthening

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, *"*Bone Lengthening,*"* for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Effective until September 1st, 2024

No medical necessity review.

Effective September 1st, 2024

Bone lengthening procedures may be considered medically necessary for correction of congenital or post-traumatic limb length discrepancies; and/or angular deformities of the limb (arm, forearm, thigh or leg) when ANY ONE of the following are met:

- Demonstrable non-union or mal-union of long bone with or without bone loss or infection;
- Where lengthening of an amputation stump is needed for proper fitting of a prosthesis;
- Where leg lengthening is needed to equalize leg length discrepancy greater than 6 cm
- For correction of congenital or post-traumatic angular-rotational deformations of the long bones;
- When used for bone defects with or without deformities.

Bone lengthening for conditions other than the above is not medically necessary and, therefore, is not eligible for payment.

Use of a bone-lengthening device for the sole purpose of altering short stature is considered cosmetic; and is therefore, not covered.

Insertion of wires and subsequent osteotomy of the affected limb are performed in the hospital. Removal of the device can be performed in an outpatient setting; thus, hospitalization to remove the bone lengthening device is not medically necessary.

NOTE: Non-union/mal-union is defined as not having united within a minimum of three (3) months of the original trauma.

Back to Top

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Hayes Health Technology Assessment

Limb-Lengthening Surgery for Short Stature

Synopsis of the Clinical Evidence: The literature search identified eight uncontrolled studies that evaluated limb-lengthening surgery for short stature. Results of these studies suggest that patients who have a wide variety of causes for short stature can undergo 7 to 10 cm of limb lengthening. Although serious or severe complications can occur during this procedure that may necessitate additional surgery, these complications are rarely life threatening. Since the available studies do not provide evidence that limb-lengthening surgery improves patient health or quality of life, this procedure must be considered elective and cosmetic.

Insights:

The available evidence suggests that limb-lengthening surgery can increase patient height; however, serious and severe complications can arise during this procedure. Since limb-lengthening surgery for short stature is elective and cosmetic, hospitals should not adopt this procedure unless they are willing to arrange for patients to cover the high costs for this procedure without any reimbursement from insurers.

Demand for limb-lengthening surgery for short stature will likely increase slowly due to societal pressures and the paucity of other options for adults to increase their height or apparent height.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description	IP only codes
24420	Osteoplasty, Humerus (e.g., shortening or lengthening) excluding 64876)	
25391	Osteoplasty, radius OR ulna; lengthening with autograft	
25393	Osteoplasty, radius AND ulna; lengthening with autograft	
27466	Osteoplasty, femur; lengthening	X
27715	Osteoplasty, tibia and fibula, lengthening or shortening	X
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/02/2024	04/02/2024[MPC]	

[MPC] Medical Policy Committee

Back to Top

Revision History	Description
04/02/2024	MPC approved to adopt criteria for Bone Leng Bone Lengthening Medicare and Non-Medicare members. Requires 60-day notice, effective date 09/01/2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Osteogenic (Bone) Stimulators

- Non-invasive Electrical Stimulators
- Implantable Electric Stimulators
- Ultrasonic Stimulators

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Osteogenic Stimulators (150.2)
Local Coverage Determinations (LCD)	Osteogenesis Stimulators (L33796)
Local Coverage Article	Osteogenesis Stimulators (A52513)

For Non-Medicare Members

Electric Bone Growth Stimulators (Non-invasive and Implantable)

Kaiser Permanente has elected to use the Bone Growth Stimulators, Electrical and Electromagnetic (A-0565) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Ultrasonic Bone Growth Stimulators

Kaiser Permanente has elected to use the Bone Growth Stimulators, Ultrasonic (KP-0414) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Orthopedics/podiatry)
- Copies of last 12 months of x-rays of involved area

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Electrical stimulation has been used as treatment for nonunion of fractures since the early 1950's with a reported success rate of 80-85%. New devices have made the use of this method of treatment more attractive. Bone Stimulators are covered in Kaiser Permanente plans that include coverage for durable medical equipment. The criteria for coverage had previously been part of the Durable Medical Equipment Formulary. The average contracted cost of the device is $3,000. Because of the renewed attention on this mode of treatment by Kaiser

Back to Top

Date Sent: 4/29/24

Permanente orthopedists, the referral management staff requested that clearer criteria be developed for reviewing coverage requests (1/97).

Fracture healing is a highly complex biological process. The healing process is delayed in approximately 10% of the 6 million fractures that occur annually in the United States. A portion of these delayed unions do not heal by 9 months after fracture and are categorized as non-unions (Hadjiargyrou,1998). There are two types of bone growth stimulators: electric and ultrasonic.

Electrical stimulation has been found to offer a reasonable means of treatment for nonunion that have failed to respond to previous bone grafting over an extended period of time. The effective use of electrical stimulation devices requires an understanding of the various principles and concepts employed by the four types of stimulators currently available. While the exact mechanism of electrically induced osteogenesis is uncertain, current theories indicate that several factors probably are involved, and more than one mechanism may be responsible.

Ultrasound, a form of mechanical energy that is transmitted through and into biological tissues, has a variety of diagnostic and therapeutic clinical applications. Research on the use of ultrasound to accelerate the healing of fractures has been done largely using animal models. For example, a study with rabbits found that bones exposed to ultrasound healed in about half the time as untreated bones. Data from animal models suggest that ultrasound may accelerate healing by increasing the blood flow at the fracture site (Rubin, 2001).

Exogen (Smith and Nephew) manufacturers a low-intensity ultrasound device for treating fractures, Sonic Accelerated Fracture Healing System (SAFHS). According to the manufacture, the SAFHS system is a portable, battery-operated device that produces ultrasonic waves of 30 milliwatts per cm^2 (comparable to ultrasound intensity levels used on sonograms for fetal monitoring). Patients apply the ultrasound waves directly to the fracture site.

The FDA approved the use of low-intensity ultrasound for fresh fractures in 1994 based on two randomized controlled trials and Exogen's registry data. In 2000, the FDA extended the use of ultrasound to treating established non-unions.

Medical Technology Assessment Committee (MTAC)

Ultrasonic Bone Stimulator

10/10/2001: MTAC REVIEW

Evidence Conclusion: *Fresh fractures:* Two of the RCTs (Heckman, Kristiansen) were conducted by some of the same investigators. Both found a significantly shorter time to healing for fractures in patients treated with an ultrasonic bone stimulator healed than those treated with a placebo device. Both studies had similar methodological flaws, the most serious of which was that neither study had a primary intention to treat analysis and about 30% of fractures were not included in the analysis. Both studies include a brief description of a secondary intention-to-treat analysis which found statistically significant differences between the ultrasonic bone stimulation and placebo groups; no point estimates, tables or figures were included to support these analyses. Both studies were funded by Exogen and included co-authored by an Exogen employee which could bias the study design and analysis. A third RCT was conducted by investigators without financial ties to Exogen. That study did not find a significant difference in time to radiographic healing between patients receiving ultrasonic bone stimulation versus placebo. This was a small study which may not have had sufficient statistical power to detect a difference if one existed. The threats to validity in the RCTs limit the ability to draw conclusions about the effect of ultrasonic bone stimulation on health outcomes among patients with fresh fractures. *Non-union fractures:* There were no published articles to evaluate the efficacy of ultrasound treatment to heal non-union fractures.
Articles: The search yielded 35 articles. Articles that were opinion pieces, editorials, reviews or on technical aspects of the treatment of fractures with ultrasound were not reviewed. There were 3 RCTs on the use of ultrasound with fresh fractures. Evidence tables were created for these 3 RCTs. There were no published articles on non-union fractures. There was one published abstract by Gebauer, but insufficient information was given in the abstract to evaluate it as evidence. *Citations for the RCTs reviewed*: Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. J Orthop Trauma 1999; 13: 252-7. See Evidence Table. Kristiansen TK, Ryabi JP, McCabe J, Frey JJ, Roe LR. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. J Bone Joint Surg 1997; 79-A: 961-73. See Evidence Table. Heckman JD, Ryaby JP, McCabe J, Frey JJ, Kilcoyne RF. Acceleration of tibial fracture-healing by non-invasive low-intensity pulsed ultrasound. J Bone Joint Surg 1994; 76-A: 26-34. See Evidence Table

The use of Ultrasonic Bone Stimulator for treatment of fresh and non-union fractures has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Electrical Bone Growth Stimulator:

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Non-Medicare: Considered not medical necessary

CPT® or HCPC Codes	Description
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications

Ultrasonic Bone Growth Stimulator:

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date	Dates Reviewed	Date Last

Back to Top

Date Sent: 4/29/24

Created		Revised
09/25/1997	06/01/2010[MDCRPC], [04]/05/2011[MDCRPC], [02]/07/2012[MDCRPC], 12/04/2012[MDCRPC], 10/01/2013[MPC],08/05/2014[MPC],06/02/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC] ,12/04/2018[MPC],12/03/2019[MPC],12/01/2020[MPC],12/07/2021[MPC], 12/06/2022[MPC], 12/09/2023[MPC], 02/13/2024[MPC]	11/06/2023

Revision History	Description
06/11/2015	CPT codes added
01/08/2019	MPC adopted hybrid criteria for Ultrasonic Bone Growth Stimulators (KP-0414)
04/03/2023	Updated Medicare links
11/6/2023	Updated codes section and Medicare links

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Benign Prostatic Hyperplasia (BPH) Treatments

- Aquablation (Transuretheral Waterjet Ablation of the Prostate)
- Rezūm System for the Treatment of LUTS due to BPH
- Prostatic Urethral Lift (PUL or UroLift)
- Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Therapeutic Embolization (20.28)
Local Coverage Determinations (LCD)	Transuretheral Waterjet Ablation of the Prostate (L38707)
Local Coverage Article	Urolift: Local Coverage Article: Urolift (A54044)-**RETIRED** Noridian retired Local Coverage Article (LCA A54044). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search.
Medicare Coverage Related to Investigational Device Exemption (IDE) Studies	**Prostate Artery Embolization:** This procedure is considered experimental and investigational and is ***not recommended*** outside of a clinical trial setting. Procedure is covered when part of an approved Investigational Device Exemption (IDE) trial. There are multiple CMS-approved IDE studies underway https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.
Kaiser Permanente Medical Policy	**Rezūm:** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Rezūm System for the Treatment of LUTS due to BPH," for medical necessity determinations. Use the Non-Medicare criteria below.

Back to Top

For Non-Medicare Members

Service	Criteria
Transuretheral Waterjet Ablation	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
UroLift	Covers prostatic urethral lift (e.g., UroLift) as medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when **ALL of the following** criteria are met: A. age 50 or above B. prostate volume < 80 cc on ultrasound imaging C. no obstructive median lobe of the prostate identified on cystoscopy D. failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Rezūm System for the Treatment of LUTS due to BPH	Water vapor thermal therapy (e.g., Rezūm System) is considered medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when ALL of the following criteria are met: • age 50 years or above • estimated prostate volume ≥ 30 cm3 and ≤ 80 cm3 • failure, contraindication or intolerance to at least six months of conventional medical therapy for BPH (e.g., at least one drug trial from one of the following categories: alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider &/or specialist
Prostate artery embolization for benign prostatic hyperplasia (BPH)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. **If requesting review for these services, please send the following documentation:** • Last 6 months of clinical notes from requesting provider &/or specialist
High Intensity Focused Ultrasound (HIFU) for the Treatment of Localized Prostate Cancer	Please see criteria **here**. **Not covered for BPH Treatments*

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back

Background

Benign prostatic hyperplasia (BPH), also known as prostate gland enlargement, is a common urologic condition that affects 14-30% of men 50 years of age or older. The enlarged prostate is often associated with progressive obstructive lower urinary tract symptoms (LUTS), which may impair the quality of life in older men. Common signs and symptoms of LUTS secondary to PBH include nocturia, frequent or urgent need to urinate, difficulty starting urination, weak urine stream or a stream that stops and starts, dribbling at the end of urination, and inability to completely empty the bladder. The severity of these symptoms varies among patients, but they tend to increase with age (Dixon 2016, Darson 2017, Helo 2017).

The treatment of LUTS depends on the patient's symptoms and level of bother. Therapeutic options include

- Watchful waiting (active surveillance) for patients with mild symptoms of LUTS secondary to BPH and for patients with moderate-to-severe symptoms who are not bothered by their symptoms and are not experiencing complications of BPH.
- Lifestyle modification is initially recommended for patients with bothersome LUTS that begin affecting their quality of life.
- Drug therapy (e.g. alpha-blockers, 5-alpha-reductase inhibitors, muscarinic receptor antagonists and phosphodiesterase 5, inhibitors) is an appropriate and effective treatment for patients with bothersome, moderate to severe LUTS secondary to BPH.
- Surgical intervention is appropriate for patients with moderate-to-severe LUTS, acute urinary retention, or other complications due BPH. Surgery is the most invasive option for BPH management and is generally performed in patients will have failed medical therapy. However, some patients may wish to pursue the most effective therapy as a primary treatment if their symptoms are particularly bothersome (American Urological Association Guideline).

Transurethral resection of the prostate (TURP) and open simple prostatectomy are currently the gold standard surgical interventions. Both are highly effective and provide durable improvement in urinary functional outcomes. However, despite the refinements made in the operative technique, these invasive procedures are associated with perioperative complications and morbidity including bleeding, erectile and ejaculatory dysfunction, urethral stricture, urinary tract infection, and urinary incontinence (Chung 2018, Christidis 2017, Magistro 2017).

Several novel minimally invasive therapies have been developed, or are at different stages of development, with the aim of improving the patients' symptoms and avoiding the adverse outcomes of associated with the more invasive surgeries. Among these therapies are the UroLift System, intraprostatic injectables, temporary implantable nitinol device, image guided robotic waterjet ablation, transurethral microwave therapy (TUMT), convective water vapor energy (WAVE) ablation, prostatic artery embolization, and others. An ideal minimally invasive treatment would be an intervention that can be easily performed in the office or in an outpatient setting, leads to rapid and durable relief of symptoms, is associated with minimal morbidity and recovery time, and preserves the erectile and ejaculatory functions of the patient (Chung 2018, (Magistro 2017).

Rezūm System; NxThera, Inc. Maple Grove, MN) is a minimally invasive transurethral therapy that uses the stored thermal energy in water vapor (steam) to treat the extra prostate tissue that is causing symptoms. Tissue ablation with Rezūm System uses the thermodynamic principle of convection energy transfer in contrast to conductive heat transfer techniques used in the transurethral microwave therapy or transurethral needle ablation. The Rezūm system utilizes radiofrequency (RF) to generate wet thermal energy in the form of water vapor (steam). Once the vapor (103oC) is injected, it disperses through the tissue spaces and immediately changes to liquid releasing and delivering approximately 208 cal of thermal energy in 9 seconds. The target tissue temperature reaches 70o resulting in irreversible and near instantaneous cell death. No thermal effects occur outside the prostate or in the peripheral zone when a transition zone is targeted. In addition, as the vapor is wet thermal energy, there is no charring, desiccation, or carbonization of the treated tissue. The dead tissue will be eventually absorbed by the body through its natural healing response (Dixon 2016, Christidis 2017, Woo 2017 Magistro 2017).

The Rezūm System is composed of a generator containing a radiofrequency power supply to create water vapor from sterile water, and a single use transurethral delivery device that incorporates a standard 4 mm 30o rod lens allowing the procedure to be performed under direct cystoscopic visualization. The tip of the delivery device

Back to Top

contains an 18-guage polyether ether ketone needle which has 12 small emitter holes spaced around its tip at 120o intervals to allow for circumferential dispersion of water vapor into the prostate tissue. (Darson 2017, Woo 2017).

The procedure is performed in the clinic or out-patient setting, under cystoscopic guidance and oral sedation. Radiofrequency energy is applied to a few drops of water (0.5ml) to create vapor inside a hand-held device. The patient is placed in the lithotomy position and the delivery device is inserted into the urethra; the total penetrating length of the vapor needle is fixed at 10.25mm. Its tip is visually positioned and inserted approximately 1cm distal to the bladder neck. Once the delivery system is within the prostate, the needle is deployed, and a 9-second burst of water vapor is injected into the prostatic tissue. This disperses rapidly and homogeneously through the tissue spaces and immediately condenses to water releasing the energy stored in the vapor into the cell membranes causing cell death and necrosis. The needle is retracted after each treatment and repositioned in 1cm increments distal from the previous site with the objective of creating adjacent overlapping lesions running parallel to the natural slope of the urethra. Usually 1-3 injections are needed for each lateral lobe and 1-2 injections for the median lobe. The total number of injections may vary according to size of the hypertrophied prostate tissue and the length of the urethra (McVary 2016, Woo 2017, Chung 2018).

Potential procedure-related side effects include acute urinary retention, failure of the procedure requiring secondary surgery, posttreatment dysuria, hematuria, frequency & urgency, hematospermia and urinary tract infection. According to the manufacturer, most of these events resolve within 3 weeks of the procedure, but there is a possibility that some may last longer.

Medical Technology Assessment Committee (MTAC)

Convection Radiofrequency Thermal Therapy with Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy
04/21/2018: MTAC REVIEW
Evidence Conclusion:

- There is no published evidence to determine the comparative efficacy and safety of convection radiofrequency thermal therapy with the Rezūm System and transurethral resection of the prostate (TURP), open simple prostatectomy, or other noninvasive intervention currently used in practice for relieving bothersome lower urinary tract symptoms secondary to benign prostatic hypertrophy.
- The published literature on Rezūm System consisted of one relatively small randomized sham- controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality.
- The published literature only provides low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

Articles: The literature search for studies on the efficacy and safety of Rezūm system for the treatment LUTS secondary to BPH, identified one randomized sham-controlled trial that reported three years follow-up results in 4 publications (McVary 2015, 2016 & 2018, and Roehrborn 2017), as well as three pretest- posttest studies (one small pilot study with 2 years follow up results [Dixon 2012, and 2016] and two retrospective analyses [Darson 2017 and Mollengarden 2017]). All 4 studies were critically appraised. See Evidence Table 1.

The use of Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Rezūm for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH)
03/04/2019: INTC REVIEW
Evidence Conclusion: There is insufficient evidence to draw a conclusion on use of Rezūm. The existing evidence is of insufficient quantity and quality.
Articles: The published literature on Rezūm System consisted of one relatively small randomized sham-controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality. Two indirect comparisons of Rezūm versus other medical therapy trial data were also reviewed.

Back to Top

The available published literature provided low quality evidence suggesting that treatment with Rezūm System may improve LUTs secondary to BPH compared to sham therapy or no treatment.
https://cl.kp.org/pkc/national/cpg/intc/topics/03_04_191.html

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)
03/21/2016: MTAC REVIEW
Evidence Conclusion: Conclusion from INTC review - "Urolift may be viable alternative to TURP for patients with LUTS secondary to BPH. Short-term data from low to moderate quality, industry-funded studies conclude that Urolift is effective and safe. The overall quality of the evidence is low to moderate. However, due to concerns regarding risk of bias in these studies, a definitive conclusion regarding the long-term safety and effectiveness of UroLift cannot be made from existing evidence. Additional, high quality studies with longer follow-up are needed to confirm preliminary findings".
Articles: Since the search did not identify new studies, and because INTC evidence review is recent, their review can be adopted. In addition, the search did not find studies comparing PUL to medical management. See Summary of RCTs.

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)
06/28/2017: MTAC REVIEW
Evidence Conclusion: One study (C Roehrborn et al., 2016) (See Evidence Table 1) assessed the long term (4 years) effectiveness and safety of PUL. PUL was compared to sham control. Characteristics of patients were similar. Patients were randomized to either PUL (N=140) or sham control (N=66) at 19 centers in North America and Australia and followed for 4 years. The authors reported that Urolift improved urinary symptoms, preserved sexual and ejaculatory function with minor adverse events. The authors indicated that durability of these effects needs to be confirmed at 5-year follow-up. The risk of bias is unclear for incomplete outcome data and the major limitation is the high attrition rate. The author of the previous study (Claus Roehrborn et al., 2017) (See Evidence Table 2) confirmed the durability of PUL effects in the 5-year follow-up study. Urinary symptoms (IPSS), BPHII, flow rate (Qmax), QoL, erectile and ejaculation functions were improved and /or preserved with minimal complications. Another abstract was reviewed (Henry Woo). Comparison was made between PUL and sham. This was a crossover study wherein 53 patients were enrolled. Patients were treated with sham, then crossover occurred, and patients were followed for 4 years. Compared to baseline, IPSS, QoL, and BPHII statistically improved at 45%, 49%, and 44% respectively (P<0.001). Flow rate (Qmax) also increased by 50% (P=0.01). Adverse events were mild. Level of evidence: In the first two studies, the risk of bias is unclear for incomplete outcome data and low in other domains of risk of bias assessment; no serious precision or directness issues were identified; findings were consistent; the quality of the study assessed by Modified Jadad Scale is high. The studies provide moderate evidence to support the use of PUL.
Conclusion:
- The long-term effectiveness and safety are based on three articles that compare PUL versus sham over 4 and 5 years. Compared to sham, moderate level of evidence indicates that PUL is effective and durable in patients with LUTS due to BPH on the long-term.
- The technology is also safe with minimal complications.

Articles: Three articles were reviewed: Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Rukstalis, D. (2016). Prospective, randomized, blinded study of Prostatic Urethral Lift (pul): four-year results. BJU Int, 117, 19-20. Roehrborn, C., Gange, S., Shore, N., Giddens, J., Bolton, D., Cowan, B., Te, A. (2017). PD27-01. 5 year prospective, randomized, controlled study results on the minimally invasive prostatic urethral lift (PUL). J Urol, 197(4), e511. Crossover study on the prostatic urethral lift (pul): 4-year results. Henry Woo, Sydney, Australia; Jack Barkin, Toronto, Canada; Damien Bolton, Heidelberg, Australia; Prem Rashid, Port Macquarie, Australia; Anthony Cantwell, Daytona Beach, FL; William Bogache, Myrtle Beach, SC; Stephen Richardson, Salt Lake City, UT; Ronald Tutrone, Baltimore, MD; James Fagelson, Englewood, CO; Peter Chin, Figtree, Australia

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate artery embolization for benign prostatic hyperplasia (BPH)

Back to Top

10/14/2019: MTAC REVIEW

Evidence Conclusion:

- Low-quality evidence shows that prostatic artery embolization (PAE) may be less effective than TURP in terms of patient-reported and functional outcomes on the short-term.
- Low-quality evidence suggests that PAE may cause fewer complications than TURP, preserve erectile function, and decrease the duration of hospitalization. More RCTs with enough power and longer follow-up are warranted.
- There is insufficient evidence to compare PAE vs open prostatectomy.

Articles: PubMed search was conducted up to August 8, 2019 with the search terms prostate artery embolization. Other search terms included low urinary tract symptoms or LUTS, and benign prostatic hyperplasia or BPH. The search yielded 7 meta-analyses. Of these, four were retained (two meta-analyses with comparative studies and two with noncomparative studies). The other meta-analyses are included in other references because their findings are similar to that of the two meta-analyses of noncomparative studies retained.
In addition, the search yielded 8 RCTs. Of the 8 RCTs, none was retained (RCTs were either included in meta-analysis or were out of scope). Regarding nonrandomized studies, search yielded 18 studies, but none was included due to their inclusion in the meta-analyses of noncomparative studies. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Prostate artery embolization for benign prostatic hyperplasia (BPH) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Transurethral Waterjet Ablation (Aquablation, Hydroblation)

04/10/2023: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence, to date, to determine that Aquablation therapy is safer and more effective than TURP, robotic simple prostatectomy, or other minimally invasive procedures in improving lower urinary tract symptoms attributed to BPH, in men with small, moderate, or large volume prostates.

- The body of evidence on Aquablation for the treatment of lower urinary tract symptoms due to BPH, consists of a single relatively small randomised controlled study (WATER trial) with limitations, several case series, conducted in different countries, and meta-analyses pooling their results. Except for WATER sub-study and WATER II studies, all the other single arm studies included men with any prostate volume (ranging from 20-154 cc). All were sponsored by PROCEPT BioRobotics the manufacturer of the device used in Aquablation which can bias the research results.

- Though the published literature includes a RCT showing that aquablation is not inferior to TURP, and may be associated with better ejaculatory function and less adverse events in highly selected participants with LUTS/BPH and prostate volume 30-80ml, the study had its limitations and risk of bias, that lowers the certainly of evidence it provides.

- More independent randomized controlled trials are needed to confirm and /or provide more evidence on the comparative safety and efficacy of Aquablation therapy to other surgical or minimally invasive procedures currently used in practice for the treatment of LUTS attributed to BPH, in men with prostate volumes up to 80 cc and in men with larger prostate volumes.

Articles: The literature search for published studies comparing transurethral aquablation of the prostate versus TURP, robotic prostatectomy, or other MITs, identified one phase 3 multicenter, international clinical trial (WATER [Gilling et al, 2018, 2019, 2020 and 2022]) that compared Aquablation therapy vs. TURP for the treatment of LUTS/BPH in men with prostate volume 30-80 ml. Other published studies on Aquablation for BPH consisted of several small to relatively small prospective, multicenter, or single center studies without controls or comparison groups, as well as three systematic reviews with meta-analyses (Hwang, et al, 2019, Manfredi, et al, 2022, and Chen, et al, 2022), two network meta-analyses (Sajan, et al, 2022, and Tanneru, et al 2021), that indirectly compared the outcome of different minimally invasive treatments for BPH; and several qualitative systematic reviews.

The search did not identify any RCT that directly compared Aquablation to TURP in men with prostate volume larger than 80 ml, or any RCT that compared Aquablation versus simple prostatectomy, laser ablation of the prostate,

Back to Top

laser enucleation of the prostate, REZUM, or any other minimally invasive therapy in men with prostate volume less or greater than 80 ml.

WATER trial was selected for critical appraisal. The single-arm studies and two meta-analyses (Chen, et al, 2022, and Manfredi et al, 2022) were also reviewed. The Cochrane review (Hwang, et al 2019) only included the WATER trial, and its assessment of the trial is a briefly summarized. The network meta-analyses with no direct comparison between aquablation and other interventions, were excluded from the current review of the technology. See Evidence Table.

Hayes Technology Assessment

Aquablation therapy is a minimally invasive procedure that ablates overgrown prostatic tissue in order to restore patency to the urethral passageway. High-velocity saline is sprayed under robotic guidance in order to ablate only the targeted prostatic tissue while sparing all surrounding tissue.

Conclusion
A low-quality body of mainly single-arm studies suggests Aquablation may improve LUTS associated with BPH at short- to intermediate-term follow-up without impact on sexual function or serious safety issues. One comparative study suggests Aquablation may be comparable to TURP; however substantial uncertainty remains due to the paucity of comparative evidence and the limited long-term evidence regarding the durability and safety of Aquablation. Furthermore, clarity is lacking as to which patient populations are likely to benefit the most from Aquablation therapy.

Hayes Rating: C

Hayes. Hayes Technology Assessment. *Aquablation for Treatment of Benign Prostatic Hyperplasia.* Dallas, TX: Hayes; March 30, 2021. Retrieved January 18, 2023, from https://evidence.hayesinc.com/report/htb.aquablation5017

Applicable Codes

Transuretheral Waterjet Ablation –

Medicare – Considered Medically Necessary when the criteria in the applicable policy statements listed above are met

Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
HCPC Codes	**Description**
C2596	Probe, image guided, robotic, waterjet ablation

Urolift - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant

Back to Top

52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

Rezūm –
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy

Prostate Artery Embolization (PAE) - Considered Not Medically Necessary:

CPT® Codes	Description
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction
ICD-10 Codes	**Description**
N35.010-N35.016; N35.1-N35.919	Urethral stricture
N40.0-N40.1	Enlarged prostate (EP)
N40.2-N40.3	Nodular prostate
C61	Malignant neoplasm of prostate

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/03/2019	12/03/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	05/04/2023

Revision History	Description
12/03/2019	Merged all BPH criteria (Urolift, Rezūm, PAE) into one document
12/03/2019	MPC approved non-coverage policy for Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)
05/05/2020	Added diagnosis codes N35.010-N35.92, N40.0-N40.3 and C61 (PAE); Added CPT code 53854 and removed 53899 (Rezum)

Back to Top

10/06/2020	MPC approved medical necessity criteria for Rezūm. Requires 60-day notice, effective date 3/1/2021.
04/25/2022	Added statement to Medicare section – Medicare covers PAE if part of an IDE study.
02/07/2023	Added 0421T code with Medicare coverage LCD. Added Hayes report.
05/02/2023	Added MTAC review for Transurethral Waterjet Ablation. MPC endorsed MTAC's decision and continued a position of non-coverage.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Brachytherapy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	4/01/2016 Noridian retired Local Coverage Determination LCD Brachytherapy: Non-Intracoronary (L34065).These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

1) Breast Cancer - Brachytherapy as an adjunct to whole breast radiation is covered when recommended by the treating practitioner. Patients eligible for brachytherapy as a sole treatment alternative to whole breast radiation therapy must meet **ALL of the following** criteria:

   A. Age ≥ 50*
   AND
   B. Diagnosis of unifocal invasive ductal cancer with **ALL** of the following:
      a. Tumor size ≤ 3cm
      b. Negative surgical margins at 2mm
      c. Negative nodal status
   OR

   C. Diagnosis of ductal carcinoma in situ (DCIS) with ALL of the following:
      a. Detected on screening
      b. Low to intermediate nuclear grade
      c. Tumor size ≤ 2.5 cm
      d. Resected with margins negative at ≥ 3 mm

*Age 40-49 meeting requirements above on a case by case basis.

Contraindicated for any of the following:

Back to Top

A. age < 40
B. lobular disease
C. DCIS that does not meet the indications above
D. EIC
E. anatomic limitations or
F. angiolymphatic space invasion

2) High-Dose Rate Brachytherapy for Prostate Cancer
a) High-dose rate (temporary seed implantation) prostate brachytherapy may be considered medically necessary under the following conditions:
- When combined with external beam radiation as a “boost” or
- When used for early stage prostate disease as monotherapy.

Standard brachytherapy is covered without medical necessity review for:
Coronary Artery Brachytherapy, Intravascular Coronary Brachytherapy
Endobronchial Brachytherapy - Lung Cancer
High-Dose or Low-Dose Brachytherapy for Cervical and Endometrial Cancer
Prostate Cancer

Procedure	Criteria
AccuBoost peripheral breast brachytherapy Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background
Brachytherapy, also called internal radiation therapy, allows a physician to use a higher total dose of radiation to treat a smaller area and in a shorter time than is possible with external radiation treatment. Brachytherapy involves placing a radioactive material directly inside or next to the tumor. It has been proven to be very effective and safe, providing a good alternative to surgical removal of the prostate, breast, and cervix, while reducing the risk of certain long-term side effects.
There are two types of brachytherapy – temporary and permanent. In temporary brachytherapy, the radioactive material is placed inside or near a tumor for a specific amount of time and then withdrawn. Temporary brachytherapy can be administered at a low-dose rate (LDR) or high-dose rate (HDR).
Permanent brachytherapy, also called seed implantation, involves placing radioactive seeds or pellets (about the size of a grain of rice) in or near the tumor and leaving them there permanently. After several weeks or months, the radioactivity level of the implants eventually diminishes to nothing. The inactive seeds then remain in the body, with no lasting effect on the patient.

Evidence and Source Documents
Breast Cancer
Coronary Artery Brachytherapy, Intravascular Coronary Brachytherapy
Endobronchial Brachytherapy - Lung Cancer
High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
High-Dose Rate Brachytherapy for Prostate Cancer
Prostate Cancer
Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma

Back to Top

Date Sent: 4/29/24

Medical Technology Assessment Committee (MTAC)

Breast Cancer Brachytherapy

BACKGROUND

In the last two decades, the treatment of early-stage breast cancer has shifted from radical mastectomy to breast conserving therapy (BCT). This involves lumpectomy followed by whole breast external beam radiotherapy (WBRT). Several large randomized controlled trials with long-term follow-up showed that BCT has equivalent survival rates to the modified radical mastectomy among patients with early stage breast cancer. In addition, BCT has better cosmesis and less psychological and emotional trauma for women compared to mastectomy. Researchers believe that whole breast irradiation after lumpectomy reduces local breast recurrence by eliminating residual cancer at the surgical site, as well as occult areas of in-situ or infiltrating cancer in remote areas in the breast. The use of BCT is underutilized in the United States mainly due to the long course of conventional whole-breast radiation therapy, which is typically delivered daily 5 days per week for 5 to 7 weeks. This may be a problem for working women, elderly patients, or those living at a considerable distance from a treatment center. WBRT may also delay or be delayed by the initiation of systemic adjuvant chemotherapy. Investigators also found that treating the entire volume of the breast may deliver small radiation doses to the adjacent tissues leading to acute and chronic toxicity to the skin, heart, lung, and contralateral breast (Fisher 1995, 2002, Baglan 2001, Veronesi 2002, Chen 2007, Cuttino 2007). Recently, accelerated partial breast radiation therapy (APBI) has been proposed as an alternative approach to WBRT. APBI involves the treatment of the lumpectomy bed plus a 1-2 cm margin of breast tissue. This is based on the assumption that the microscopic tumor rarely extends 2 cm beyond the initial resection cavity when the margins are negative on final pathologic examination. Reducing the target allows the delivery of APBI and completing the treatment in less than one week. Several methods for delivering APBI were proposed and/or used. These approaches include multicatheter interstitial brachytherapy, balloon catheter brachytherapy, 3-D CRT (conformal radiation therapy) and intraoperative radiation therapy. These techniques are widely different in terms of radiation delivery, degree of invasiveness, length of treatment, and acceptance by radiation oncologists (Chen 2007, Chao 2007). Breast brachytherapy involves the placement of radioactive sources inside the breast to deliver a relatively high dose of radiation to the tissue immediately surrounding the lumpectomy site, and very little dose to the surrounding normal structure. The interstitial multicatheter system, the most common method used, involves the placement of a number of catheters into the breast to guide the radioactive materials to the intended area. Pellets of iridium-192 are then inserted into the catheters over the course of the treatment. The catheters are briefly connected to a dose-rate brachytherapy machine for internal radiation treatment, which takes about ten minutes each. After the course of treatment is completed the catheters are removed. The procedure requires significant technical expertise, and can be difficult and challenging (Chen 2007, Bovi 2007, Haley 2008, Kacso 2008). Balloon-based brachytherapy Several balloon-based brachytherapy devices were developed as an alternative to the interstitial multicatheter system to be more user-friendly to the clinician and more accessible and better tolerated by the patient. The MammoSite brachytherapy (MSB) system (Hologic, Marlborough, MA) was the first developed balloon-based brachytherapy device. It consists of a small balloon connected to an inflation channel and a catheter for the passage of a high dose rate brachytherapy dose (Iridium-1 92 [192Ir]. The device is implanted in the lumpectomy cavity during or following breast surgery. The balloon is inflated with sterile saline containing a small amount of radiographic contrast to a size that completely fills the cavity and ensures conformance of the tissue to the balloon. A computed tomography scan is obtained to assess the balloon conformance to the lumpectomy cavity and determine its symmetry, diameter, distance from skin, planning target volume, and the dose distribution. After treatment is completed in several days, the balloon is deflated, and the catheter is removed. The treatment with the MammoSite device generally delivers 34 Gy in 10 fractions (3.4 Gy /fraction twice daily with a minimum of 6 hours between the fractions on the same day). Investigators recommend the system for patients with ductal carcinoma in situ, invasive ductal carcinoma, and primary tumors with a diameter less than 3cm. It may not be suitable for patients with small breast or for tumors located in the upper inner quadrant because of the requirement for skin-to-cavity distances (Bensaleh 2009, Njeh 2010). Xoft Axxent® (Xoft, Inc., Fremont, CA) electronic brachytherapy is a modified form of balloon-based brachytherapy. Similar to MammoSite, Xoft Axxent consists of a balloon catheter that is percutaneously inserted into the lumpectomy cavity. The system uses 50 kiloVolt (kV) X-ray source (an electronic radiation source) rather than radioisotope, such as iridium-192 high dose rate (HDR) source. The x-ray source consists of a miniature x-ray tube that is inserted in the balloon catheter and delivers the radiation therapy to the patient. The system may be operated at variable currents and voltages to change the dose rate and penetration properties. The Xoft Axxent does not require a high-dose rate afterloader unit, or treatment in a shielded vault. Another potential advantage is the lower energy dose deposited in adjacent normal tissues, compared to other forms of balloon brachytherapy. It is unknown if these advantages would be outweighed by a potential harm of fat necrosis as a result of a significant dose inhomogeneity (Strauss 2009, Dickler 2009). SenoRx Contura device (SenoRx, Inc, Aliso Viejo, CA) differs from MammoSite in that it has multiple lumens for passage of 192Ir HDR source. In addition to the central lumen, the Contura balloon has 4

Back to Top

surrounding channels to accommodate the HDR source. The surrounding channels have 5 mm offset around the central channel. The approach provides additional flexibility and has the potential of improving normal tissue sparing. The device includes a port which can be connected to suction to remove seroma fluid or air in an effort to improve conformity (Strauss 2009, Njeh 2010). Image guided radiation therapy: AccuBoost peripheral breast brachytherapy. The AccuBoost® peripheral breast brachytherapy system (Advanced Radiation Therapy of Billerica, MA) was developed to provide a means of delivering partial breast irradiation treatment regimen noninvasively under mammographic image guidance. The AccuBoost system consists of three main components: (1) A conventional mammography unit to immobilize the breast and localize the lumpectomy site. (2) Computed Radiography (CR) system to provide radiographic images of the lumpectomy cavity (and/or implanted fiducial markers) for cavity/ margin localization at the beginning of each fraction. The CR system can also record the exit dose distribution and provide information on the therapeutic dose. (3) AccuBoost Applicators: high dose rate (HDR) Ir192 brachytherapy source remote afterloading system to deliver brachytherapy in a peripheral noninvasive manner. The applicators are made from tungsten in the form of half-cylinders. The patient's breast is compressed to a thickness of 3-8 cm between two mammography paddles and imaged with a radiopaque coordinate grid. The radiation oncologist determines the isocenter coordinates and appropriate applicator size and shape based on the image. The collimating HDR 192Ir brachytherapy applicators are then applied on either side of the breast along a common axis and the brachytherapy dose delivered. The process is repeated along an orthogonal axis to distribute the entrance dose (Rivard 2009, Yang 2009, AccuBoost website). MammoSite, multi-lumen MammoSite, Axxent Electronic brachytherapy, and SenoRx Contura device are all FDA approved to deliver intracavity radiation to the surgical margins following lumpectomy for breast cancer. AccuBoost® system for delivering guided radiation therapy is also FDA approved.

06/12/2002: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: The studies reviewed aimed at determining the equivalence between brachytherapy and external beam radiation, yet none of them was designed or analyzed in a fashion to study equivalence, which is a major threat to their validity. The authors set no equivalence boundary but took the lack of statistically significant difference between the two treatments as a proof of equivalence, which could lead to an erroneous judgment. Moreover, the studies were prospective, with a historical control group. The patients were not randomly assigned to the treatment group, and it is not discussed if they were consecutive, which may be a source of selection bias. The cohorts of women treated with brachytherapy were prospectively followed for a variable period of time (median 36 months in Vicini's study, and 74 months in King's study). The follow-up period was as short as a few months among some patients, and the dropout rate in the brachytherapy group was 82% after 5 years in Vicini's study. The reason for this high dropout rate was not discussed. In the two studies, data on the control group were obtained from retrospective chart reviews. Patients in the brachytherapy group received the treatment at either a low- or high-dose rate but were analyzed as one group. There were some differences in the baseline characteristics that were not adjusted for in the analysis of the results. The overall control and cosmetic outcomes of the brachytherapy as a sole treatment after lumpectomy were similar to that achieved by the external beam radiation therapy. However, these results cannot be generalized mainly due to the design of the study as well as the selection, observation and other biases in the studies. Randomized controlled studies with large sample size, power, and longer follow-up periods are needed to determine the long-term benefits and harms of brachytherapy used as a sole treatment after breast conservative therapy.
Articles: The search yielded 81 articles. Many were review articles, opinion pieces, or addressed brachytherapy as a boost, not a sole treatment after lumpectomy. The literature did not include any randomized controlled trials, or meta-analyses. There was a number of small case series with no control group, and two prospective studies that compared brachytherapy with external beam irradiation. These two studies were selected for critical appraisal. Vicini FA, Baglan KL, Kestin KL, et al. Accelerated treatment of breast cancer. *J Clin Oncol* 2001; 19:1993-2001. See Evidence Table. King TA, Bolton JS, Kuske RR, et al. Long-term results of wide field brachytherapy as the sole method of radiation therapy after segmental mastectomy for $T_{is, 1, 2}$ breast cancer. *Am J Surg* 2000; 180:299-304. See Evidence Table.

The use of brachytherapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/07/2005: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: Brachytherapy as an adjunct or boost to whole breast radiation therapy:
The two randomized controlled trials reviewed (Polgar 2002, and Poortmans 2004) evaluated brachytherapy for early stage breast cancer with no or limited spread to the axillary lymph nodes. Both trials compared boost to no boost therapy after breast conserving surgery and whole breast external radiation therapy. Different techniques for the boost therapy were used (brachytherapy and electrons in Polgar's trial, and electrons, photon beams, and

Back to Top

interstitial brachytherapy in Poortman's trial). The trials were not blinded, and the patients were randomized to boost or no boost treatment but were not randomized to the different boost techniques used. The latter was selected according to the physicians' preference. Poortman et al's trial was still ongoing, and in this publication the authors did not present a comparison between boost and no boost treatments but compared the outcomes of the different boost techniques used. Polgar et al reported a significant improvement with the boost vs. no boost treatment. The analysis provided however does not indicate that there was a statistically significant improvement as reported by the authors. The boost treatment was also found to be associated with an increased incidence of moderate to severe complications. Brachytherapy as a sole treatment alternative to whole breast radiation therapy. Vicini 2003, and Polgar 2004 were prospective cohort studies with a comparison group. Patients, however, were not randomly assigned to the treatment groups but matched to historical controls from the records or databases. The criteria used to assess the effect of the treatment included the degree of local control, disease free, relapse-free, and cancer free survival, as well as cosmetic outcome, and side effects. These two studies aimed at determining the similarity between brachytherapy and external beam radiation, yet none of them was designed or analyzed in a fashion to study equivalence, which is a major threat to their validity. The authors set no equivalence boundary but took the lack of statistically significant difference between the two treatments as a proof of equivalence, which could lead to an erroneous judgment. In conclusion, interstitial brachytherapy may be a promising treatment, but the studies reviewed do not provided sufficient evidence to conclude that it may be used as an alternative to whole breast radiation therapy after breast conserving surgery. Randomized controlled studies with large sample size, power, and longer follow-up periods are underway to determine the long-term benefits and harms of brachytherapy used as a sole treatment after breast conservative therapy.
Articles: The search revealed more than 200 articles. Many were reviews, editorials, or dealt with the technical aspects of the technology. There were several case series, retrospective studies, and small trials. Others compared mastectomy with external beam radiation therapy, and in one trial brachytherapy was compared to WBRT without breast lumpectomy. Studies were selected for review according to the following criteria: 1. Evaluating brachytherapy as an adjunct to whole breast radiation therapy or as a sole treatment after breast-conserving surgery, 2. Prospective design, and 3. Including a comparison or control group. Two large RCTs on the use of brachytherapy as a boost to WBRT were identified and critically appraised. Several studies on the use of brachytherapy as an alternative to WBRT were published after MTAC reviewed the technology in 2002. All evaluated brachytherapy for early stage breast cancer with no or limited spread to axillary lymph nodes. Harms et al (2002), Keisch et al (2003), Perera et al (2003), Richard et al (2004), and Shah et al (2004) studies were case series with no control or comparison groups. These studies mainly evaluated the safety of the treatment rather than efficacy. Only two of the identified studies (Vicini 2003 and Polgar 2004) included a comparison group and were selected for critical appraisal. *Evidence tables were created for the following studies: For the use of brachytherapy as an adjunct to whole breast radiation therapy:* Polgar C, Fodor J, Orosz Z, et al. Electron and high dose-rate brachytherapy boost in the conservative treatment of stage I-II breast cancer. First results of the Randomized Budapest Boost Trial. *Strahlenther Onkol* 2002; 178:1205-1211. See Evidence Table Poortmans P, Bartelink H, Horiot JC, et al. The influence of the boost technique on local control in breast conserving treatment in the EORTC "boost versus no boost randomized trial. *Radiother Oncol* 2004; 72:25-33. See Evidence Table *For the use of brachytherapy as a sole treatment alternative to whole breast radiation therapy:* Vicini F, Kestin L, Chen P, et al. Limited field radiation therapy in the management of early-stage breast cancer. *J Natl Cancer Inst* 2003; 95:1205-1211. See Evidence Table Polgar C, Major T, Fodor J, et al. High dose-rate brachytherapy alone versus whole breast radiotherapy with or without tumor bed boost after breast conserving surgery: seven-year results of a comparative study. *Intl J Radiat Oncol* 2004; 60:1173-1181 See Evidence Table

The use of brachytherapy as an adjunct or boost to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of brachytherapy as a sole treatment alternative to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/15/2011: MTAC REVIEW
Breast Cancer Brachytherapy
Evidence Conclusion: There is insufficient evidence to date to determine whether accelerated partial breast irradiation delivered by balloon-based brachytherapy or AccuBoost is safe and provides non-inferior or superior local tumor control and survival compared to conventional whole breast irradiation in patients with early stage breast cancer treated with breast conservative therapy. Polgar and colleagues' (2008) RCT, reviewed earlier, and Antonucci et al's study (evidence table 1) had several methodological flaws which limit generalization of their results. Large RCTs with long-term follow-up are needed to determine the equivalence or superiority of accelerated partial breast irradiation therapy to whole breast external beam radiation therapy. A phase 3 trial comparing APBI to whole breast irradiation in over 4,000 women with stage 0, I, or II breast cancer is underway. The trial is jointly conducted by the National Surgical

Back to Top

Adjuvant breast and Bowel Project (NSABP) and the Radiation Therapy Oncology Group (RTOG). Patients in the APBI will be treated using one of three modalities: interstitial brachytherapy, MammoSite brachytherapy, or 3-D conformal EBRT. Outcome measures include overall survival, recurrence free survival, distant disease-free survival, toxicity, cosmesis, and convenience of the care. The primary aim of the trial is determining whether APBI would provide equivalent local breast control as WBRT in early stage breast cancer. Other ongoing trials include the Canadian RAPID trial which is recruiting over 2000 patients to be randomized to either whole breast irradiation or 3-D CRT, and an international phase III large trial supported by the European Brachytherapy Breast Cancer GEC-ESTRO Working Group. This trial will randomize 1170 women between WBRT and APBI using high-dose rate or pulsed-dose rate brachytherapy. The results of these, and a number of other ongoing trials, will provide data on the efficacy and toxicity of partial breast irradiation in the treatment of early stage breast cancer as compared to WBRT. They may also provide data on appropriate candidates for APBI and on the advantages and disadvantages of each method.

Articles: Objectives: To determine whether accelerated partial breast irradiation leads to non-inferior or superior local tumor control and survival compared to conventional whole breast irradiation, when used as an adjuvant therapy after lumpectomy in patients with early stage breast cancer. To determine whether the use of balloon-based brachytherapy systems is safe and effective for delivering adjuvant radiation therapy after lumpectomy in patients with early stage breast cancer. To determine whether the image guided radiation therapy using AccuBoost peripheral breast brachytherapy system is safe and effective for delivering adjuvant radiation therapy after lumpectomy in patients with early stage breast cancer. Screening of articles/selection: The search revealed around 150 articles on accelerated partial breast irradiation (ABPI). The majority of the published empirical studies were phase I/II trials with no comparison group, different sizes, and follow-up durations. There were no new randomized trials, published after the last review, on APBI therapy delivered by MammoSite, Axxent, Contura, or AccuBoost systems. The search identified a recently published interim analysis on the acute toxicity in a trial that compared conventional whole breast radiation with APBI plus IMRT, a nonrandomized study that examined the dosimetric advantage of Contura catheter vs. MammoSite, and a small case series of patients treated with Contura catheter. The literature search also revealed a report on four-year outcomes of a prospective study, with no control group, on the efficacy and toxicity of 3-D-CRT to deliver APBI, and a feasibility study with 11 patients treated with intraoperative radiation using the Axxent electronic brachytherapy system. No published clinical studies on AccuBoost system were identified. A recent analysis comparing APBI with WBRT was critically appraised. See Evidence Table**.** Antonucci JV, Wallace M, Goldstein NS, et al. Differences in patterns of failure in patients treated with accelerated partial breast irradiation versus whole-breast irradiation: a matched-pair analysis with 10-year follow-up. *Int J Radiat Oncol Biol Phys.* 2009;74:447-452. See Evidence Table.

The use of brachytherapy as an adjunct or boost to whole breast radiation therapy in the treatment of breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Coronary Artery Brachytherapy Intravascular Coronary Brachytherapy

BACKGROUND

Percutaneous transluminal coronary angioplasty (PTCA) is a widely used therapy for obstructive coronary artery disease. It is limited however by the high rate of restenosis which occurs in 30-60% of patients after a successful PTCA. The main mechanisms of restenosis include elastic recoil of the vessel, rapid platelet deposition, vascular remodeling and neointimal hyperplasia. Endovascular stents have been shown to reduce stenosis by preventing the elastic recoil and pathological remodeling. However, stents do not prevent the restenosis caused by neointimal hyperplasia, but rather initiate an inflammatory reaction that induces more proliferation than other coronary devices. An effective treatment of restenosis within the stent will be the suppression of this neointimal hyperplasia. Radiation therapy which is known for its antiproliferative effect has been proposed as a treatment for in-stent restenosis. Over the past six years, studies on the use of various techniques to apply intracoronary radiation which is known as intracoronary brachytherapy have been showing encouraging results. Brachytherapy uses a relatively large localized dose of beta or gamma radiation. It does not provide an immediate outcome. If effective, it reduces the rate of restenosis in the vessel in the target area. This effect can be measured by angiograms performed six months after the procedure. Brachytherapy requires a multidisciplinary team to deliver it including an interventionist cardiologist, a radiation oncologist, physicist and safety officer.

06/13/2001: MTAC REVIEW

Coronary Artery Brachytherapy Intravascular Coronary Brachytherapy

Evidence Conclusion: GAMMA-One (Leon et al), beta-WRIST (Waksman et al), SCRIPPS (Teirstein et al), and the START (In press) trials are four of the well-designed RCTs evaluating the use of brachytherapy in the management of in-stent restenosis. There are several other ongoing studies. These trials showed that patients

Back to Top

with in-stent restenosis treated with brachytherapy needed less revascularization than those treated with PTCA or PTCA and stents without radiation. In two of the studies, intracoronary brachytherapy tended to increase the risk of late thrombus formation, but this was statistically insignificant. Although these trials reported that major cardiac events (MACE) were lower among patients who received brachytherapy, none of them had adequate power, or follow-up to detect the difference in myocardial infarction and death rates alone. Brachytherapy may also cause acute damage in the coronary arteries including aneurysm, pseudoaneurysm, arterial dissection, or rupture of the artery. None of these acute complications was reported in any of these trials. In addition, radiation may lead to a long-term damage on the surrounding tissue and have adverse effects on the clinical personnel. These long-term complications are unknown. The longest data available is the three-year follow-up in the SCRIPP trial (Teirstein et al). The nature of radiation needs a long-term follow-up.

Articles: The search yielded 79 articles. Many were just reviews and literature. There were eleven articles on randomized controlled studies, more than one publication for each of the major trials, GAMMA-one, beta-WRIST and SCRIPPS. The START trial was still in press. These major randomized controlled studies were evaluated in detail. *Evidence tables were created for the following studies:* Leon MB, Teirstein PS, Moses JW, et al. Localized Intracoronary Gamma-Radiation Therapy to Inhibit the Recurrence of Restenosis After Stenting. N Engl J Med 2001; 344: 250-256 See Evidence Table Teirstein PS, Massulo V, Jani S, Popma JJ, et al. Three-Year Clinical and Angiographic Follow-up After Intracoronary Radiation. Circulation 2000; 101: 360-365. See Evidence Table Waksman R, White L, Chan RC, et al. Intracoronary Gamma -Radiation Therapy After Angioplasty Inhibits Recurrence In Patients With In-Stent Restenosis. Circulation 2000; 101: 2165-2171 See Evidence Table
The use of Coronary Artery Brachytherapy for the treatment of restenosis of stent passes all *Kaiser Permanente Medical Technology Assessment Criteria.*

Endobronchial Brachytherapy - Lung Cancer

BACKGROUND

Among all types of malignancy, lung cancer is one of the most difficult to manage and is associated with the highest mortality rate. Its incidence is continuously increasing, with no improvement in mortality. 80-85% of the cases is non-small cell lung cancer (NSCLC). Squamous cell carcinoma and adenocarcinoma account for the majority of the NSCLC. Regardless of the histological type, surgery offers the best potential for cure. However, approximately 75% of the patients present with locally advanced non-resectable disease at the time of diagnosis. The treatment options for these patients are chemotherapy and / or external irradiation therapy, which have low survival rates, and high rates of local recurrence. Endobronchial brachytherapy (EBT or EBB) is an additional treatment increasingly used for centrally localized lung cancer. It can be used alone, or with the external radiation therapy (XRT) to boost the total dose of irradiation used. In earlier studies, it was used as a palliative treatment in case of endobronchial recurrence after XRT. In later studies it is used in combination with high-dose of XRT as a potential curative primary treatment in selected cases. With brachytherapy, radioactive sources usually iridium-192 are placed at the tumor site in the involved branch of the tracheobronchial tree. These will deliver a radiation dose that rapidly and progressively declines with the increasing distance from the source. Any adverse effects on normal tissue should be confined to the immediate vicinity of the bronchus, sparing the lung parenchyma and the esophagus. The procedure is done on outpatient basis. Bronchoscopy is performed under topical anesthesia to determine the field of treatment. A guidewire is then placed in the instrumentation channel of the endoscope, and the bronchoscope is removed. An after-loading catheter is passed on the guidewire, the guidewire is removed, and an applicator for placement of the radiation source is inserted in the catheter. Depending on the number of airway branches involved, 1 to 4 catheters may be placed. The position of the catheter is verified by fluoroscopy. The applicator is then connected to the iridium192 afterloading unit and the irradiation source advanced to the intended position under computer control. The application time ranges from 2 to 15 minutes depending on the dose, and length of the irradiated area. After removing the radioactive source, the catheters are removed, and the patient is observed for 30 minutes. High-dose brachytherapy may be delivered in fractionated doses by repeating the procedure at weekly or biweekly intervals, or twice a day until the entire dose is delivered. The dose varies individually and depends on the patient's clinical condition, history, and concurrent use of XRT. Endobronchial brachytherapy may be associated with acute complications. It could lead to fibrotic airway obstruction and may be linked to fatal hemoptysis depending on the dose, dose per fraction and the concurrent use of XRT.

08/08/2001: MTAC REVIEW

Endobronchial Brachytherapy - Lung Cancer

Evidence Conclusion: The RCTs reviewed were conducted to evaluate the effect of endobronchial brachytherapy either used alone, or in addition to external radiation therapy. Langendijk's study found a statistically significant benefit of adding EBT to XRT in treating atelectasis in patients with endobronchial obstruction in the main bronchus. Huber's study did not show any statistical difference between the two treatments. On the other hand, Stout's study found that external irradiation therapy, had a statistically significant better outcome than EBT (used alone) on the patients' survival and palliation of some symptoms. EBT was not found to be associated with a higher rate of fatal hemoptysis in all three trials. The studies had some limitations

Back to Top

including likelihood of observation bias, incomplete data (all three RCTs), premature termination and lack of power (Langendijk). In conclusion, the efficacy and safety of endobronchial brachytherapy cannot be fully determined from the available evidence.
Articles: The search yielded 54 articles. Selection was based on study type. There were 3 articles on randomized control trials comparing the effect of external irradiation therapy (XRT) vs. endobronchial brachytherapy (EBT) / XRT + EBT, on patients with non-small cell lung cancer. Reviews, editorials and comments were reviewed, but no evidence tables were created. *The three RCTs selected for critical appraisal were:*
Huber RM, Fischer R, Hautmann H, et al. Does Additional Brachytherapy Improve the Effect of External Irradiation? A Prospective, Randomized Study in Central Lung Tumors. Int.J.Radiation Oncology Biol. Phys.1997: 38 (3): 533-540. See Evidence Table Langendijk H, Jong JD, Tjwa M, et al. External Irradiation Plus Endobronchial Brachytherapy in Inoperable Non-small Cell Lung Cancer: a Prospective Study. Radiotherapy and Oncology 2001; 58: 257-268 See Evidence Table Stout R, Barber P, Burt P, et al. Clinical and Quality of Life Outcomes in the First United Kingdom Randomized Trial of Endobronchial Brachytherapy Treatment of Inoperable non-small Cell Lung Cancer. Radiotherapy and Oncology 2000; 56: 323-327 See Evidence Table

The use of endobronchial brachytherapy in the treatment of lung cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* 2 for effectiveness.

High-Dose Rate Brachytherapy for Prostate Cancer
BACKGROUND
Prostate cancer is one of the most common cancers, and the second leading cause of cancer death in men in the United States. The standard management options for localized disease included surgery, radiotherapy, and watchful waiting. However, the optimal treatment is not well defined. Both surgery and radiation therapy are reported to have equivalent outcomes, and each approach has its advantages and disadvantages. Researchers reported that for intermediate and high-risk disease, external beam radiation therapy (EBRT) is the standard treatment, and that there is a dose response for biochemical relapse-free survival. However, dose escalation to >70 Gy is associated with an increase in genitourinary and gastrointestinal side effects. Several techniques have been developed to deliver high doses of radiation to the prostate while sparing surrounding normal tissue. Among these are the three-dimensional conformal radiotherapy (3DCRT), intensity modulated radiation therapy (IMRT), photon therapy, and brachytherapy (Vordermark 2006, Hoskin 2007, Rades 2007). Prostate brachytherapy was introduced in the late 1980s after the development of transrectal ultrasonography and sophisticated treatment planning software. It can be performed as monotherapy or in conjunction with hormone therapy or EBRT. Monotherapy is usually reserved for low-risk cancer, and the combined therapies are used for high-risk disease (Nelson 2007). Interstitial brachytherapy can be delivered using permanent low-dose-rate (LDR) seed implants or temporary high-dose-rate (HDR) implants. The latter entails the temporary placement of higher energy radioactive sources in and near the tumor. An automated machine called an afterloader sequentially moves a high-intensity radioactive source to and from a set of catheters in and around the prostate to deliver a pre-determined radiation dose to the patient's tumor. Following treatment, the radioactive source is withdrawn. Both LDR and HDR have the advantage of conforming high doses of radiation according to the precisely localized target, rapid dose fall-off, and no target movement during treatment. The dose distribution of the LDR mainly depends on the position of the implanted seed, while the HDR uses a steeping source, usually iridium-192, and is thus able to vary both the position and /or dwell time of the source. This has the potential of better target volume coverage and a greater sparing of neighboring organs at risk (Chin 2006). Unlike LDR brachytherapy, HDR brachytherapy usually requires hospitalization of the patient. HDR brachytherapy is also associated with a number of acute and chronic side effects, including urinary urgency and frequency, dysuria, nocturia, urinary retention, urethral stricture, rectal irritation, and impotence.

06/06/2006: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: There is insufficient evidence to draw conclusions about the effectiveness and safety of HDR brachytherapy monotherapy compared to an accepted treatment for prostate cancer.
There is some evidence that HDR brachytherapy plus EBRT results in better biochemical control than EBRT alone. Data are from 2 comparative studies, one randomized and one non-randomized; both studies have threats to validity. There is insufficient evidence to determine whether HDR brachytherapy added to EBRT improves disease-specific or overall survival. In the randomized controlled trial, there was no significant increase in overall survival with HDR brachytherapy plus EBRT; data were not reported for disease-specific mortality. In the non-randomized study, there was not a significant difference in disease-specific mortality. Overall survival was significantly higher in the combined treatment group when 5-year outcomes were modeled using Kaplan-Meier analysis—actual patient data on survival were not reported.
There is insufficient evidence on adverse effects associated with HDR brachytherapy plus EBRT. In the RCT, rates of adverse effects did not differ significantly between groups—however, these comparisons were likely

Back to Top

underpowered. In the cohort study, adverse effects were only reported for the HDR brachytherapy plus EBRT group; 29% of patients developed impotence.
Articles: Note: Studies were identified using N California report but selection of articles for critical appraisal was re-done for the MTAC report. *HDR brachytherapy monotherapy:* There were no randomized controlled trials or non-randomized controlled trials that compared the safety and effectiveness of HDR brachytherapy monotherapy to a different treatment such as observation, surgery or EBRT. All of the studies were case series. Two publications from a single institution compared series of patients who received either HDR brachytherapy or LDR brachytherapy (Vargas et al., 2005 ; Grills et al., 2004). No studies were selected for critical appraisal since none compared HRD brachytherapy to another treatment for prostate cancer. *Combination therapy (HRD brachytherapy plus EBRT):* There was one randomized controlled trial comparing HRD brachytherapy plus EBRT to EBRT alone. There were also two nonrandomized comparison studies and nine case series. One of the non-randomized comparative studies (Jo et al., 2005) was a survey that only reported on quality of life, not clinical outcomes and thus this study was excluded from further review. The RCT (Sathya et al., 2005) and the other non-randomized comparison study (Kestin et al., 2000) were critically appraised. *The studies reviewed were:*
Sathya JR, Davis IR, Julian JA et al. Randomized trial comparing iridium implant plus external-beam radiation therapy with external-beam radiation therapy alone in node-negative locally advanced cancer of the prostate. J Clin Oncol 2005; 23: 1192-1199. **See** Evidence Table Kestin LL, Martinez AA, Stromberg JS et al. Matched-pair analysis of conformal high-dose-rate brachytherapy boost versus external-beam radiation therapy alone for locally advanced prostate cancer. J Clin Oncol 2000; 18: 2869-2880. **See** Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/01/2007: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: High-dose rate (HDR) brachytherapy for prostate cancer was previously reviewed by MTAC on 6/5/06. The report conclusion indicated that there was insufficient evidence to determine the effectiveness and safety of HDR brachytherapy monotherapy compared to an accepted treatment for prostate cancer. For the current review, the literature search revealed one more recent RCT conducted in the UK (Hoskin 2007), that compared external-beam radiation therapy (EBRT) given as a monotherapy vs. its combination with high-dose rate brachytherapy boost for the treatment of prostate cancer. The primary outcome was biochemical relapse free survival. The secondary outcomes were the overall and relapse-free survival, acute and late toxicity, and quality of life. The study had its advantages and limitations. It was randomized, controlled, had sufficient statistical power, high completeness rate, and analysis was based on intention to treat. However, the authors did not discuss blinding of the investigators to the patient allocation, the 55 Gy dose of external beam radiotherapy is considered suboptimal, and the technique of delivering the EBRT changed along the study. Moreover, the follow-up duration was relatively short, and the primary outcome was biochemical relapse free survival which is a surrogate outcome for overall survival. It is considered acceptable by some investigators, due to the long natural history of the disease. Overall, the results of the trial indicate that that the biochemical relapse-free survival was significantly higher among patients in the HDR brachytherapy in combination with external beam radiotherapy group versus those treated with external beam radiotherapy alone. The HDR brachytherapy was also associated with an improved quality of life, without any increase in toxicity. Soumarova and colleagues (2007) compared the acute genitourinary and gastrointestinal toxicity in 97 patients treated with external beam radiotherapy (3D conformal radiotherapy [CRT]) or 3D CRT combined with interstitial conformal HDR brachytherapy for the treatment of histologically verified localized carcinoma of the prostate. The study was prospective but non-randomized: 57 patients received 3D CRT and 40 patients were irradiated with 3D CRT+ HDR brachytherapy. The patients were followed by a radiation oncologist and urologist at 1-3 months intervals, and the acute genitourinary and gastrointestinal toxicities were evaluated using the RTOG criteria. The overall results of the study showed a lower incidence of acute gastrointestinal toxicity in HDR brachytherapy combination therapy group versus those in the 3D CRT monotherapy group. In conclusion the studies published to date do not provide sufficient evidence to determine the efficacy and safety of HDR brachytherapy in the treatment of histologically proven carcinoma of the prostate.
Articles: *HDR brachytherapy monotherapy:* The literature search did not reveal any randomized controlled trials or non-randomized controlled trials that compared the safety and effectiveness of HDR brachytherapy monotherapy to no, or a different mode of treatment as surgery or EBRT. All published studies on monotherapeutic brachytherapy for organ confined or locally advanced prostate cancer, were case series with variable sizes and duration of follow-up. None included a comparison or control group and thus were not critically appraised. *HDR brachytherapy in combination with external beam radiotherapy (EBRT):* There was one recent randomized controlled trial (Hoskin 2007) that compared HDR brachytherapy plus EBRT to EBRT alone, and a non-randomized controlled trial (Soumarova 2007) that compared the acute toxicity of EBRT with and without

Back to Top

HDR brachytherapy, as well as several case series. The two studies were reviewed, Hoskin and colleagues RCT was presented in an evidence table.
Hoskin PJ, Motohashi K, Bownes P, et al. High dose rate brachytherapy in combination with external beam radiotherapy in the radical treatment of prostate cancer: initial results of a randomized phase three trial. Radiother Oncol 2007; May 24. See Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
High-Dose Rate Brachytherapy for Prostate Cancer
Evidence Conclusion: HDR brachytherapy as a monotherapy A recent retrospective cohort study combined data from two centers to evaluate the safety and efficacy of HDR brachytherapy compared to LDR brachytherapy for the treatment of prostate cancer. The primary outcome measures were biochemical control and rate of acute and chronic toxicities. There was no significant difference in biochemical control rates between the HDR brachytherapy and the LDR brachytherapy groups (88% vs. 89%, P=0.62). However, compared to patients treated with LDR brachytherapy, patients treated with HDR brachytherapy experienced significantly lower rates of acute and chronic dysuria, acute urinary frequency and urgency, and acute rectal pain. Results from this study should be interpreted with caution as there was no adjustment for confounding factors, treatment techniques evolved over the study period, the two centers had different treatment procedures, and approximately 29% of patients received neoadjuvant androgen deprivation (Martinez 2009). HDR brachytherapy combined with external beam radiation therapy. A retrospective cohort study that compared the efficacy of HDR brachytherapy in combination with 3D- conformal external beam radiation (3DCRT) with 3DCRT alone for the treatment of prostate cancer found no significant difference in biochemical control, overall survival, or cause-specific mortality between the treatment groups. As side effects were only reported for the combined group, it cannot be determined if patients in the combined group experienced more side effects compared to patients in the 3DCRT alone group (Zwahlen 2010). Conclusion: There is insufficient evidence to determine whether HDR brachytherapy given alone or in combination with EBRT is safe and effective for the treatment of prostate cancer.
Articles: The literature search did not reveal any randomized controlled trials that addressed the safety and efficacy of HDR brachytherapy. A retrospective cohort study was identified that evaluated the safety and efficacy of HDR brachytherapy given as a monotherapy compared to LDR brachytherapy was selected for review. There were several studies that evaluated the safety and efficacy of HDR brachytherapy combined with EBRT; however, the majority of these were case series. A recent study by Zwahlen and colleagues was selected for review as it was the only study with a control group. The following studies were critically appraised:
Martinez AA, Demanes J, Vargas C, et al. High-dose-rate prostate brachytherapy: An excellent accelerated hypofractionated treatment for favorable prostate cancer. *Am J Clin Oncol* 2009 November 30. See Evidence Table Zwahlen DR, Andrianopoulos N, Matheson B, et al. High-dose-rate brachytherapy in combination with conformal external beam radiotherapy in the treatment of prostate cancer. *Brachytherapy 2010;* 9:27-35. See Evidence Table

The use of High-dose rate brachytherapy in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
BACKGROUND
The standard treatment for cervical cancer is external beam radiation therapy (EBRT) combined with intracavity brachytherapy. There is no accepted standard treatment for early endometrial cancer. However, brachytherapy is often used, alone or in combination with EBRT. Intravaginal brachytherapy is believed to be useful for endometrial cancer in part because the vaginal apex is a common site of endometrial cancer recurrence. Brachytherapy refers to internal or local irradiation. In intracavity brachytherapy, radioactive sources are placed in body cavities that are close to the tumor. The relative balance between the two types of radiation treatment (brachytherapy and EBRT) depends on the stage and volume of disease. Generally, as the tumor volume increases, EBRT is favored to achieve a larger volume of homogenous dose (Stitt, 1999). Low-dose rate (LDR) brachytherapy has been available longer and is still used more frequently than high-dose rate (HDR) brachytherapy. There are several potential advantages of HDR brachytherapy, including the ability to treat large clinical patient volume, the lack of need for general anesthesia or bed rest, the ability to individualize treatment, complete radiation protection for staff and the application of multiple fractions on an outpatient basis. Disadvantages of HDR brachytherapy are the higher costs of staffing, equipment and the changing of iridium source every three months. In addition, optimal fractionation schemes for HDR brachytherapy are yet to be well defined and long-term complications are unclear (Stitt, 1999). In a LDR brachytherapy session, instruments need to be in place for 2-3 days. Cervical cancer treatment involves two procedures, approximately one week apart. Radium was used originally, but now cesium-

Back to Top

137 is used. In contrast, with HDR brachytherapy, a treatment session takes minutes. Multiple sessions are generally required; five is a common number for treating cervical cancer. For the treatment of endometrial cancer (brachytherapy alone or in combination with EBRT after a hysterectomy), two sessions of about 1 hour each are required. High-dose rate is generally accepted as being between 50-500 cGy/minute (Tewari & DiSaia, 2002; Hogberg et al., 1999).

06/11/2003: MTAC REVIEW
High-Dose vs. Low-Dose Brachytherapy for Cervical and Endometrial Cancer
Evidence Conclusion: Cervical cancer: With few exceptions, the studies reviewed did not find statistically significant differences in survival between patients receiving HDR and LDR brachytherapy for the treatment of cervical cancer. There were also no significant differences in adverse effects between the HDR and LDR groups. Although the studies suggest that the safety and effectiveness of the two treatments are similar, the studies were not designed as equivalence studies. The lack of a statistically significant finding could be due to a design flaw such as insufficient statistical power or bias. Neither of the RCTs discussed statistical power and both may have been underpowered to detect differences in survival and/or adverse effects between groups. This is particularly true because the results were reported separately by stage of disease which resulted in a smaller sample size for each comparison. The studies also had several threats to validity. Neither of the RCTs had adequate randomization (one allocated patients by birth month and the other alternated patient assignment to treatment group) which could introduce selection bias. In all three studies, there may have been baseline differences between groups that were not controlled for in the statistical analyses. The studies also differed in the extent of external beam radiation treatment the patients received. Endometrial cancer: There are no studies that specifically compare the safety and effectiveness of HDR and LDR brachytherapy for the treatment of endometrial cancer.
Articles: *Cervical cancer:* The search yielded 135 articles. Many of the studies were reviews, opinion pieces or dealt with technical aspects of the procedure. There were four studies that compared the outcomes of patients who received high-dose or low-dose brachytherapy. Two of the studies were randomized and two were non-randomized. The two randomized studies and the prospective non-randomized study were critically appraised:
Hareyama M, Sakata K, Oouchi A et al. High-dose versus low-dose-rate intracavity therapy for carcinoma of the uterine cervix. *Cancer* 2002; 94: 117-124. See Evidence Table
Teshima T, Inoue T, Ikeda H. High-dose rate and low-dose rate intracavity therapy for carcinoma of the uterine cervix. *Cancer* 1993; 72: 2409-2414. See Evidence Table
Endometrial cancer: The search yielded 36 articles. No randomized controlled trials were identified. There were no empirical studies comparing low-dose rate and high-dose rate brachytherapy. No articles were critically appraised.

The use of high-dose brachytherapy in the treatment of cervical and endometrial cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Prostate Cancer Brachytherapy
BACKGROUND
At the December 14, 1994 Committee on Medically Emerging Technologies the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer was originally discussed. Dr. Blasko presented information on the 800 patients for which the procedure was performed. Only 252 of those patients had a minimum follow-up of two years. The conclusion of the committee was that there was inadequate follow-up data supporting the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer. The question of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer was restated and evaluated at the January 16, 1997 Clinical Policy Committee Meeting. Committee members agreed that there was inadequate evidence to compare the benefits of the three active treatment options but that there was adequate evidence (large case series) to compare the complications of the three options. Among the three active treatment options, it was agreed that brachytherapy appeared to have the lowest rate of complications. Based on this information the Committee recommended to the Clinical Planning and Improvement Council and the Delivery System Operating Team that brachytherapy be added to the list of covered treatment options for localized prostate cancer. This recommendation was accompanied by the stipulation that educational material outlining the treatment options be developed for patient education in order that they can make an informed decision about their treatment course. Not all patients with Prostate Cancer are eligible candidates for Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer. Documentation of the screening criteria used to identification of the eligible candidates is the purpose of this document. In late 2001 the criteria were reviewed by Dr. Nico DeWette and updated based on the current practice and experience with Prostate Seed Implant and Combined Therapy

Back to Top

12/14/1994: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: he conclusion of the committee was that there was inadequate follow-up data supporting the efficacy of Transperineal Ultrasound Guided Iodine^{125} or Palladium^{103} Brachytherapy for Prostate Cancer.

01/16/1997: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: Committee members agreed that there was inadequate evidence to compare the benefits of the three active treatment options but that there was adequate evidence (large case series) to compare the complications of the three options. Among the three active treatment options, it was agreed that brachytherapy appeared to have the lowest rate of complications. Based on this information the Committee recommended to the Clinical Planning and Improvement Council and the Delivery System Operating Team that brachytherapy be added to the list of covered treatment options for localized prostate cancer. This recommendation was accompanied by the stipulation that educational material outlining the treatment options be developed for patient education in order that they can make an informed decision about their treatment course.

2001: MTAC REVIEW
Prostate Cancer Brachytherapy
Evidence Conclusion: In late 2001 the criteria were reviewed by Dr. Nico DeWette and updated based on the current practice and experience with Prostate Seed Implant and Combined Therapy.
Articles: Wennberg, John E., Assessing Therapies for Benign Prostatic Hypertrophy and Localized Prostate Cancer (PORT), Agency for Health Care policy and Research, Medical Outcomes and Guidelines Sourcebook, 273-288 Stock et al. Prostate Specific Antigen and Biopsy Results following Interactive Ultrasound Guided Transperineal Brachytherapy for Early Stage Prostate Carcinoma. Cancer. 1996, 77:2386-92
Wallner et al. Tumor Control and Morbidity Following Transperineal Iodine 125 Implantation for Stage T1/T2 Prostatic Carcinoma. Journal of Clinical Oncology. 1996, 14:449-53.
Kaye, Keith W., et al. Detailed Preliminary Analysis of ^{125}Iodine Implantation for Localized Prostate Cancer Using Percutaneous Approach. The Journal of Urology. March 1995. 153: 1020-1025.
Blasko, John C., et al., Brachytherapy and Organ Preservation in the Management of Carcinoma of the Prostate. Seminars in Radiation Oncology. 1993: 3(4), 240-249.

Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma
BACKGROUND
Gliomas are the most common primary tumors of the adult brain. Primary brain tumors are those that arise from brain tissue itself, rather than metastasizing to the brain from another location. One of the most commonly diagnosed types of glioma is glioblastoma multiforme (GBM) which is defined as a Grade 4 (high-grade) astrocytoma. High-grade tumors are by definition, rapidly growing and typically develop at a distinct focus in the brain and become more diffuse in their spread as they progress. Several therapies for high-grade glioblastomas are currently employed. No treatment has been shown to cure these tumors, most likely because tumor cells infiltrate into surrounding tissue and this tumor cell type has been shown to be moderately resistant to chemo and radiation therapy. Treatment for glioblastoma multiforme typically involves surgery to reduce the size of the tumor and external beam radiation therapy. External beam radiotherapy can be delivered using a standard x-ray machine or focused on a small area of three dimensionally localized tissue using stereotactic radiosurgery. Systematic chemotherapy is usually a third line treatment and. One proposed treatment for glioblastoma is the use of stereotactically implanted radioactive seeds (brachytherapy) at the site of the tumor. The potential advantage of brachytherapy is that it allows high dose radiation to be applied directly to the tumor site and may avoid radionecrosis caused by high doses of externally applied radiation and toxic effects of chemotherapy. Glioblastoma is typically associated with a fatal outcome. Brachytherapy for malignant brain tumors has been practiced since the early 1980s. Brachytherapy applied as a boost to external beam radiation therapy has become part of the initial treatment of patients with malignant gliomas. Previous reports on the use of brachytherapy for patients with malignant gliomas have suggested improved survival for some patients. The largest experience to date has been with temporary high-activity brachytherapy implants. However, temporary implants have certain disadvantages compared with permanently implanted seeds, including higher costs and the need for more rigorous radiation safety precautions during the period of implantation.

13/13/2000: MTAC REVIEW
Radioactive Seeds for Treatment of Recurrent High-Grade Glioblastoma
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1990-1999 using the terms: glioblastoma, brachytherapy and neoplasm recurrence. The published scientific evidence consists of 4 case series with no comparison group or comparison only to historical controls. Case series do not provide

Back to Top

reliable information regarding efficacy as they are subject to bias because they lack control groups that allow elimination of confounding and selection bias. Publication bias can also influence whether negative results are reported in the literature. The studies reviewed in November 2000 have a number of limitations including a small sample size, potential selection bias, lack of a proper control group, and in one of the studies, the fact that different methods variables were used to compare groups of patients. Given these limitations, there is insufficient evidence to draw conclusions about the efficacy and safety of brachytherapy for patients with glioblastoma. It was noted that glioblastoma has the worst prognosis and shortest survival times of any type of primary brain tumor. All treatments serve only to extend survival, usually by a matter of 2-3 months usually at the cost of significant treatment related morbidity. Recent improvement in imaging techniques and more complete surgical resection makes it impossible to use historical control patients as valid comparisons with respect to clinical outcomes.
Articles: The search yielded 20 articles. 18 articles were not directly relevant or were review articles, letters, or case reports. Two (2) empirically relevant case series were identified (evidence tables attached). *The articles selected for critical appraisal include:* Patel et al. Permanent Iodine-125 interstitial implants for the treatment of recurrent glioblastoma multiforme. Neurosurgery 2000; 46:1123-1130. See Evidence Table
J Clin Oncol 1998;16:2202-12 entitled Iodine 131-labeled antitenascin monoclonal antibody 81C6 treatment of patients with recurrent malignant Gliomas: Phase I trial results. See Evidence Table
Shrieve, DC et al, *Neurosurgery*, 1995, 36:275-284 See Evidence Table
Halligan, JB et al, *Int J. Radiation Oncology Biol. Phys*. 1996, 35:541-547 See Evidence Table
Sneed, PK et al, *Seminars in Surgical Oncology*, 1997;13 See Evidence Table
Gaspar, LE, et al. Int J. Radiation Oncology Biol. Phys. 1999, 43:977-82 See Evidence Table
Gaspar, LE, et al. Int J. Radiation Oncology Biol. Phys. 1999, 43:977-82 See Evidence Table
Koot et al. Brachytherapy: Results of two different therapy strategies for patients with primary glioblastoma. Cancer 2000;88:2796-802. See Evidence Table

Radioactive Seeds for Treatment of Recurrent Malignant High-Grade Glioblastoma does not meet *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy
19297	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)
19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure)
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application
58346	Insertion of Heyman capsules for clinical brachytherapy
61770	Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source
76965	Ultrasonic guidance for interstitial radioelement application
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote

Back to Top

	afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care)
77761	Intracavitary radiation source application; simple
77762	Intracavitary radiation source application; intermediate
77763	Intracavitary radiation source application; complex
77768	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
77789	Surface application of low dose rate radionuclide source
77799	Unlisted procedure, clinical brachytherapy
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed
HCPC Codes	**Description**
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
1998	06/01/2010[MDCRPC], 12/07/2010[MDCRPC], 09/06/2011[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 04/01/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC], 03/12/2024[MPC]	07/07/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of change
06/14/2016	Added retired LCD language
05/18/2015	Added AccuBoost to insufficient evidence table
09/08/2015	Revised LCD L34065
11/10/2015	Removed Electronic Brachytherapy for non-melanoma skin cancer. See separate criteria.
04/19/2016	Changed Medicare language as LCD 34065 was retired.
08/11/2016	Revised retired LCD language
06/02/2020	Removed deleted codes 77326, 77327, 77328, 77785, 77786, 77787, 0182T
06/24/2022	Remove codes 55875, 55876, 55920, 57155, 57156
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Breast Implant Removal & Re-Implantation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Breast Reconstruction Following Mastectomy (140.2)
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Articles	Plastic Surgery (A57222)

For Non-Medicare Members

Breast implant removal is covered when **All of the following** criteria are met:

1. Breast implants were part of a reconstructive procedure meeting criteria for breast reconstructive surgery.
2. **One of the following** clinical symptoms are present:
   a. Infection related to implant
   b. Implant extrusion
   c. Ruptured implant
   d. Baker Classification* Class II to IV contracture
   e. Interference with diagnosis and/or treatment of breast cancer

Additionally, breast implant removal and subsequent re-implantation may be covered if the implants were placed for a diagnosis of breast cancer or other malignancy involving the breast if criteria are met - see Breast Reconstruction or Breast Prostheses following Mastectomy/Lumpectomy.

*Baker Classification:
Class I augmented breast feels as soft as a normal breast
Class II augmented breast is less soft, and implant can be palpated, but is not visible
Class III augmented breast is firm, palpable and the implant (or distortion) is visible
Class IV augmented breast is hard, painful, cold, tender, and distorted

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Breast implant removal is medically necessary under limited circumstances.

Back to Top

Date Sent: 4/29/24

Medical Technology Assessment Committee (MTAC)

Silicone Breast Implant Removal

09/11/1999: MTAC REVIEW

Evidence Conclusion: The committee reviewed the available data on the safety of silicone breast implants and concluded: There is no evidence linking silicone breast implants to cancer in women, the elective removal of existing implants is not recommended. There is concern and there may be a relationship between silicone breast implants and the development of connective tissue disease, although there is no epidemiological evidence Silicone breast implants can impede early detection of breast cancer in cases of cosmetic breast augmentation, but do not in cases of breast reconstruction following extractive surgery.

Articles: Committee reviewed the available data on the safety of silicone breast implants and concluded: There is no evidence linking silicone breast implants to cancer in women, the elective removal of existing implants is not recommended. There is concern and there may be a relationship between silicone breast implants and the development of connective tissue disease, although there is no epidemiological evidence. Silicone breast implants can impede early detection of breast cancer in cases of cosmetic breast augmentation, but do not in cases of breast reconstruction following extractive surgery. Capsular contracture does occur in many patients and patients should be advised, before implantation, that it is a possible side effect that is normal and not harmful to their health.

The use of silicone breast implant removal for prevention of breast cancer does not meet the Kaiser Permanente *Medical Technology Assessment Criteria*.

2001: MTAC REVIEW

Silicone Breast Implant Removal

Evidence Conclusion: Evidence update outside of committee process that supported the 1999 outcome.

Articles: Intern Med J 2001 Mar31 (2):77-89 Women's health after plastic surgery.

Englert H, Joyner E, McGill N, Chambers P, Horner D, Hunt C, Makaroff J, O'Connor H, Russell N, March L. Westmead Hospital, Sydney, New South Wales, Australia. Laing TJ, Schottenfeld D, Lacey JV Jr, Gillespie BW, Garabrant DH, Cooper BC, Heeringa SG, Alcser KH, Mayes MD. Department of Internal Medicine, University of Michigan.

No meeting discussion.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Back to Top

Date Created	Date Reviewed	Date Last Revised
3/1999	10/5/2010[MDCRPC], 8/2/2011[MDCRPC], 4/02/2013[MDCRPC], 02/04/2014 [MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC] 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/17/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
10/01/2015	Revised LCD Local Coverage Determination (LCD): Non-Covered Services L34886 and L35008
12/19/2017	Added LCD 37020
04/06/2021	Updated LCA to Plastic Surgery (A57222)
04/18/2023	Updated LCA to Plastic Surgery (A57222)

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Breast Reconstruction or Breast Prostheses

- Following Mastectomy/Lumpectomy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Breast Reconstruction Following Mastectomy (140.2)
Local Coverage Determinations (LCD)	Plastic Surgery (L37020) External Breast Prothesis (L33317)
Local Coverage Articles	External Breast Prosthesis (A52478)

Effective until July 01, 2023

For Non-Medicare Members

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy member must qualify both in A and B:

A. **ONE of the following** must be met:
   1. Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity

   OR

   2. Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer

B. And must be **ONE of the following** procedures:
   1. **For the diseased**/ injured/affected breast must meet **ONE of the following**:
      a) Tissue/muscle reconstruction procedures (flaps)
      b) Capsulotomy
      c) Capsulectomy
      d) Implantation of tissue expander
      e) Implantation of U.S. Food and Drug Administration (FDA) approved internal breast prosthesis
      f) Areolar and nipple reconstruction
      g) Areolar and nipple tattooing
      h) Breast implant removal and subsequent re-implantation

   2. **For the non-diseased**/non-injured/unaffected/contralateral breast to produce symmetry in appearance must meet **ONE of the following**:
      a) Breast reduction by mammoplasty or mastopexy
      b) Augmentation mammoplasty
      c) Augmentation with implantation of FDA internal breast prosthesis when unaffected breast is smaller than the smallest available internal prosthesis

Back to Top

d) Areolar and nipple reconstruction
e) Areolar and nipple tattooing
f) One reconstructive procedure to produce a symmetrical appearance
g) Breast implant removal and subsequent re-implantation performed to produce a symmetrical appearance when the original implant was in the unaffected breast prior to the disease in the affected breast.
h) Capsulotomy
i) Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:
1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoform Dermis
6. Strattice tissue matrix
7. SurgiMend

Autologous fat injections for post-mastectomy breast reconstruction (autologous fat grafting, autologous fat transfer, breast fat grafting, lipoinjection, lipofilling)
A. Autologous fat injection coverage is covered only for breast reconstruction (dimpling and contouring), if medical necessity criteria for breast reconstruction is met.
B. Total breast reconstruction is not covered using the Brava system (autologous fat injection for complete reconstruction).

The following are <u>not covered</u>:
A. All other bioengineered skin substitutes other than listed above - see Wound Care criteria
B. Suction lipectomy or ultrasonically assisted suction lipectomy for correction of donor site asymmetry.
C. Reconstructive surgical revisions are for restoration and not for cosmetic. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.
D. Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

Pulsed electromagnetic field (PEMF) for pain reduction after breast reconstruction surgery
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies

External breast prostheses and bras - If the member has not undergone breast reconstruction, external breast prostheses and bras are covered after a medically necessary mastectomy or a lumpectomy, when surgery results in significant deformity.

- External prosthesis (one silicone every 2 years or one foam every 6 months) Post-mastectomy bras/forms, limited to 2 every 6 months. Replacements within this 6-month period are covered when medically necessary due to a change in the Member's condition.

Effective July 01, 2023

For Non-Medicare Members

For breast reconstruction or breast prosthesis following a mastectomy or lumpectomy member <u>must qualify both in A and B:</u>

A. **ONE of the following** must be met:
   1. Medically necessary lumpectomy or complete or partial mastectomy due to disease, injury or illness (such as breast cancer, chronic and severe fibrocystic disease, or infection unresponsive to medical therapy, chest wall surgery, or trauma) resulting in significant deformity

   OR

Back to Top

2. Prophylactic mastectomy to prevent the onset of breast cancer when a clinical determination has been made that there is a high risk for breast cancer

B. And must be **ONE of the following** procedures:
   1. **For the diseased**/ injured/affected breast must meet **ONE of the following**:
      a. Tissue/muscle reconstruction procedures (flaps)
      b. Capsulotomy
      c. Capsulectomy
      d. Implantation of tissue expander
      e. Implantation of U.S. Food and Drug Administration (FDA) approved internal breast prosthesis
      f. Areolar and nipple reconstruction
      g. Areolar and nipple tattooing
      h. Breast implant removal and subsequent re-implantation

   2. **For the non-diseased**/non-injured/unaffected/contralateral breast to produce symmetry in appearance must meet **ONE of the following**:
      a. Breast reduction by mammoplasty or mastopexy
      b. Augmentation mammoplasty
      c. Augmentation with implantation of FDA internal breast prosthesis when unaffected breast is smaller than the smallest available internal prosthesis
      d. Areolar and nipple reconstruction
      e. Areolar and nipple tattooing
      f. Breast implant removal and subsequent re-implantation performed to produce a symmetrical appearance when the original implant was in the unaffected breast prior to the disease in the affected breast.
      g. Capsulotomy
      h. Capsulectomy

The following products are covered for breast reconstruction when medically necessity criteria are met:
1. Alloderm
2. AlloMax
3. DermaMatrix
4. FlexHD
5. Neoform Dermis
6. Strattice tissue matrix
7. SurgiMend

Autologous fat injections for post-mastectomy breast reconstruction (autologous fat grafting, autologous fat transfer, breast fat grafting, lipoinjection, lipofilling)
A. Autologous fat injection coverage is covered only for breast reconstruction (dimpling and contouring), if medical necessity criteria for breast reconstruction is met.
B. Total breast reconstruction is not covered using the Brava system (autologous fat injection for complete reconstruction).

The following are <u>not covered</u>:
A. All other bioengineered skin substitutes other than listed above - see Wound Care criteria
B. Suction lipectomy or ultrasonically assisted suction lipectomy for correction of donor site asymmetry.
C. Reconstructive surgical revisions are for restoration and not for cosmetic. Ongoing surgery for treatment of natural changes due to age or weight changes is considered cosmetic and not covered.
D. Breast MRI is not covered for routine surveillance of silicone breast implants. The FDA made a recommendation (not a requirement) when they re-approved silicone implant use that members receive periodic breast MRIs. The FDA did not fund this screening. The choice of silicone vs saline is a patient preference and the use of MRI in this case cannot be described as medically necessary.

Pulsed electromagnetic field (PEMF) for pain reduction after breast reconstruction surgery
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies

Back to Top

External breast prostheses and bras - If the member has not undergone breast reconstruction, external breast prostheses and bras are covered after a medically necessary mastectomy or a lumpectomy, when surgery results in significant deformity.

- External prosthesis (one silicone every 2 years or one foam every 6 months) Post-mastectomy bras/forms, limited to 2 every 6 months. Replacements within this 6-month period are covered when medically necessary due to a change in the Member's condition.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

While breast reconstructive surgery can be considered a cosmetic procedure, under both state and federal law, carriers must provide coverage for this type of surgery in certain clinical circumstances.

The Women's Health and Cancer Rights Act (WHCRA) of 1988 (also known as Janet's Law) is a federal law that requires Kaiser Permanente plans and carriers offering coverage in connection with group or individual plans to provide benefits for mastectomy-related services, including breast reconstruction surgery. WHCRA states that a Kaiser Permanente plan or carrier (in a manner determined in consultation with the attending physician and the patient), must provide coverage for:

- All stages of reconstruction of the breast on which the mastectomy has been performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance; and
- Prostheses and physical complications of mastectomy, including lymphedema.

U.S. Code – Title 29 Chapters - § 1185b, § 300gg-27, and § 300gg-52.

Washington state law also has provisions for the coverage of reconstructive surgery following a mastectomy. Both RCW 48.46.280 (HMOs) and RCW 48.330 (Health Care Service Contractors) require that carriers shall provide coverage for:

- Reconstructive breast surgery resulting from a mastectomy which resulted from disease, illness, or injury.
- All stages of one (1) reconstructive breast reduction on the non-diseased breast to make it equal in size with the diseased breast after definitive reconstructive surgery on the diseased breast has been performed.

In addition to the above statutes, guidance for interpretation of these state statutes is found in Carr v. Blue Cross of Washington and Alaska, 93 Wash. App. 941 (1999).

Kaiser Permanente has developed the criteria above with these laws as a guide.

Evidence and Source Documents

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction
BRAVA® Breast Expansion System
Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery
SERI® Surgical Scaffold for Breast Reconstruction

Medical Technology Assessment Committee (MTAC)

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

BACKGROUND

Autologous fat transfer, also known as breast fat grafting (BFG), fat transplantation, lipofilling, or lipoinjection, is a process in which fat cells from one area of the body are transferred to another. Fat transfer was first performed by

Back to Top

Neuber in 1893 for the correction of a depressed face scar, and two years later it was performed by Czerny for breast construction after excision of a large fibroadenoma. Since then, several surgeons have used free fat grafts for the reconstruction of breast defects. Autologous fat is considered an ideal injectable agent for soft tissue augmentation; it is easily available for most patients, easy to use, inexpensive, nontoxic, biocompatible, and potentially long lasting, and removable (Mu 2009, Fraser 2011, Bucky 2011). Breast fat grafting is a promising technique to correct contour deformities in breasts reconstructed with either prosthesis or autologous tissues. The value of the procedure is controversial due concerns about its safety and efficacy. The degree of reabsorption of the adipose tissue transplanted is unpredictable. The mechanism underlying the survival of dissected autologous fat after grafting is unknown but is believed to be dependent on revascularization of fat granules. The lipogenic activity may vary by donor site (e.g. abdomen, thigh, and flank), patient age, weight, smoking habits, co-morbidities, condition of recipient site (scarring, radiation, previous surgery) and other factors. One of the main concerns with autogenous fat grafting for the breast is the development of fat necrosis leading to liponecrotic cysts and microcalcifications that could be mistaken for cancerous calcifications. Compression of the breast tissue by the transferred fat may also make it difficult to identify subtle changes in architectural patterns seen with early breast cancer presentation. Another concern relates to the potential oncologic risks of breast fat grafting, as fat transfer into a previous breast-cancer area may potentially stimulate local recurrence. Other complications with autologous fat transfer include edema, hematoma, induration, infection, granuloma formation, oil cyst formation, fat liquefaction, sclerosis and resorption (Pulagam 2006, Mu 2009, Mizuno 2010, Fraser 2011, Bucky 2011, Rietjens 2011, Serra-Renom 2011). After gaining much popularity, the interest in autologous fat transfers waned in the 1950s and 1960s due to low rates of graft survival and the increased use of artificial material. The interest in autologous fat grafting for aesthetic and reconstructive purposes was renewed in the 1980s with the introduction of liposuction that provided a minimally invasive means of obtaining large amounts of adipose tissue in a semiliquid form. However, the procedure was again discontinued for some time due to concerns over post-operative calcifications and risk of obscuring developing malignant lesions. More recently, autologous fat transfer re-emerged after a number of surgeons introduced “lipomodelling” and used the technique alone or with in combination with other reconstructive procedures. Several harvesting and transplantation techniques have been developed and refined, yet no standard procedures have been adopted by all practitioners. There is no consensus on the ideal cannula, technique for harvesting, processing, or grafting the fat. Harvesting approaches include syringe aspiration and lipoaspiration. Once harvested, the fat is prepared for injection by one of several methods including: washing with physiological buffers, centrifugation for separating the cells from the debris, decantation, or concentrating it using cotton towels or other adsorbent media. For grafting, the fat is injected with a variety of delivery methods using sharp or blunt needles. It is reported that the fat “takes” if it is obtained using atraumatic methods, but it does not acquire the shape of the breast and remains flattened. It is difficult to remodel the grafted fat to acquire the desired cone shape. The procedure is not simple and should be performed by skilled and trained surgeons. It requires careful calculation of the amounts of fat injected at one time, number of injections needed, appropriate sites for injections, and proper administration of the transferred fat (Hyakusoku 2008, Mu 2009, Fraser 2011, Bucky 2011, Parrish 2010). In 1987, the American Society of Plastic and Reconstructive Surgeons (ASPRS) Ad-Hoc committee on New Procedures issued a position statement recommending that autologous fat transfer to the breast be prohibited due to its complications that may compromise breast cancer screening. In 2007, the ASPS and the American Society for Aesthetic Plastic Surgery (ASAPS) again determined that fat grafting for breast augmentation is not recommended due to the lack of clinical data on the efficacy and safety of the procedure, and also because it may interfere with the detection of breast cancer. In 2009, the ASPS Fat Graft Task Force took a more lenient position stating that, “Fat grafting may be considered for breast augmentation and correction of defects associated with medical conditions and previous breast surgeries.” This Task Force based the recommendation on low quality evidence from case series, and/or expert opinion and the gave it a B grade. They emphasized that the patients should be made aware of the potential risks and complications of the procedure and indicated that physicians should be cautious when considering high-risk patients (Gutowski 2009, Mizuno 2010).

08/15/2001: MTAC REVIEW

Autologous Fat Injections for Post-Mastectomy Breast Reconstruction

Evidence Conclusion: The published studies are limited to case series and case reports which do not provide sufficient evidence to determine the efficacy, safety, and durability of autologous fat transfer for breast reconstruction after a mastectomy. The studies used different techniques, donor site, volume of fat transplant, as well as various outcome measures and follow-up durations. Most of the series included patients undergoing the procedure for breast augmentation, reconstructive surgery after mastectomy, as well as other indications. The largest published series of 880 patients over 10 years was reported by Delay, et al in 2009. The majority (83.4%) of the patient population underwent autologous fat grafting for breast reconstruction, the rest were for correction of congenital deformities, aesthetic breast surgeries, or to correct previous surgeries. The intervention was not compared to another procedure, and the study had several limitations including, but not limited to, lack of

Back to Top

reporting inclusion/exclusion criteria, patient characteristics, and lack of clearly defined outcomes and reporting of duration or completeness of follow-up. The authors indicate that the procedure was successful to the patients and surgeons but did not clearly define success other than comparison of photographs. They reported that the incidence of fat necrosis was 15% for the first 50 patients and declined to 3% for the last 100 patients suggesting a surgical learning curve. The authors concluded, "None of the imaging results are likely to confuse the diagnosis of cancer for radiologists who are experienced in breast imaging. Oncologic follow-up (now at 10 years for our first patients) shows no increased risk of local recurrence or of development of a new cancer". Illouz and Sterodimas (2009), reported on a series of 820 consecutive patients who underwent autologous fat transplantation over 25 years. These included patients undergoing the procedure for breast reconstruction after a mastectomy, patients with congenital asymmetry, or women requesting breast augmentation. A total amount of fat transplanted in each breast ranged from 25-900 ml (mean 540 ml), and a mean of 3 sessions (range 1-5) were needed to achieve the desired results. The authors indicted that the majority of patients were satisfied with the results. They did not measure the longevity of the transplantation, did not discuss loss of follow-up, injected fat survival, or necrosis. They indicate that calcifications, cysts, and cancer were not apparent in the first year after the procedure and thought that they may not be directly associated with the procedure. Long-term follow-up data that ranged from 2-25 years (mean 113.3 years) were only available for 28% of the patients. In conclusion, data from published studies do not provide sufficient evidence to determine the components of a successful, consistent, durable, and safe autologous fat transplantation for breast reconstruction. The Breast Reconstruction and Augmentation with Brava Enhanced Autologous Fat Micro Grafting (BRAVA) trial is an ongoing nonrandomized study on fat grafting of the breast post-mastectomy as well as other indications.

Articles: Assessment objective: To determine the safety and efficacy of autologous fat grafting for post-mastectomy breast reconstruction. Screening of articles: The literature search revealed around 100 articles on autologous fat grafting for post-mastectomy breast reconstruction and/or augmentation. No published meta-analyses or randomized controlled trials were identified; only case series and case reports. The majority of the published literature was on breast augmentation. The two largest published series of patients who underwent autologous fat transplantation to the breast, mainly for reconstruction after mastectomy, were selected for critical appraisal. Delay E, Garson S, Tousson G, et al. Fat injection to the breast: technique, results, and indications based on 880 procedures over 10 years. *Aesthet Surg J.* 2009; 29:360-376.

See Evidence Table Illouz YG, Sterodimas A. Autologous fat transplantation to the breast: A personal technique with 25 years of experience Aesth *Plast Surg. 2009;33:706-715.* See Evidence Table

The use of autologous fat grafting does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

BRAVA® Breast Expansion System

10/21/2013: MTAC REVIEW

Evidence Conclusion: The developer of the Brava device (Brava LLC, Miami, Fla.) conducted a multicenter, prospective, magnetic resonance imaging-documented study to determine the safety and efficacy of single-stage large-volume autologous fat transfer to the breast treated with the Brava external breast expander. The population included 81 women between the ages of 17 and 63 years who desired breast augmentation. It is not clear from the study if patients seeking reconstruction following mastectomy were included or excluded (Khouri, Eisenmann-Klein et al. 2012). Currently, the evidence on the use of BRAVA® Breast Expansion System is limited and provided insufficient evidence to determine the safety and efficacy for use superficially in breast reconstruction surgery with autologous fat transfer. Conclusion: There is no evidence to permit conclusions concerning the safety and efficacy of the BRAVA Breast Expansion System used in breast reconstructive surgery with fat implants.

Articles: A search of PubMed and the National Institute of Health Clinical Trials records was completed for the period through September 2013 for studies on BRAVA® Breast Expansion System used for the treatment of patients following mastectomy for breast cancer. The search strategy used the terms *Brava, breast expansion, reconstructive surgery, fat implants, flap surgery* and *mastectomy* with variations. Articles were limited to those published in English language and enrolling human subjects. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function. Screening of Articles: A literature search was conducted and revealed one publication (funded by the manufacturer) on the use of the Brava system plus autologous fat transfer in breast augmentation. There are no current publications on the use of the BRAVA Breast Expansion System in breast reconstruction. One ongoing clinical trial was discovered (Breast Reconstruction and Augmentation with the BRAVA Enhanced Autologous Fat Micro Grafting) with an estimated completion date of April 2014. No studies were selected for review.

The use of the BRAVA® Breast Expansion System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

BACKGROUND

Pulsed electromagnetic field (PEMF) therapy, also known as electromagnetic therapy, uses an electromagnet to generate electric current, and nonthermal pulsed electromagnetic energy to deliver the current. PEMF utilize generators designed to create radiofrequency signals that are delivered through coils which do not come in direct contact with the skin. The electric current is generated in short bursts into in the injured tissue without the production of heat or interfering with nerve or muscle function. Unlike electrical stimulation, FEMF therapy does not involve the use of current, leads, or electrodes. The FEMF devices are noninvasive and can be applied over or as part of the dressing in the wound healing area directly following a procedure for the postoperative management of a surgical wound (Kinney 2005, Gupta 2009, Strauch 2009). The mechanism of action of PEMF on tissue growth and repair is not completely known. In vitro and animal research showed that PEMF can increase blood flow, enhance circulation, induces collagen synthesis, granulocyte infiltration, and inhibit growth of some wound pathogens. The literature also suggests that this modality of therapy can modify the inflammatory process, reduce edema, and enhance tissue repair. The effects of PEMF are immediate and are not limited by pharmacokinetics because the induced currents are instantaneously present when the coil is transmitting into the affected area (Kinney 2005, Gordon 2007, Strauch 2009). Electromagnetic therapy is currently being used in physical medicine, orthopedic and sports injuries, and other musculoskeletal conditions. PEMF therapy use is proposed for other conditions as the reduction of pain and edema after facial surgery, breast surgery, and abdominoplasty. Several trials are currently underway or planned to study the use of PEMF in several other fields of medicine (Kinney 2005, Gupta 2009).

06/18/2012: MTAC REVIEW

Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

Evidence Conclusion: The two published trials on the use of pulsed electromagnetic field therapy (PEMF) to reduce pain and the use of pain medications after breast reconstruction surgery were small pilot studies with valid methodology. Both trials were randomized, blinded, used sham therapy as a control, and had sufficient power to detect statistically significant differences between PEMF and the sham therapy. Hedén and Pilla's trial randomized 42 women to receive bilateral active PEMF therapy, bilateral breast sham therapy, or one of the two therapies on each breast. The results of the study showed a significant difference between the active and sham therapies in the pain experienced and in the use of postoperative pain medication. Those who received PEMF on one breast and sham therapy on the other breast showed no significant differences between the two breasts or between them and the active treatment. This was attributed to the fact that the breast randomized to sham treatment received 40- 60% of signal amplitude delivered to the active treatment breast due to the propagation of PEMF signal from the coil application. Based on this observation, Rohde and colleagues (2009) randomized their study participants to receive either bilateral active therapy or bilateral sham therapy. The trial included 24 patients and reported outcomes for only 48 hours. Similar to Hedén and Pilla's results, women who received PEMF therapy experienced less pain and used fewer narcotics in the 48 postoperative hours. Conclusion: The overall results of the published small pilot studies show that PEMF therapy may reduce pain and use of pain medication after breast reconstruction surgery. Both trials noted that no adverse events were reported, but neither studied the effect of PEMF on the reduction of postoperative edema, or on the speed and quality of wound repair

Articles: The literature search revealed two relatively small randomized controlled trails that evaluated the use of PEMF therapy after breast reconstruction therapy. Both trials were critically appraised.

Hedén P and Pilla AA. Effects of pulsed electromagnetic fields on postoperative pain: A double-blind randomized pilot study in breast augmentation patients. Aesth Plast Surg.2008; 32:660-666. See Evidence Table

Rohde C, Chiang A, Adipoju O, et al. Effects of pulsed electromagnetic fields on interleukin-1β and postoperative pain: A double-blind, placebo-controlled, pilot study in breast reduction patients. Plast Reconst Surg.2010; 125:1620-1629. See Evidence Table

The use of Pulsed electromagnetic field (PEMF) therapy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

SERI® Surgical Scaffold for Breast Reconstruction

04/20/2015: MTAC REVIEW

Evidence Conclusion: There is a lack of published evidence on the use of SERI® Surgical Scaffold for breast reconstruction after mastectomy. The largest published study to date, SURE-001 (Fine et al, 2014, Evidence table 1) was a prospective observational study with no comparison or control group. It included 139 patients undergoing two-stage, implant-based breast reconstruction using SERI® Surgical Scaffold in multiple centers in the US. The study is planned to follow the patients for 2 years, but the published article reports the interim data for 71 patients followed for 1 year after surgery. The patients underwent tissue expander placement during stage one of

Back to Top

reconstruction, with SERI® sutured into place for soft-tissue support of the lower-breast mound. Once expansion was complete with drain placement, the second stage of surgery was performed, where the expander was replaced with a permanent breast implant. The primary outcome of the study was the investigator satisfaction at 6 months. Other outcomes included the investigator satisfaction at 12 months after stage 1 surgery; ease to use of SERI®; visibility and palpability of SERI® through the skin at first postoperative visit, and during follow-up; patient satisfaction, and adverse events associated with the implant. The interim results of the study showed that the mean investigator satisfaction scores were 9.2 at 6 months where a score of 10 indicates being very satisfied with results. The mean patient satisfaction with the treated breast was 4.3 at 6 months and 4.5 at 12 months with a score of 5 signifying very satisfied with results. Adverse events occurred in 18 of the 71 patients with 1-year follow-up after stage I surgery, and most occurred within the first 6 months. Tissue necrosis occurred in 8.5% of the patients, seroma in 7%, hematoma in 7%, cellulitis in 4.2%; implant loss in 4.2%, capsular contracture in 1.4% and breast infection occurred in 1.4%. These results have to be interpreted with caution as the study was only observational with no control or comparison group and had a subjective primary outcome. The study was sponsored by Allergan, Inc. and all the investigators had financial ties to the manufacturer of SERI ®Surgical Scaffold. Conclusion: There is insufficient evidence to determine the efficacy and safety of SERI surgical scaffold in women undergoing breast reconstructive surgery after mastectomy.

Articles: The literature search did not reveal any randomized controlled trials that compared the use of SERI® Surgical Scaffold versus currently used practices or alternative material used for tissue support. To date, the published empirical studies consist of one prospective case series with 139 women undergoing breast reconstruction after mastectomy (SURE-001 study, Fine et al, 2014), a very small retrospective case series, and case reports on the use of SERI® for other indications as abdominoplasty and brachioplasty.
The prospective case series was selected for critical appraisal. Fine NA, Lehfeldt M, Gross JE, et al. SERI Surgical Scaffold, Prospective Clinical Trial of a Silk-Derived Biological Scaffold in Two-Stage Breast Reconstruction: 1-Year Data. Plast Reconstr Surg. 2015; 135(2):339-351. See Evidence Table 1

The use of the SERI® Surgical Scaffold for Breast Reconstruction does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction; with latissimus dorsi flap
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap

Back to Top

Date Sent: 4/29/24

19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)
19396	Preparation of moulage for custom breast implant
HCPC Codes	**Description**
C1789	Prosthesis, breast (implantable)
L8000	Breast prosthesis, mastectomy bra, without integrated breast prosthesis form, any size, any type
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8015	External breast prosthesis garment, with mastectomy form, post mastectomy
L8020	Breast prosthesis, mastectomy form
L8030	Breast prosthesis, silicone or equal, without integral adhesive
L8031	Breast prosthesis, silicone or equal, with integral adhesive
L8032	Nipple prosthesis, prefabricated, reusable, any type, each
L8033	Nipple prosthesis, custom fabricated, reusable, any material, any type, each
L8035	Custom breast prosthesis, post mastectomy, molded to patient model
L8039	Breast prosthesis, not otherwise specified
L8600	Implantable breast prosthesis, silicone or equal

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Medicare – Considered Not Medically Necessary

HCPC Codes	Description
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/13/2011	08/02/2011[MDCRPC], 09/006/2011[MDCRPC], 06/05/2012[MDCRPC], 07/03/2012[MDCRPC], 08/07/2012[MDCRPC], 04/02/2013[MDCRPC], 11/05/2013[MPC], 12/03/2013[MPC], 09/02/2014[MPC], 12/02/2014[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	02/07/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

06/02/2015	MPC approved MTAC recommendation of insufficient evidence for Seri Surgical Scaffolding for Breast Reconstruction
09/01/2015	Added language per that external prosthesis and bras are covered “before, during and after” surgery per WHCRA regs
11/2/2015	Aligned external prosthesis language with contract policy
03/08/2018	Added Plastic Surgery LCD
4/14/2020	Added non-covered statement for routine surveillance of silicone breast implants
07/31/2020	Added CPT codes 15769, 15771 and 15772
04/06/2021	Updated applicable codes
02/07/2023	MPC approved to adopt the modified changes to remove the indication for *one reconstructive procedure to produce a symmetrical appearance*. Requires 60-Day notice, effective 07/01/2023.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Bronchial Thermoplasty for Treatment of Severe Bronchial Asthma

- Alair Bronchial Thermoplasty System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**Bronchial Thermoplasty for Treatment of Severe Bronchial Asthma**" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* (A-0634) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (pulmonary/allergy)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Asthma is an increasingly prevalent disease that affects over 20 million people in the United States. It is estimated that 15 -20% of asthma patients have a severe condition despite receiving the new effective therapies. Asthma is characterized by chronic inflammation of the airways, airway wall edema, bronchial hyper responsiveness, and remodeling of the airways that include increased airway smooth muscle mass. Each of these factors alone or in combination can result in recurrent episodes of wheezing, coughing, chest tightness, and breathlessness (Castro 2010, Cox 2011).

Although inflammation of the airways is a main feature of asthma, researchers believe that the contraction of the

Date Sent: 4/29/24

excess airway smooth muscles, in response to various asthma triggers, is the main cause of airway constriction and restricted airflow leading to breathing difficulty during asthma attacks. This led to a hypothesis that decreasing the mass and /or contractility of airway smooth muscle would reduce airway bronchoconstriction and ameliorate the symptoms of asthma. Based on this hypothesis, investigators suggested that the application of thermal energy to the airway wall, termed bronchial thermoplasty, can reduce the bronchoconstrictor response in asthma (Cox 2007, Pavord 2007, Wechsler 2008).

Bronchial Thermoplasty (BT) is a device-based approach for severe persistent asthma that involves the application of controlled heat from a radiofrequency (RF) source to the airway wall resulting in a prolonged reduction in airway smooth muscle mass. The Alair System (Asthmatx Inc., Sunnyvale, CA) is the first device designed to use RF to selectively reduce the amount of excess airway smooth muscle in airways distal to the main stem bronchi down to 3 mm in diameter. The Alair system consists of the Alair RF catheter that has an expandable electrode array on the tip, and the Alair RF controller which supplies energy via the catheter to heat the airway wall. The catheter is deployed under direct vision through a compatible flexible bronchoscope, which is navigated to the first target treatment site, typically the most distal airway in the targeted lobe. Once the bronchoscope is inserted in the airways, the catheter is passed through the bronchoscope and its electrode array expanded such that all its sides are in contact with the airway wall. The bronchoscopist steps on a footswitch attached to the RF controller for approximately 10 seconds. This delivers low-power, temperature-controlled RF thermal energy to the treated airway. A single activation of the catheter delivers RF energy over a distance of approximately 5 mm. The catheter is then repositioned so that other adjacent areas of the airways may be treated, following a mapped treatment plan, and avoiding overlap. All visible and reachable airways 3-10 mm in diameter that are distal to the main stem bronchi are treated with a series of contiguous activations. A systematic approach from distal to proximal, working methodologically from airway to airway across the lung being treated is recommended to ensure that all accessible airways are carefully identified and treated only once. BT is performed under conscious sedation in an outpatient setting, and the procedure takes 30-45 minutes to complete. The treatment is administered in three sessions approximately 3 weeks apart. A different region of the lung is treated during each session: one lower lobe in session 1; the second lower lobe in session 2; and both upper lobes in session 3. Depending on the patient size and anatomy, a range of approximately 60-100 energy cycles are performed (Duhamel 2010, Wechsler 2008, Castro 2010).

Patients are selected for BT by an asthma specialist and an experienced bronchoscopist and should not considered for the procedure if they have acute respiratory infection, known coagulopathy, active respiratory infection, or with asthma exacerbation or changing dose of systemic corticosteroids for asthma (up or down) 14 days before the procedure (Duhamel 2010).

This Alair Bronchial Thermoplasty system received marketing clearance from the U.S. Food and Drug Administration (FDA) in April 2010 for the control of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists. The FDA approved the system based on data from AIR2 trial and is requiring a five-year post-approval study of the device to study its long-term safety and effectiveness. The FDA list of potential adverse events associated with the use of the device includes: upper respiratory tract infection, throat irritation, pharyngolaryngeal pain, rhinitis, nasopharyngitis, asthma (multiple symptoms), sinusitis, wheezing, dyspnea, airway bleeding, cough, laryngospasm, bronchospasm, bronchitis, excess mucus production, chest discomfort, increased airway reactivity, atelectasis, hemoptysis, bronchial stenosis, bronchiectasis, pneumothorax, and others.

Medical Technology Assessment Committee (MTAC)

Bronchial Thermoplasty

04/18/2011: MTAC REVIEW

Evidence Conclusion: The Asthma Intervention Research (AIR) trial examined the efficacy of BT in patients with moderate to severe asthma while AIR2 and Research in Severe Asthma (RISA) trials studied the efficacy of the procedure in patients with symptomatic severe asthma despite the use of high doses of inhaled corticosteroids (ICS) and long acting β_2 adrenergic agonists (LABA). AIR and RISA trials compared BT in addition to usual care with standard medications versus usual care alone and had no sham control. The AIR2 trial compared the BT to sham therapy, which was an advantage of the trial as it addressed the concern about the placebo effect of bronchial thermoplasty in the control of severe asthma. All three trials were supported by Asthmatx Inc., the manufacturer of Alair Bronchial Thermoplasty System, and the authors had financial ties to the industry and other pharmaceutical companies. The AIR trial conducted by Cox and colleagues (Evidence Table 1) enrolled 112 patients aged 18 to 65 years with moderate to severe asthma symptoms despite receiving combined therapy with ICS and LABA, and in whom the withdrawal of LABAs resulted in a worsening of asthma control. Eligible patients were randomly allocated to a treatment group that received BT in addition to the standard therapy, or to a control group that only received the standard treatment. Initially the patients were followed up for 12 months after which they were invited to participate in

a 4-year safety study. The primary outcome for the first 12 months was the difference between the BT group and the controls in the change in rate of mild exacerbation between baseline and later time points. The trial results showed a significant difference between the BT group and the controls in the change of mild exacerbations rate from baseline to three months and 12 months. No such significant difference between the two treatment groups was observed for severe exacerbations. The 5-year follow-up of 80% of patients in the BT group showed no increase in rate of hospitalization or emergency department visits for respiratory symptoms in years 2 to 5 compared to year one. The AIR2 trial by Castro and colleagues (Evidence Table 2) enrolled 288 highly selected patients with severe symptomatic asthma despite treatment with high doses of ICS and LABA. They were randomized in a 2:1 ratio to receive BT or sham therapy in which the controls underwent three bronchoscopies and sham thermoplasty treatment that duplicated the BT procedure except for the delivery of radiofrequency energy. Patients were followed-up for 12 months and the primary outcome was improvement in Asthma Quality of Life Questionnaire (AQLQ) at 6, 9, and 12 months. Both the BT and sham therapy groups experienced a large improvement in the AQLQ that lasted for 12 months. The absolute difference between the two groups was statistically significant but was too small and might not be clinically relevant. Other secondary outcomes including the Asthma Control Questionnaire (ACQ) score, symptom scores, airflow, airway hyper responsiveness, and rescue medication use showed a trend towards more improvement with BT over sham treatment, but none was statistically significant. The authors did not study the effect of BT on step-down of maintenance asthma medications, which according to the national guidelines is the main goal in the long-term management. Both AIR and AIR2 trials show that BT therapy temporarily aggravated asthma symptoms and increased the risk of adverse events some of which required hospitalization.

Articles: The literature search revealed around 30 articles on bronchial thermoplasty. The majority were review articles, editorials, and correspondences. Three RCTs conducted by the same group of authors were identified (AIR, AIR2, and RISA trials). RISA trial was too small (N=32), AIR trial had a 5-year follow-up, and AIR2 trial had a sham comparison group. Both AIR and AIR2 trials were selected for critical appraisal. Castro M, Rubin AS, Laviolette M, et al for the AIR2 trial Study group Effectiveness and safety of bronchial thermoplasty in the treatment of severe asthma: a multicenter, randomized, double-blind, sham-controlled clinical trial. *Am J Respir Crit Care Med,* 2010;18:116-124. See Evidence Table. Cox G, Thompson NC, Rubin AS, et al for the AIR trial Study group. Asthma control during the year after bronchial thermoplasty. *N Engl J Med.* 2007;356:1327-1337 See Evidence Table. Thomson NC, Rubin AS, Niven RM, et al. Long term (5 Year) safety of bronchial thermoplasty: Asthma Intervention Research (AIR) trial. *BMC Pulm Med*. 2011;1: 8.

The use of Bronchial Thermoplasty does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/04/2011	Added to annual review because of Medicare changes 05/01/2014[MPC], 05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 03/12/2024[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Date Sent: 4/29/24

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
04/07/2016	Removed Medicare coverage language
08/04/2020	Added Kaiser Permanente Medical Policy statement under Medicare section

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Canaloplasty

- Circumferential Viscodilation and Tensioning of Schlemm's Canal for Primary Open-Angle Glaucoma

Criteria

For Medicare Members

No review required for Medicare members

For Non-Medicare Members

Canaloplasty is covered when all of the following criteria have been met:

1. Diagnosis of glaucoma with eye pressures inadequately controlled on maximum tolerated topical medications and laser treatment
2. Documented risk for greater problems with standard glaucoma surgery (trabeculectomy or valve implant) as defined by one of the following:
   - Myopic diopters greater than 5
   - Hyperoptic diopters greater than 3
   - Moderate to severe dry eye
   - Blepharitis
   - Preservative allergy
   - Has allergy or side effects preventing the use of one or more of the standard glaucoma eye drops
   - Had problems with trabeculectomy or glaucoma valve implant surgery in the contralateral eye (such as bleb dysesthesia (chronic eye pain) or need for re-operation)

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Glaucoma is a common eye disease caused by elevated intraocular pressure (IOP) that leads to optic nerve damage and visual field loss. Glaucoma is frequently referred to as the "silent thief of sight" because it is not usually associated with ocular or systemic symptoms but can cause irreversible blindness if left undiagnosed and untreated. It is estimated that over 2 million people in the United States have glaucoma, 80,000 of whom are legally blind as the result of the disease (Lee 2005).

Glaucoma has been classically categorized into primary or secondary angle-closure glaucoma (closure of the anterior chamber angle), and primary or secondary open-angle glaucoma (where the anterior chamber angle of the eye remains open). The condition is considered primary if the eye has no pre-existing disease and secondary in an eye with a pre-existing disease. Primary open-angle glaucoma is the most common type in the US. It occurs insidiously and is usually asymptomatic in its early stages. In the later stages, when the optic nerve is damaged,

Back to Top

Date Sent: 4/29/24

the patient experiences progressive worsening of vision, and eventually peripheral followed by central visual loss (Lee 2005, Rotchford 2005).

The treatment goal for patients with glaucoma is preventing functional vision loss by lowering the IOP to a level where progressive glaucomatous optic neuropathy is stopped, or at least slowed. Conventional treatment usually begins with the use of topical IOP-lowering agents. These include beta-blockers, alpha-adrenergic agonists, carbonic anhydrase inhibitors, cholinergic, and prostaglandin analogs. Laser trabeculoplasty has also been used to further lower the IOP to decrease or eliminate the need for antiglaucoma medications. Incisional filtering surgery is considered if the patient's IOP cannot be reduced with the maximal tolerated medical therapy, laser trabeculoplasty or a combination of both. Trabeculectomy is a filtration surgical procedure commonly used to lower the IOP. The procedure involves creating an opening in the anterior chamber angle to allow the aqueous humor flow from the anterior chamber into a space beneath the conjunctiva under the surface of the eye. A successful trabeculectomy procedure is marked by an elevated conjunctival zone, the bleb, where the aqueous gathers in pockets prior to absorption into the surrounding blood vessels and lymphatics. Trabeculectomy with or without antimetabolites can successfully control IOP, but not without risks. It may be associated with numerous intraoperative or postoperative complications including hypotony, bleb leaks, bleb infections /endophthalmitis, hyphaema, loss of visual acuity, increased risk of cataract formation, scar tissue which causes obstruction of the channel created and in turn blocking the drainage of the aqueous humor, and several other complications (Lee 2005, Rotchford 2005, Lewis 2007).

Nonpenetrating glaucoma procedures were first introduced in the late 1950s and early 1960s, and revived in the 1980s and 1990s, as alternatives to standard filtration surgeries for controlling IOP in open-angle glaucoma without penetration of the intraocular space. These procedures include deep sclerectomy with and without an implant, and viscocanalostomy. The latter is performed by several techniques that basically involve the production of superficial and deep scleral flaps, excision of the deep scleral flap to create a scleral reservoir, and unroofing of Schlemm's canal. An ophthalmic viscoelastic device is then injected into the deep scleral lake and toward the cut ends of Schlemm's canal to open it and create a passage from the scleral reservoir to the canal. The superficial scleral flap is then sutured water tight trapping the viscoelastic until healing takes place (Filippopoulos 2008, Green 2007, Noureddin 2006).

Recent advances in technology, ocular ultrasound, and viscoelastics have led to the development of canaloplasty as a promising nonpenetrating surgical technique for lowering the IOP in patients with open-angle glaucoma. The procedure aims at increasing the flow of aqueous humor from the anterior chamber through the trabecular meshwork and Descemet's window into and around the Schlemm's canal and out through the collector channels, thus reducing the IOP by restoring the trabeculocanalicular outflow pathway. The procedure utilizes the full 360 degrees of the canal and outflow system without creating a fistula or need for a bleb. Unlike viscocanalostomy, canaloplasty aims at opening the entire length of the canal rather than opening only a section of it. Canaloplasty uses viscoelastic and specialized flexible microcatheter with an illuminated tip (iScience surgical Ophthalmic Microcannula) to forcibly open the Schlemm's canal (Lewis 2006, 2007, Godfrey 2009).

Similar to viscocanalostomy, canaloplasty is completed under a scleral flap. A one-half thickness parabolic shaped scleral flap is dissected. A deep flap is then dissected down to a depth very close to the ciliary body/choroid and carefully carried forward anteriorly until the Schlemm's canal is unroofed. The canal is identified and intubated with a cannula which has a lighted tip to identify its location as it passes through the canal. The cannula has a lumen to allow for the passage of viscoelastic for dilatation of the canal. Once it has passed the full length of Schlemm's, a 10-0 Prolene suture is tied to the cannula which is then withdrawn leaving the suture in its place. Tying off the suture provides tension that holds the canal open. The scleral flap is then tightly closed as well as the conjunctiva. The procedure is usually performed under special ultrasound imaging to help identify the canal and its instrumentation (Lewis 2006, 2007).

Canaloplasty has a steep learning curve. Identifying and entering the Schlemm's canal, inserting the catheter, placing the tension suture, and providing the right tension in the suture depend on the surgeon's skill and experience. The outcome of the surgery also depends on the selection of the patients; those who had previous trabeculectomies with scarring in the canal are not good candidates. According to the authors of a review article, the ideal candidates would be patients who cannot have a bleb because they wear contact lenses, have a dry eye, or for cosmetic reasons. The procedure is contraindicated in patients with angle recession, neovascular glaucoma, chronic angle closure, narrow-angle glaucoma, narrow inlets with plateau iris, and in patients with previous surgery which would prevent 360o catheterization of Schlemm's canal (Lewis 2006, Godfrey 2009).

Back to Top

Date Sent: 4/29/24

In June 2008 The FDA cleared the iScience Interventional Canaloplasty Microcatheter for marketing for catheterization and vasodilatation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma.

Medical Technology Assessment Committee (MTAC)

Canaloplasty

10/06/2008: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers with the same group of investigators, and possibly with a population overlap. None had a control or comparison group. Three of the principal authors had consulting agreement with iScience Interventional, the manufacturer of the microcatheter used. The interim analysis of one-year results of a multicenter case series (Lewis 2007) that included 94 patients from the 14 centers in US and Germany, showed that IOP dropped significantly after the procedure among all patients (from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months), and among the sutured subgroup (from 23.9 + 4.3 mmHg at baseline to 15.3 + 3.8 mmHg at 12 months). The medication uses also dropped from a mean of 1.9 +1 per patient to 0.6 + 0.9 per patient at 12 months. The most common adverse events observed were hyphaema and increased IOP which occurred at a rate of 3% each. The other published series that included 54 patients with open-angle glaucoma and cataract reported similar outcomes. None of the two studies compared the procedure to any other established surgical or nonsurgical intervention. Conclusion: There is insufficient evidence to determine that canaloplasty has the same or better effect than medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty has the same or better effect than filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer for the patient than filtration surgical interventions as trabeculectomy.

Articles: The search yielded only two studies on canaloplasty: Lewis 2007, and Shingleton 2008. Both were prospective case series with no comparison or control groups. Lewis and colleagues reported the interim results of canaloplasty performed on 94 patients with open-angle glaucoma. Shingleton et al reported one-year results of canaloplasty combined with cataract surgery performed on 54 patients with open-angle glaucoma and cataract. The authors of the latter study were co-authors in the first study. Both studies involved the same 14 clinical sites and same group of ophthalmologists. It appears also that there could be an overlap of the patients participating in the two studies. Both reported on one-year results. The published case series with the larger population size was selected for critical appraisal. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Interim clinical study analysis. J Cataract Refrat Surg 2007; 33:1217-1226. See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW

Canaloplasty

Evidence Conclusion*:* The available literature does not provide sufficient evidence to determine the safety and efficacy of canaloplasty in the management of open angle glaucoma among adults. There are no published controlled trials that compared the outcomes of canaloplasty to other established medical therapies, laser trabeculoplasty, or filtration surgeries as trabeculectomy. The only published studies were 2 relatively small case series, conducted in the same centers by the same study group, and possibly with a population overlap. Lewis and colleagues, reported on the one- and two-year interim results of canaloplasty with or without corneal phacoemulsification cataract surgery, and Shingleton et al (2008) reported on the results of a subgroup that underwent the two procedures. Neither of the two series had a control or comparison group. iScience Interventional, the manufacturer of the microcatheter used in the studies, supported the studies and had consulting agreement with three of the principal authors. In their first publication, Lewis and colleagues (2007) reported the one-year interim results of canaloplasty performed on 94 patients with open-angle glaucoma, and in their 2009 publication they reported on the results of the procedure among 127 patients. No explanation was provided why there were more patients in the 2-year follow-up. The interim analysis of one-year results showed that IOP dropped significantly after the procedure among all patients from 24.7 + 4.8 mmHg at baseline to 15.3 +3.9 mmHg at 12 months. The medication uses also dropped from a mean of 1.9 +1 per patient at baseline to 0.6 + 0.9 at 12 months. Eyes that underwent a combined canaloplasty and posterior chamber intraocular lens (IOL) implantation had lower IOP and medication use than those undergoing canaloplasty alone. The two-year

Back to Top

postoperative data were similar to those observed at the end of the first-year follow-up with a minimal increase in the mean IOP and medication use. Overall 32% reduction in IOP and 74% reduction on medication use were achieved in 24 months. Surgical complications were reported in 15 patients (16%) in the first publication and in 10 patients in the second report, with hyphaema and increased IOP >30mmHg being the most common. Conclusion: There is insufficient evidence to determine that canaloplasty is better than or equivalent to medical treatment in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is better than or equivalent to filtration surgical procedures as trabeculectomy in reducing intraocular pressure in adult patients with open angle glaucoma. There is insufficient evidence to determine that canaloplasty is safer than filtration surgical interventions as trabeculectomy.
Articles: The search yielded only one more recent report (Lewis et al 2009) on the 2-year results of the same case series on canaloplasty that was published earlier in 2007 and reviewed by MTAC in 2008. No randomized or nonrandomized controlled trials comparing canaloplasty to another treatment or intervention were identified. The new report by Lewis and colleagues (2009) was critically appraised. Lewis R A, von Wolff K, Tetz M, et al. Canaloplasty: Circumferential viscodilation and tensioning of Schlemm's canal using a flexible microcatheter for the treatment of open-angle glaucoma in adults. Two-year interim clinical study results. J Cataract Refrat Surg 2009; 35:814-824 See Evidence Table.

The use of canaloplasty in the treatment of primary open-angle glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Medicare – Medical Necessity Review not required

CPT® Codes	Description
66174	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); without retention of device or stent
66175	Transluminal dilation of aqueous outflow canal (eg, canaloplasty); with retention of device or stent

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
11/12/2008	01/05/2010 MDCRPC, 11/02/2010 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	07/26/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
07/26/2017	Added no review required for Medicare members

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Capsule Endoscopy

- Given ® AGILE Patency System
- M2A™ Capsule Endoscopy
- PillCam™ SB
- Wireless Capsule Enteroscopy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	**Esophagus:** In April 2011 Noridian retired Wireless Capsule Enteroscopy (L23785). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. **Colon:** Colon Capsule Endoscopy (CCE) (L38826)
Local Coverage Article (LCA)	Billing and Coding: Colon Capsule Endoscopy (CCE) (A58438)

For Non-Medicare Members

Effective until August 1, 2024

Kaiser Permanente has elected to use the Capsule Endoscopy (KP-0134) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective August 1, 2024

Kaiser Permanente has elected to use the Capsule Endoscopy (KP-0134 08012024) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente and share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

Back to Top

Date Sent: 4/29/24

If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider &/or specialist (gastroenterology)
- Most recent lab works

Patency Capsule

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Wireless Endoscopy

Approximately 5% of patients presenting with obscure gastrointestinal (GI) bleeding do not have a source identified after evaluation with upper endoscopy, colonoscopy and/or barium studies. Enteroscopy, evaluation of the small bowel, is indicated in many of these patients. Push enteroscopy, sonde enteroscopy and intraoperative enteroscopy are commonly used options. Push enteroscopy is relatively easy to perform but is limited by its inability to examine beyond the mid to distal jejunum in most patients. Sonde-type enteroscopes are longer than push enteroscopes and in some cases can examine as far as the terminal ileum. Disadvantages include long procedure times and a steep learning curve to master the technique. Intraoperative enteroscopy was first reported in 1976 and is considered the “gold standard” for evaluating the small bowel for the source of unexplained GI bleeding. However, this is an invasive procedure that requires a laparotomy (Adrain and Kversky, 1996).

The M2A (mouth-to-anus), a pill-sized disposable endoscope, is proposed as an alternative non-invasive tool for identifying obscure GI bleeding. The M2A capsule contains a video camera, lights, transmitter and batteries. It is swallowed by the patient and, as it moves through the digestive tract, it transmits video signals which are stored in a recorder attached to the patient’s belt. The M2A moves through the digestive tract with the aid of peristalsis and is then excreted normally by the patient. About five hours of continuous reading is possible. The video can be downloaded from the recorder to a computer workstation with special software (Reporting and Processing of Images and Data, RAPID).

The M2A capsule, manufactured by Given Imaging (Yoqneam, Israel), received FDA approval in August 2001.

M2A capsule endoscopy for unexplained chronic gastrointestinal blood loss or anemia was previously reviewed by MTAC in December 2001. At that time there were no studies of health outcomes and no data on patients with unexplained chronic gastrointestinal blood loss.

Iron Deficiency Anemia:
Iron deficiency anemia (IDA) represents a major public health problem. Its estimated prevalence in the US is 2% of adult men and 9-12% of non-Hispanic white women. It is most commonly secondary to chronic occult bleeding from the gastrointestinal tract and is one of the common reasons for referral to gastroenterology clinics (Apostolopoulos 2006, Killip 2007).

Obscure gastrointestinal bleeding (OGIB) is defined as bleeding of unknown origin that persists or recurs after a negative initial endoscopy. OGIB accounts for at 5-10% of all gastrointestinal (GI) bleeds and may be overt or occult. Overt GI bleeding is clearly signified by rectal bleeding, bloody stools, or melena. Occult blood loss, on the other hand, is subtle and may only present as iron deficiency anemia or as a positive fecal occult blood test (Triester 2005, Concha 2007, Estevez 2006).

Diagnosing the cause of OGIB might be clinically challenging, especially when the origin of bleeding is a very small lesion in parts of the small bowel that is not apparent or accessible for direct viewing. Patients with OGIB may undergo multiple diagnostic procedures and invasive testing. Diagnostic work-up may include barium x-ray studies of the bowel, endoscopy, enteroscopy, computed tomography (CT), radionucleide scans, angiography, intraoperative endoscopy, and exploratory surgery.

Evaluation of the small bowel by conventional endoscopy has the advantage of allowing for intervention if the bleeding site is identified, but may be difficult due to the length, motility, tortuosity, looping, and free hanging course of the small bowel. Typically, an endoscope will reach only the proximal small bowel. Enteroscopy is an

Back to Top

extension of an upper endoscopy where a longer endoscope that reaches down to the ileum is used. There are different types of enteroscopes including the push type and the sonde-type. Push enteroscopy allows the evaluation of the jejunal mucosa up to 150 cm beyond the ligament of Trietz; however, it is an invasive procedure that requires deep sedation or anesthesia, has a variable diagnostic yield (38-75%), and does not explore lesions in the ileum. Double balloon enteroscopy (DBE) is a modified push enteroscopy that is emerging as an alternative for operative enteroscopy. The balloons grip the intestinal wall allowing further insertion of the scope and the examination of larger areas of the small bowel reaching up to 300 cm in the oral direction. The entire small bowel could be potentially evaluated when a DBE is carried out with oral and anal approaches in conjunction (Lewis 2000, Mitchell 2004, Concha 2007).

Laparotomy with intraoperative enteroscopy is used after all other techniques fail to detect the source of bleeding, when there are adhesions that require lysis via a laparoscopic approach, or and when the risk of bleeding exceeds the risk of the procedure. It is considered the gold standard for a complete endoscopic evaluation of the small bowel. However, intraoperative endoscopy is invasive, risky, and may cause artifacts that could be falsely identified as the cause of bleeding. Moreover, it was reported that intraoperative endoscopy can examine only 50-80% of the small bowel and detect the source of bleeding in up to 40% of undiagnosed cases (Mitchell 2004).

Other indirect methods for visual examination of the small bowel such as x-ray series and enteroclysis, radioisotope bleeding scans, angiography, computed scans, and MRIs have been found to have low sentivities in detecting the source of bleeding, especially for vascular lesions which are the most frequent cause of OGIB (Estevez 2006, Leighton 2006).

Capsule endoscopy (M2A video capsule endoscope, Given Imaging Ltd, Yoqneam, Israel) was introduced in 2001 as a noninvasive direct endoscopic technique for visualization of the small bowel. It is a swallowable wireless capsule endoscope 26 mm in length and 11 mm in diameter. The device consists of an optical dome, 4 light emitting electrodes, a sensor, 2 batteries, and a micro transmitter. The capsule acquires and transmits digital images at the rate of 2/second to a sensory array attached to the patient's abdomen. It is able to capture video-images of the mucosal surface of the entire length of the small intestine directly for 7-8 hours. The capsule is propelled forward through the GI tract with the peristaltic movement and is excreted normally by the patient after 8-72 hours. The images can be downloaded from the recorder to a computer workstation with special software (Hara 2005, Eliakim 2007).

The capsule endoscopy is noninvasive and easy to perform. However, it lacks the ability to obtain a tissue sample for biopsy, deliver therapy, or treat pathology when it is found. In addition, it was reported that some lesions could be missed due to rapid or delayed small bowel transit. It might also be difficult to identify the precise location of the pathology when it is discovered. Unlike endoscopy, the lesion cannot be washed, and re-examined, and large amounts of intraluminal bile could be mistaken for blood. Interpretation of the small bowel images is highly subjective, and the potential inter-observer variation may compromise the reliability and accuracy of the technology. Moreover, some investigators have reported that the quality of the images taken by the capsule was not satisfactory, and that the duodenum was not effectively visualized. The 8 hour-battery life of the capsule is estimated to be enough time for 85% of the patients to image the entire small intestine. For the rest, the battery life expires before the capsule reaches the cecum. The major potential complication with capsule endoscopy is the risk of capsule retention due to stenosis, stricture, diverticulum, or fistula. The documented incidence of entrapment is 1%, however a retained capsule may potentially lead to intestinal obstruction, and its retrieval may necessitate surgical extraction (Concha 2007, Mazzarola 2007, Enns 2007).

The PillCam TM, previously marketed as M2A TM, manufactured by Given Imaging (Yoqneam, Israel), received FDA approval in August 2001 for detecting problems in the small bowel in adults and children ten years of age or older. The most common application for capsule endoscopy is the evaluation of obscure gastrointestinal bleeding. The second most studied indication is the evaluation of suspected Crohn's disease. It is also being used to detect polyps, cancers, other causes of chronic inflammation, bleeding, and anemia. Capsule endoscopy is contraindicated in patients with intestinal blockage, strictures or fistulas, pregnant women, patients with swallowing disorders, or those with a cardiac pacemaker or other implanted electromagnetic devices.

Patency Capsule

The capsule endoscopy is relatively noninvasive, easy to perform, well tolerated, and has a low incidence of complications. The most worrisome complication is capsule retention due to stenosis, stricture, diverticulum, or fistula. Overall, the documented incidence of capsule retention or entrapment is as low as 1% but may be higher in some population at risk. Studies reported retention rates of 5-13% in patients with known Crohn's disease, and a rate of 21% in suspected bowel obstruction. A retained or impacted capsule may potentially lead to small bowel ileus,

Back to Top

intestinal obstruction, or fragmentation of the capsule with potential toxic hazard. Risk factors for capsule retention include major abdominal surgery, known or suspected Crohn's disease, previous intestinal obstruction, prolonged NSAID use, ischemic bowel disease, radiation injury, and suspected bowel tumors. Retrieval of a retained capsule requires medical, endoscopic or surgical intervention (Sears 2004, Signorelli 2006, Concha 2007, Enns 2007, Caunedo-Alvarez 2008).

Due to the risk of capsule retention, wireless capsule endoscopy is contraindicated in patients with suspected small bowel strictures. In most centers, a radiographic evaluation of the small bowel patency is mandatory before performing a wireless capsule endoscopy in patients with a risk of small bowel strictures. Standard imaging techniques include small bowel (SB) follow-through, barium enema, enteroclysis, or CT enteroclysis. Limitations of these techniques include a tendency to underestimate or overestimate SB strictures. They can identify long or medium stenosis with great reduction in their lumen size but may not detect a short intestinal stenosis or obstruction, leading to false negative results (Boivin 2005, Caunedo-Alvarez 2008, Karagiannis 2009).

Given Imaging, the manufacturer of the PillCam SB has developed a new system (The Given® Patency Capsule) to identify patients with strictures that may cause retention of the video capsule. The first generation was the M2A patency capsule, which due to the risk of obstruction, was modified to the AGILE Patency Capsule (PC). This consists of a dissolvable capsule and a scanner. The capsule is composed of a lactose body with 5% barium (to induce radiopacity) that surrounds a small radiofrequency identification tag (RFID). The body is coated with an impermeable cellophane membrane with two wax timer plugs located at each end of the capsule. The timer plugs seal the capsule's body, and each has a small window or opening that allows penetration by gastrointestinal (GI) fluids.

The Agile patency capsule (PC) has the same dimensions and shape as the PillCam. Once the patient ingests the capsule, it is propelled through the GI tract by normal peristalsis. The Agile PC is designed to remain intact for 30 hours (40 hours in the first generation). It is assumed that it will be excreted intact if there is no bowel obstruction. In this case a PillCam capsule can be administered. If there is any kind of stricture hindering its passage for more than 30 hours, the patency capsule starts to disintegrate (except for the identification tag), allowing the insoluble outer membrane to collapse and be excreted deformed or in fragments. The persistence of the PC inside the GI tract can be verified by means of radiology or with a radiofrequency emitting external detector device locating the RFID (Signorelli 2006, Caunedo-Alvarez 2008).

It is reported that the Given patency capsule may provide direct evidence of functional patency of the gut lumen, even in those patients showing radiological evidence of small bowel stricture. This information may allow a distinction between rigid fibrotic strictures and flexible ones (Spada 2005, Karagiannis 2009).

The Given® AGILE Patency System received marketing clearance from the U.S. Food and Drug Administration (FDA) in 2006, as an accessory to the PillCam to verify adequate patency of the gastrointestinal tract in patients with known or suspected strictures prior to administration of the PillCam video capsule.

Medical Technology Assessment Committee (MTAC)

Capsule Endoscopy

12/12/2001: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence on which to base a conclusion about the effect of M2A capsule endoscopy on health outcomes.
The search yielded 4 articles. One of these was a historical piece, one was a letter to the editor describing the use of the technology with 4 cases. The third was an empirical study conducted in dogs. The fourth was description of the technology including acceptability (e.g. ability to swallow, quality of images, mouth-to-evacuation time) in 10 normal human volunteers. There were no studies of health outcomes and no data on patients with unexplained chronic gastrointestinal blood loss. In addition to the studies found on Medline, there were several published abstracts in the Given Imaging reference list. None of the articles were suitable for critical appraisal.

The use of M2A™ (Given Imaging) capsule in the diagnosis of small bowel lesions/chronic bleed sites does not meet the *Kaiser Permanent Medical Technology Assessment Criteria* 2 for effectiveness.

12/10/2003: MTAC REVIEW
Capsule Endoscopy
Evidence Conclusion: The prospective comparative studies that were reviewed suggest that M2A capsule endoscopy has a significantly greater diagnostic yield than push enteroscopy among patients with unexplained

Back to Top

gastrointestinal bleeding. The studies did not use the gold standard evaluation tool, an invasive surgical procedure, so diagnostic accuracy (e.g. sensitivity, specificity) cannot be calculated.
Articles: The search yielded 23 articles. The ideal study would be an independent, blind comparison of M2A and a gold standard diagnostic test. There were 5 comparative studies in patients with gastrointestinal bleeding. No articles specifically studied use of the M2A for anemia, but patients with anemia suggestive of overt bleeding were included in some of the GI bleeding studies. The methodology was similar in the 5 studies. All compared M2A evaluation with push enteroscopy and none of the studies included evaluation with intraoperative enteroscopy, the invasive "gold standard" procedure. The primary outcome in each study was diagnostic yield (the ability to diagnose the source of bleeding) of the two procedures. All 5 studies included blinded evaluation of test results. Results of the studies were similar; all found a higher rate of diagnostic yield with the M2A. Findings were statistically significant in 4 of the 5 studies and did not reach statistical significance in the smallest study. Sample sizes ranged from 20 to 60 patients. The two largest studies (n=52, n=60) were critically appraised:
Mylonaki M, Fritscher-Ravens A, Swain P. Wireless capsule endoscopy: a comparison with push enteroscopy in patients with gastroscopy and colonoscopy negative gastrointestinal bleeding. *Gut* 2003; 1122-1125. See Evidence Table Saurin J-C, Delvaux M, Gaudin J-L. et al. Diagnostic value of endoscopic capsule in patients with obscure digestive bleeding: Blinded comparison with video push-enteroscopy. *Endoscopy* 2003; 35: 576-584. See Evidence Table

The use of M2A™ (Given Imaging) capsule in the diagnosis of small bowel lesions/chronic bleed sites does meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

12/03/2007: MTAC REVIEW
Capsule Endoscopy
Evidence Conclusion: Diagnostic accuracy: Triester, Leighton and colleagues' meta-analyses (2005, 2006) as well as the other published meta-analyses compared CE with one or more alternative diagnostic modalities for evaluation the small bowel in patients with OGIB. Triester's meta-analysis included studies either published in full or in the abstract form. The studies compared the performance of CE mainly to push enteroscopy and barium radiography, none of which is considered as a gold standard, nor is able to identify all kinds of lesions in the entire small bowel. The performance of CE and other diagnostic modalities were thus measured as diagnostic yield, which mainly depends on subjective interpretation, rather than sensitivity and specificity. CE was found to be associated with significantly higher incremental yield and number needed to test around 3. A higher yield might indicate that CE is superior to the alternative method but does not assess sensitivity of the test, nor is it able to discriminate the false positive findings. Hartmann and colleagues' 2005, study (not included in the meta-analysis) compared capsule endoscopy to the gold standard of intraoperative enteroscopy. In that study 47 consecutive patients with OGIB and a negative initial work-up underwent both capsule and intraoperative endoscopy. The source of bleeding was located by intraoperative endoscopy in 72.3% of cases and by capsule endoscopy in 74.5%. Compared to the gold standard CE had a sensitivity of 97%, specificity of 85%, positive predictive value of 95% and negative predictive value equal to 86%. CE was not associated with any major adverse events, while one patient died of postoperative peritonitis after laparotomy. Apostolopoulos and colleagues 2006, compared the performance of CE to enteroclysis among 51 patients with unexplained iron deficiency anemia after negative endoscopic evaluation of the upper and lower gastrointestinal tract. This was a highly selected group of patients which may limit generalization of the results. Upper GI series and push enteroscopy were not included among the diagnostic procedures performed. The authors compared the yield of CE with enteroclysis which is not considered as a gold standard, and the results were presented as diagnostic yields not sensitivity and specificity. Its results show that CE had a diagnostic yield of 56.9% vs. 11.8% for the enteroclysis ($p<.0001$). Impact of capsule endoscopy on patient management: The published studies, to date, on the influence of capsule endoscopy on patient management included highly selected groups of patients with wide variations in their baseline characteristics as age, indication of endoscopy, duration of bleeding, number and type of previous investigations undergone, as well as other variables. In addition, the investigators used different diagnostic criteria for the identification of the bleeding pathology, as reflected in the wide range of diagnostic yield. The latter was also influenced with the experience and number of researchers interpreting the CE images. Thus, the published studies with their potential biases and confounding factors, and with the lack of randomized controlled trials, do not provide sufficient evidence to determine that capsule endoscopy would lead to any incremental improvement in the management of patients. Impact of CE on patient outcome: There is insufficient evidence to determine the impact of CE on patient outcome. The published outcome studies were small case series with no control groups. The therapies and interventions received by the patients were not standardized and varied between studies. Patients were treated with medical, endoscopic or surgical interventions and complete resolution of bleeding was achieved in 40-85% of cases. This varied according to study, eligibility criteria, patient characteristics, bleeding condition, condition, and treatment received. Randomized controlled trials with long-term follow-up periods are needed to determine the effect of capsule endoscopy on patient management and outcomes. Assessment

Back to Top

objective: To evaluate the diagnostic accuracy for the capsule endoscopy (CE) in identifying the lesion of, IDA or obscure gastrointestinal bleeding (OGIB)? To determine whether CE contributes substantially to improved diagnosis and/or replaces other diagnostic tests or procedures. To determine if diagnosing the source of IDA/OGIB with the CE would influence the management decisions? Would it result in providing more appropriate therapy? To determine whether using CE for locating the source of OGIB would improve the clinical and patient-oriented outcomes? Diagnostic accuracy: There were three meta-analyses (Triester 2005, Triester 2006, and Leighton 2006) that evaluated CE for OGIB and/or Crohn's disease. All three were conducted by the same investigators and the two meta-analyses on OGIB included the same studies. There was also another meta-analysis that compared CE to double-balloon enteroscopy, one study that compared CE with the gold standard intraoperative enteroscopy, and several other studies that compared the performance of CE with other diagnostic modalities. Almost all studies investigated the use of CE for patients with OGIB. Two very small studies investigated the use of CE for patients with iron deficiency anemia (IDA) after negative endoscopic evaluation of the upper and lower GI. Apostolopoulos et al 2006 performed CE on 51 out of 253 patients referred for the evaluation of iron deficiency anemia, and Bar-Meir et al 2004, assessed the diagnostic yield pf a second CE for 20 patients with severe IDA). Diagnostic/therapeutic impact:
Articles: The literature search identified several prospective studies on the influence of capsule endoscopy on management decisions and/or treatment outcomes. All were case series with no control or comparison groups. The largest more recent meta-analysis of studies that compared CE to other diagnostic modalities, the prospective study that compared it with intraoperative endoscopy, the study on its role in investigating unexplained iron deficiency anemia, a case series on its impact on patient management, as well as 4 outcome studies were critically appraised. The four outcome studies were summarized in one table. *The following studies were critically appraised:* Triester SL, Leighton JA, Leontiadis GL, et al. A meta-analysis of the yield of capsule endoscopy compared to other diagnostic modalities in patients with obscure gastrointestinal bleeding. Am J Gastroenterol; 2005; 100:2407-2418. See Evidence Table Leighton JA, Triester SL, Sharma VK. Capsule endoscopy: A meta-analysis for use with obscure gastrointestinal bleeding. And Crohn's disease. Gastrointest Endosc 2006;16:229-250 See Evidence Table Hartman D, Schmidt H, Bolz G, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure gastrointestinal bleeding. Gastrointest Endosc 2005;61:826-832 See Evidence Table Apostolopoulos P, Liatos C, Gralnek IM, et al. The role of wireless capsule endoscopy in investigating unexplained iron deficiency anemia after negative endoscopic evaluation of the upper and lower gastrointestinal tract. Endoscopy 2006; 38:1127-1132. See Evidence Table Sidhu R, Sanders DS, Kapur K et al., Capsule endoscopy changes patient management in routine clinical practice. Dig Dis Sci 2007; 52:1382-1386. See Evidence Table Viazis N, Papaxoinis K, Theodoropoulos I, et al. Impact of capsule endoscopy in obscure small-bowel bleeding; defining strict diagnostic criteria for a favorable outcome. Gastrointest Endosc 2005; 62:717-722 See Evidence Table Estevez, Gonzalez-Conde B, Vazquez-Iglesias JL, et al. Diagnostic yield and clinical outcomes after capsule endoscopy in 100 consecutive patients with obscure gastrointestinal bleeding. Europ J Gastroenterol Hepatol 2006;18:881-888 See Evidence Table Neu B, Ell C, May A, et al. Capsule endoscopy versus standard tests in influencing management of obscure digestive bleeding: results from a German multicenter trial. Am J Gastroenterol; 2005; 100:1736-1742. See Evidence Table Pennazio M, Santucci R, Rondonotti E, et al. Outcome of patients with obscure gastrointestinal bleeding after capsule endoscopy: report of 100 consecutive cases. Gastroenterol 2004; 26:643-653. See Evidence Table

The use of M2A™ (Given Imaging) capsule in the diagnosis of unexplained iron deficiency anemia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

4/18/2011: MTAC REVIEW
Capsule Endoscopy
Evidence Conclusion: There is limited published evidence on the usefulness and safety of Agile patency capsule in identifying patients who can safely undergo capsule endoscopy. There are no published randomized controlled trials, to date, that compared the accuracy of Agile capsule to any of the radiographic methods used to assess small bowel patency prior to capsule endoscopy. The case series by Herrerias and colleagues (2008) examined the ability of the Agile system in determining which patients with known strictures can safely undergo capsule endoscopy (CE). 106 eligible patients with evidence of intestinal stricture ingested the patency capsule and were followed up periodically with scanning devices until the capsule was excreted. The intestinal tract was considered sufficiently patent if the patency capsule was excreted intact without any changes in its original dimensions, or if the radiofrequency identification tag (RFID) was not detected by scanning the patients at 32-38 hours after ingestion. 59 patients (56%) excreted the patency capsules intact and underwent capsule endoscopy with the PillCam video capsule, with no cases of capsule retention. The majority of patients who excreted intact patency capsules still had to undergo fluoroscopy as the capsules were passed after the scheduled 38 hours (over 25% were excreted after 60 hours). A total of 17 patients had adverse events mainly abdominal pain; one

Back to Top

patient had intestinal obstruction and underwent surgical resection of the proximal colon and terminal ileum. The authors indicate that no remnants of the capsule were found at surgery. The study may suggest that patients who pass the Agile Patency Capsule intact may be suitable candidates for capsule endoscopy but does not provide sufficient evidence that it is safer and more accurate than other radiographic methods used.
Articles: The literature revealed a limited number of articles on the Given Patency System. The published empirical studies were all case series and mainly on the first generation of the patency capsule (M2A Patency Capsule). Only one case series on the newer generation, the Agile Patency System, was identified, and critically appraised. Herrerias J, Leighton JA, Costamagno G, et al. Agile patency system eliminates risk of capsule retention in patients with known intestinal strictures who undergo capsule endoscopy. *Gastrointest Endosc.* 2008;67:902-909. See Evidence Table

The use of patency capsule does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
91110	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus with interpretation and report
91113	Gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), colon, with interpretation and report

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
12/12/2001	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 01/08/2013 MDCRPC,02/05/2013 MDCRPC,12/03/2013 MPC, 10/07/2014MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC,11/07/2017MPC ,10/02/2018MPC , 10/01/2019MPC , 10/06/2020MPC, 10/05/2021MPC, 10/04/2022MPC, 10/03/2023MPC , 03/12/2024MPC	03/12/2024

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
05/05/2015	Slight modifications to the policy were made to include esophageal varices. Also, a notation and to allow approval for NSAIDS if ASA is used for anticoagulation.
08/31/2016	Added retired LCD language
07/11/2017	MPC approved to adopt revised indication
10/05/2021	Added Colon Capsule Endoscopy LCD/LCA for Medicare.
12/08/2022	Added applicable new CPT code to criteria; removed applicable deleted CPT code
03/12/2024	MPC approved the modified hybrid criteria for capsule endoscopy effective August 1st, 2024, 60-day notice required.

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Capsule pH Monitoring System for Diagnosis of Gastroesophageal Reflux Disease (GERD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	24-Hour Ambulatory Esophageal pH Monitoring (100.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

The disposable capsule pH monitor (Bravo pH Monitoring System) is considered an acceptable alternative to standard catheter-based ambulatory pH monitoring for adults and does not require medical necessity review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastroesophageal reflux disease (GERD) is a common condition, with an estimated lifetime prevalence of 25-35% in the US. Patients with GERD often report a compromised quality of life due to symptoms, dietary restrictions, and functional limitations. Complications of GERD include esophagitis, strictures, ulcerations and Barrett's esophagus. GERD can be diagnosed clinically when patients present with classic symptoms, heartburn and regurgitation. It is more difficult to diagnose in the absence of typical symptoms. Some less typical symptoms such as chest pain and weight loss may indicate GERD or a more serious condition (Scott & Gelhot, 1999).

Diagnostic tests are often used when the diagnosis is unclear or when there is a concern about complications. Possible diagnostic methods are response of symptoms to omeprazole (a proton pump inhibitor), radiology, endoscopy and ambulatory pH monitoring. Radiographic studies may not be useful because only about one-third of patients with GERD have radiologic signs of esophagitis. Endoscopy is more useful for diagnosing Barrett's esophagus and other complications of GERD than for diagnosing GERD itself.

Ambulatory pH monitoring is currently considered the "gold standard" for diagnosing GERD. It involves placing a nasally passed catheter into the esophagus. The catheter is connected to a monitoring device worn on the patient's belt and levels of pH are recorded over 24-hours. Many patients find this test uncomfortable. Patients

Back to Top

Date Sent: 4/29/24

may restrict their daily activities which could result in false negative findings or may not complete the test due to discomfort (Pandolfino & Kahrilas, 2005; Scott & Gelhot, 1999).

The Bravo pH monitoring system (Medtronic) is a non-invasive alternative to catheter-based ambulatory pH monitoring. This system involves attaching a radiotelemetry pH-sensing capsule (approximately the size of a gel cap) to the mucosal wall of the esophagus. The capsule is placed approximately 6 cm above the squamocolumnar junction using a customized delivery system that is removed after the capsule is in place. The capsule can be placed orally or trans-nasally, and the procedure is often done during endoscopy.

The capsule measures the pH in the esophagus and transmits the information via radio signal to an external receiver. The pager-sized receiver can be worn on the patient's belt or waistband. The receiver has a range of 3-5 feet. At the end of the 24-hour or 48-hour testing period, the information from the receiver is uploaded to a computer (Pandolfino, 2005; Medtronic website). Potential advantages of the Bravo system are increased comfort and patient compliance.

The Bravo system had been approved by the FDA and has not been previously reviewed by MTAC.

Medical Technology Assessment Committee (MTAC)

Capsule PH Monitoring System (Bravo System)

08/01/2005: MTAC Review

Evidence Conclusion: Only one study was identified that compared the findings of pH monitoring using the Bravo system and the "gold standard", catheter-based esophageal monitoring. This study (des Varannes et al., 2005) found that the Bravo system under-reported esophageal acid exposure compared to standard testing. The investigators used a correction factor obtained from their data to determine a cut-off value for abnormal acid exposure as measured by Bravo. After this correction, there was an 88% concordance in diagnostic yield between the two methods. As the authors noted in their conclusion, correction factors have not been standardized. Additional studies are needed to validate an appropriate cut-off value for diagnosing GERD with the Bravo system.

The other study that was reviewed (Pandolfino et al, 2003) primarily evaluated the feasibility of using the Bravo system. The investigators were highly successful at placing the Bravo system and recording pH levels. The Pandolfino study included an analysis that compared patient satisfaction with the Bravo and conventional systems. Findings were that the Bravo patients reported more esophageal discomfort and the conventional patients reported more throat discomfort. Overall satisfaction was higher in the Bravo group. Both studies were limited by small sample sizes.

Articles: The search yielded 12 articles, four of which were empirical studies. The ideal study would be an independent, blind comparison of the accuracy of GERD diagnosis using the Bravo PH monitoring system with the "gold standard", catheter-based esophageal PH monitoring. There was one study that compared these two diagnostic tests (des Varannes et al., 2005) and this was critically appraised. Another study that compared the findings of the Bravo pH monitoring system in healthy patients and patients with a clinical diagnosis of GERD (Pandolfino et al., 2003) was also critically appraised. There were also two case series (n=30 and n=60) that examined the feasibility of using the Bravo pH monitoring system and these were not evaluated further.

des Varannes SB, Mion F, Ducrotte P et al. Simultaneous recordings of esophageal pH monitoring and a wireless system (Bravo). Gut 2005; Published on-line before journal publication. See Evidence Table. Pandolfino JE, Richter JE, Ours T et al. Ambulatory esophageal pH monitoring using a wireless system. *Am J Gastroenterology* 2003; 98: 740-749. See Evidence Table.

The use of capsule PH monitoring system (Bravo System) in the evaluation of gastroesophageal reflux disease (GERD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare: Medical Necessity Review no longer required:

CPT® Codes	Description
91035	Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Back to Top

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
08/01/2005	Initiated annual review because of Medicare criteria 05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013MDCRPC, 03/04/2014 MPC, 09/02/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC , 05/02/2023MPC, 03/12/2024MPC	04/23/2020

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
04/23/2020	Added clarification that this criteria policy is applicable to adults.

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Defibrillators

- Implantable Cardioverter Defibrillator (ICD)
- Subcutaneous implantable Cardioverter Defibrillator (SICD)
- Substernal implantable Cardioverter Defibrillator

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual, Change Request 11605 – Transmittal 4513, section 19: ***Extravascular Implantable Cardioverter Defibrillator (EV ICD)*** **Covered if performed as part of an approved Investigational Device Exemption (IDE) study*
National Coverage Determinations (NCD)	Implantable Cardioverter Defibrillator (ICD) requires Level of Care review ***AND*** medical necessity review against NCD Implantable Cardioverter Defibrillators (ICD) (20.4)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Implantable Cardioverter Defibrillator (ICD) requires requires Level of Care review ***AND*** medical necessity review Billing and Coding: Implantable Automatic Defibrillators (A56342)

For Non-Medicare Members

Service	Criteria
Subcutaneous Implantable Cardioverter Defibrillator (SICD)	The use of the SICD may be considered medically necessary for all appropriate pacemaker patients who meet the following criteria: A. Have a contraindication to a transvenous ICD due to at least **ONE of the following**: 1. Lack of adequate vascular access; or 2. The need to preserve existing vascular access due to chronic dialysis; or 3. Repeat transvenous ICD placement not indicated due to complications with previous transvenous ICD placement; or 4. Congenital heart disease; or 5. Increased risk for bacteremia The use of the SICD is considered investigational when the

Back to Top

	above criteria are not met.
Substernal Implantable Cardioverter Defibrillator	The use of a substernal ICD (CPT Codes 0571T-0580T, 0614T) is considered investigational.
Implantable Cardioverter Defibrillator (ICD)	Requires Level of Care review ***AND*** medical necessity review. Kaiser Permanente has elected to use coverage guidance from Medicare's National Coverage Determination (NCD) Implantable Cardioverter Defibrillators (ICD) (20.4)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Cardiovascular disease is the most common cause of death in the Western world, and sudden cardiac death (SCD) accounts for approximately 60% of all cardiovascular mortality. SCD is responsible for ~300,000 annual deaths in the United States; with ventricular fibrillation (VF) accounting for up to one-third of cases (Zipes 1998, Estes 2011, Majithia 2014, Rhyner 2014).

The implantable cardioverter defibrillator (ICD) was developed and introduced to clinical practice around the 1980s to address this issue of fatal SCD from ventricular tachyarrhythmia. The ICD continuously monitors the heart, identifies malignant ventricular tachyarrhythmia, and delivers an electric counter shock to restore normal rhythm. The first defibrillator received FDA approval in 1985 to be used in patients who had survived cardiac arrests. In 2002, the FDA expanded its use to patients with a history of a heart attack and depressed heart function. ICDs are widely used and studies have shown significant mortality benefit in selected patients at increased risk of SCD. However, the use of ICDs may at times be complicated with the implantation procedure, programing, device malfunction, and lead performance deterioration by time. Traditionally, the ICD is implanted transvenously by creating a pocket in the subclavicular areas and gaining vascular access to reach the heart. This approach has its drawbacks and is associated with short- and long-term adverse events. Reported complications associated with ICD systems include lead dislodgement, lead fracture, conductor coil breaks, pneumothorax, cardiac perforation, pericardial effusion, cardiac tamponade, and systemic infection. Lead malfunction occurs in up to 40% of the transvenous leads at 8 years after implantation. Lead failure either generates inappropriate shocks or impedes appropriate therapy. Extraction of the lead is recommended in cases of lead fracture, malfunction, or other mechanical problems that prevent safe and effective ICD shock therapies. This extraction is complex and can be associated with significant risks including death (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014Majithia 2014).

The complications associated with the intracardiac leads of the implantable cardioverter defibrillators have led to the development of a totally subcutaneous ICD (S-ICD) with the intention to provide the same protection, but with less procedural and device-related risks. The S-ICD system senses, detects, and treats malignant ventricular tachycardia (VT)/ventricular fibrillation (VF) without requiring vascular access or fluoroscopy. The S-ICD system (model SQ-RX 1010, Cameron Health, Inc., San Clemente, CA) includes a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The lead-electrode is composed of proximal and distal sensing electrodes separated by a shocking coil. The pulse generator is implanted in a subcutaneous pocket created over the fifth intercostal space between the mid and anterior axillary lines. The single lead is tunneled from the xiphoid process to the pocket and to the sternal manubrium joint. Fixation is achieved with the addition of a suture sleeve at the level of the xiphoid and a single suture at the superior parasternal portion of the lead. Implantation of the device relies entirely on anatomic landmarks and does not require fluoroscopy (although some investigators advocate brief screening to verify the final position). The currently used pulse generator weighs 145 g, has a volume of 69 ml, and an estimated 5-year battery life. The greatest advantage of S-ICD is that the lead does not pass through the central veins in the chest, nor is it attached to the tissue within the heart chambers. However, the pulse generator of the S-ICD is approximately twice the volume and weight of the currently used transvenous ICD, which may prevent its use in children, and increase the risk of erosion, discomfort, and infection. In addition, the

Back to Top

weight of the device may cause its dislodgement and changes in the shock configuration (Olde Nordkamp 2012, Weiss 2013, Aziz 2014, Chang 2014, Grace 2014, Majithia 2014).

The S-ICD system detects changes in the ventricular rate by using subsurface electrocardiography through a primary, secondary, or alternate vector. The device is programmed to select the vector that best avoids double QRS counting or T-wave oversensing events that could lead to misinterpretation of the rhythm and delivery of inappropriate shock. The heart rate is measured as the average of 4 consecutive sensed intervals. VF is diagnosed when 18 of 24 consecutive sensed events exceed the shock zone limit. Once the system detects a malignant arrhythmia, it delivers up to 80 J shock to terminate the arrhythmia and will automatically reverse polarity if the initial shock fails to terminate the arrhythmia. The mean defibrillation threshold is significantly higher than with transvenous devices, and some investigators suggest that high-energy shocks may be harmful to the myocardium (Aziz 2014, Majithia 2014, Nair 2014).

Unlike the conventional ICD devices, S-ICD is unable to provide long-term bradycardia pacing or antitachycardia pacing due to the absence of an endocardial lead. It is thus not suitable for patients with an indication for antibradycardia pacing or cardiac resynchronization therapy, or for those with a history of repetitive monomorphic ventricular tachycardia that would benefit from antitachycardia pacing. S-ICD may not be used concurrently with unipolar pacemaker as that would interfere with the S-ICD arrhythmia detection. This absence of bradycardia pacing in the S-ICD might lead to more bradycardia related events as syncope or even death. The device may be potentially useful for patients who are not eligible for transvenous ICDs, or are at high risk of complications e.g. subjects with congenital heart disease, complicated vascular anatomy, at high risk of infection, or in patients in whom vascular access is limited or needs to be conserved e.g. for renal dialysis or long-term intravenous drug therapy (Akerstrom 2013, Olde Nordkamp 2012, Chang 2014, Majithia 204).

S-ICD received US FDA approval in September 2012, “To provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmia in patients who do not have sympathetic bradycardia, incessant (continual) ventricular tachycardia, or spontaneous frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia Pacing”. The FDA required that a post-approval registry be created to track outcomes of patients and devices for at least 60 months after implantation.

S-ICD has not been previously reviewed by MTAC; it is being reviewed based on a request for the Clinical Review Unit for coverage decision.

Medical Technology Assessment Committee (MTAC)

Subcutaneous Implantable Cardioverter Defibrillator

10/20/2014: MTAC REVIEW

Evidence Conclusion: The results of the published observational studies suggest that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias, however, the incidence of inappropriate therapy was as high as 13.1% (in a mean duration of 11 months in Weiss et al 2013). Inappropriate shock therapy may decrease the quality of life and increase the mortality risk.

The published studies evaluated the accuracy, efficacy and safety of S-ICD in reversing induced rather than spontaneous arrhythmias. The arrhythmia is not always predictable and as seen in one study (Kobe 2013) the S-ICD system had to be changed to transvenous ICD in a patient who needed antitachycardia pacing (ATP) therapy. A group of investigators (Gold and colleague 2012) noted that though there is no reason to suspect that electograms may differ between induced and spontaneous rhythms of similar rates and regularity, this possibility of this difference cannot be excluded. *Conclusion:* The results of the published literature indicate that: There is some evidence that S-ICD may be accurate in detecting and reversing induced ventricular arrhythmias. There is insufficient evidence to date, to determine the efficacy or effectiveness to S-ICD in terminating spontaneous VT/VF episodes. S-ICD may lead to inappropriate shock therapy in up to 13.1% of cases. There is insufficient evidence to determine the long-term safety of the S-ICD system. There is insufficient evidence to determine that S-ICD is safer or more effective than conventional transvenous ICD. No randomized controlled trial that compared the two devices head to head was published to date. There is insufficient evidence to determine that the use of S-ICD prevents or reduces sudden death from ventricular arrhythmias.

Articles: The literature search revealed over 300 citations on subcutaneous implantable cardioverter defibrillator. The majority were reviews or opinion pieces. No published RCTs that compared the safety and efficacy of the S-ICD head to head with the conventional transvenous ICD or other therapeutic interventions were identified; only the published rationale and design of the ongoing PRAETORIAN trial that is comparing the subcutaneous to the transvenous implantable defibrillators. There were a number of published observational studies including those that led to the European approval as well as the pivotal study (Weiss et al, 2013) leading to the US Food and

Back to Top

Drug Administration approval. The search also identified a paper documenting the early results from the EFFORTLESS S-ICD Registry that was created to document the clinical, system, and patient-related outcome data from patients implanted with S-ICD in multiple centers in Europe and New Zealand. The pivotal prospective study (Weiss et al, 2013) and a study with a comparison group (Kobe 2013) were selected for critical appraisal: Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013; 128(9):944-953. See Evidence Table. Köbe J, Reinke F, Meyer C, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm. 2013;10 (1):29-36. See Evidence Table.

The use of Subcutaneous Implantable Cardioverter Defibrillator does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

References

Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. National Coverage Determinations (NCDs). Updated January 3, 2008. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed November 07, 2023.

Applicable Codes

Subcutaneous ICD (SICD)
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)

Substernal ICD

Medicare - Considered medically necessary when performed as part of an approved Investigative Device Exemption (IDE) study:
Non-Medicare – Considered not medically necessary - experimental, investigational or unproven:

CPT® or HCPC Codes	Description
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed
0572T	Insertion of substernal implantable defibrillator electrode
0573T	Removal of substernal implantable defibrillator electrode
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode
0575T	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with

 Back to Top

	substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional
0576T	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter
0577T	Electrophysiologic evaluation of implantable cardioverter-defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional
0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
0580T	Removal of substernal implantable defibrillator pulse generator only
0614T	Removal and replacement of substernal implantable defibrillator pulse generator

Implantable Cardioverter Defibrillators

Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber
C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/23/2014	11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC , 03/07/2023MPC	11/07/2023

MPC Medical Policy Committee

Back to Top

Revision History	Description
07/18/2016	Added NCD 20.4
09/08/2015	Revised LCD L35008
11/07/2017	MPC approved to adopt criteria for SICD
03/01/2022	Added Medicare links and codes related to subcutaneous ICD, noted that substernal ICD is considered investigational for non-Medicare.
11/07/2023	MPC approved adopting Medicare coverage criteria of Defibrillator and Pacemaker placement for commercial members and gold card WPMG Cardiology subject to ongoing audits of compliance with the stated criteria.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Rehabilitation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual Chapter 32, Section 140
National Coverage Determinations (NCD)	Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1)
Local Coverage Determinations (LCD)	None
Local Coverage Article	11/01/2023 Noridian retired LCA A54070 Billing and Coding Outpatient Cardiac Rehabilitation**.** These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCAs are not retired because they are incorrect. Therefore, continue to use LCA A54070 for determining medical necessity.

For Non-Medicare Members

Kaiser Permanente has elected to use the Cardiac Rehabilitation (KP-0358) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of cardiology notes

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Cardiovascular disease (CVD) is the most common cause of office visits, hospitalizations, and deaths in the United States. In recent years, there has been great progress in pharmacological therapies as well as technology-based diagnostic and therapeutic interventions for CVD. As a consequence, a greater number of patients survive acute events, but with a heavier burden of chronic conditions and clinical needs. In addition to medication and

interventional cardiology, these patients also need structured support to restore their quality of life and to maintain or improve functional capacity.

Cardiac rehabilitation (CR) was initially developed in response to the profound deconditioning caused by the prolonged bed rest that was common in the management of patients following acute cardiac events in the first half of the 20th century. Since then it has developed into multidisciplinary programs to optimize the health of patients with an expanding range of cardiovascular disease (Gordon 2010). CR is a multifactorial, comprehensive intervention defined as the coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post-acute CVD event may, by their own efforts, preserve or resume optimal functioning in society, and through improved health behaviors, slow or reverse progression of disease (Taylor 2004). It is also viewed as the clinical application of preventive care by means of a professional multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients (Piepoli 2010).

The American Heart Association (AHA), the American College of Cardiology (ACC), and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) consider cardiac rehabilitation / secondary prevention programs integral to the comprehensive care of patients with CVD. They recommend that all cardiac rehabilitation/secondary prevention programs should contain specific core components that aim at optimizing cardiovascular risk reduction, foster healthy behaviors and compliance with these behaviors, reduce disability, and promote an active lifestyle for patients with cardiovascular disease. The core components include baseline patient assessment, nutritional counseling, risk factor management (weight, blood pressure, lipids, diabetes mellitus and smoking), psychological interventions, physical activity counseling, and exercise training (Balady 2007). The goals of CR consist primarily of mobilizing the patient, optimizing drug therapy, implementing measures of secondary prevention, providing means for understanding the disease through education and advice, facilitating behavior modification, supporting the patient in overcoming the disease, treating psychological disturbances, and improving reintegration into professional life (Farin 2007). It is clearly understood and accepted that an isolated exercise program is not cardiac rehabilitation; however, physical activity and exercise training are considered the core components on which a comprehensive CR program is built (Piepoli 2010).

Most CR programs are held for groups in hospitals, gyms, or community centers. These may be inconvenient to patients (especially women and older patients) who may have problems with accessibility, dislike of groups, and/or work on domestic commitments. Home-based programs were thus introduced as an alternative to traditional CR in an attempt to increase participation rates. These programs have been defined as structured programs with clear objectives to the participants, including monitoring, follow-up, visits, letters, telephone calls from staff, or at least self-monitoring diaries (Dalal 2010).

Medical Technology Assessment Committee (MTAC)

Cardiac Rehabilitation

12/20/2010: MTAC REVIEW

Evidence Conclusion: The majority of the studies on cardiac rehabilitation for heart failure or stable MI were small trials, with short follow-up duration, and mainly examined the safety and efficacy of exercise-based programs. The CR programs undergone in the trials differed in their duration (range 1-6 months), frequency (1-5 sessions per week), and session length (20-60 minute /session), and most exercise programs and rehabilitation interventions were tailored on the individual patient's needs. Several meta-analyses were thus conducted to pool the results of these trials to provide sufficient power to adequately address the effect of comprehensive CR programs on morbidity, mortality, HRQoL, and modifiable risk factors. Cardiac rehabilitation programs for patients with CHD: Several earlier meta-analyses examined the effects of exercise based cardiac rehabilitation on patients with MI and found a survival benefit of the programs. The latest of these meta-analyses was performed by Taylor and colleagues (2004) and included 48 trials with 8,840 participants**.** Most studies recruited patients at low risk of another event after an MI. The exercise program, as well as the duration of follow-up varied widely between studies. The results of the pooled analysis showed that, compared with usual care, CR reduced total mortality by 20% and cardiac mortality by 26%. There were also significant reductions in some modifiable risk factors including total cholesterol, triglycerides, systolic blood pressure, and smoking. There were no statistically significant reductions in the rate of recurrent MI or revascularization. The main analysis combined the results of exercise only trials with studies on comprehensive cardiac rehabilitation. A subgroup analysis performed by the authors showed a significant mortality benefit with comprehensive CR programs. A decrease in total and cardiac mortality with CR may be due at least in part, to the serial surveillance provided by the rehabilitation staff, which may lead to the detection of any deterioration in the clinical status before it progresses to a more morbid condition or event.

Back to Top

Date Sent: 4/29/24

Cardiac rehabilitation programs for patients with heart failure: Davies et al's Cochrane review in 2010, on the effect of exercise training in patients with systolic heart failure showed that exercise training reduces heart-failure related hospital admission and improves HRQoL in patients who were mainly men with a mean age ranging from 43-72 years, and with NYHA class II-III systolic HF. No effect on mortality was observed. All studies included in the analysis, except for one relatively small (N=200) trial, were exercise only interventions. The analysis included the HF-ACTION study which was a large trial (N=2,331) on the effect of exercise training on HF patients. CR programs aim at enhancing self-management and are not restricted to exercise but should also include education, risk factor management, pharmacological therapies, and psychological input. An earlier meta-analysis (van Tol 2006), evaluating the effect of exercise training on cardiac performance in 35 RCTs including 1,486 patients with stable mild to moderate CHF showed that exercise training leads to significant improvements in cardiac performance and quality of life. The meta-analysis did not study the effect on mortality or rate of hospitalization due to HF. Austin et al, 2008, reported on long term results of a trial that randomized 200 patients over 60 years of age with LV systolic dysfunction NYHA class II-III, to receive either standard care or undergo a comprehensive CR program for 24 weeks. Five-year follow up of 56% of the patients showed some long- term benefit on the functional performance and perceived exertion of the patients. In a more recent small study that included older HF patients, and HF patients with normal ejection fraction, Davidson and colleagues (2010) showed that a multidisciplinary heart failure CR program significantly reduced hospital admission rates due to a cardiovascular or any other event. Home-based versus center based cardiac rehabilitation for patients with coronary heart disease: A large number of trials compared the outcome of home versus center-based CR on patients with CVD. The majority of trials were small in size with the exception of a more recent trial (Birmingham Rehabilitation Uptake Maximization [BRUM]), which included 525 participants after experiencing an acute MI or coronary revascularization. The results of this trial found no difference in risk factor control or self-reported physical activity between patients randomized to home versus center-based CR. The study was not designed as an equivalence trial, and a lack of significant difference between the two strategies does necessarily indicate that they have similar effects. A recent Cochrane review (Dalal 2010) pooled the results of the 12 RCTs involving almost 1200 participants in total. The trials excluded high risk patients (those with arrhythmias or severe ischemia) and only 2 studies included HF patients. The patient characteristics as well as duration, frequency, and session lengths of CR programs varied widely between studies, and several of the home-based programs started with center-based CR then transitioned to CR at home. The results of the analyses showed no significant differences between the home versus center-based CR programs in risk factors control, HRQoL measures, and all-cause mortality. The authors concluded that home-based and center-based CR programs appear to be equally effective in improving clinical and health related QOL outcomes in patients with low risk after MI or revascularization. The results may suggest that the outcomes between home-based and center-based CR are similar, however lack of significant differences does not necessarily imply that the two strategies are equally effective.

Conclusion**:** There is fair evidence that exercise-based cardiac rehabilitation programs reduces mortality, morbidity, and improves health related quality of life (HRQoL), and modifiable risk factors in low risk patients with coronary heart disease. There is fair evidence that exercise-based cardiac rehabilitation programs reduce hospital admission and improves HRQoL among low- to moderate- risk patients with stable heart failure.

There is inconclusive evidence that home-based and center-based CR have similar benefits. The results of trials and meta-analyses comparing the two strategies suggest that they have similar outcomes. However, due to the study designs, a lack of significant statistical differences in the outcomes does not necessarily imply that the two strategies are equivalent.

Articles: The literature search revealed at least 15 meta-analyses on cardiac rehabilitation, and a large number of randomized controlled trials, and observational studies. The great majority of the meta-analyses and trials were performed on individual components of the cardiac rehabilitation (CR) program, mainly exercise-based programs, in stable patients post myocardial infarction or coronary revascularization, or in patients with heart failure. Overall, the randomized trials on the comprehensive CR were relatively small and with short duration of follow-up. One trial (Austin 2008), reported on 5 years outcome of patients with heart failure after undergoing a multidisciplinary 8-week CR program. The literature search also revealed 4 recent meta-analyses of RCTs that compared home-based cardiac rehabilitation versus center-based programs for patients with cardiovascular disease.

Studies (e.g. HF-ACTION) or meta-analyses (e.g. ExTraMATCH) that examined the safety and efficacy of exercise training or other single components of the program in patients with chronic heart failure or CAD were not included in the current review which evaluates the multidisciplinary cardiac rehabilitation program.

The following meta-analyses of trials on comprehensive CR for patients with heart failure or CHD, that compared and home-based vs. center-based CR as well as the RCT with 5-year follow-up were selected for critical appraisal.

Davies EJ, Moxham T, Rees K, et al. Exercise training for systolic heart failure: Cochrane systemic review and meta-analysis. *Eur J Heart Fail* 2010; 12:706-715. See Evidence Table. Davidson PM, Cockburn J, Newton PJ, et al. Can a heart specific cardiac rehabilitation program decrease hospitalization and improve outcomes in high-risk patients? *Eur J Cadiovasc Prev Rehabil 2010*; 17:393-402. See Evidence Table. Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis

Back to Top

of randomized controlled trials. *Am J Med* 2004; 116:682-692. See Evidence Table. Austin J, Williams WR, Ross L, et al Five-year follow-up findings from randomized trials of cardiac rehabilitation for heart failure. *Eur J Cardiovasc Prev Rehabil 2008*; 15:162-167. See Evidence Table. Dalal HM, Zawada A, Jolly K, et al. Home based versus center based cardiac rehabilitation: Cochrane systemic review and meta-analysis. *BMJ* 2010;340:C 1133. See Evidence Table.

The use of cardiac rehabilitation facility and home based does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session
S9472	Cardiac rehabilitation program, nonphysician provider, per diem

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/15/1998	06/01/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC] ,11/05/2013[MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC], 11/07/2023[MPC]	11/13/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/10/2015	Link for Medicare Pub 100-03 Cardiac Rehabilitation added
09/27/2016	Added NCD 20.31.3 and NCD 20.10.1
11/13/2023	Updated Medicare link for A54070 which was retired 11/1/2023

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Contractility Modulation Device

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cardiac Contractility Modulation Device"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Kaiser Interregional New Technologies Committee Assessment
Date: 04/27/2020

There is insufficient evidence regarding the efficacy and safety of Optimizer (cardiac contractility modulation [CCM]) as compared to optimal medical management for heart failure.

Based on the review of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone, there is moderate-quality evidence that treatment of heart failure with Optimizer CCM is associated with short-term improvements in quality of life and peak Vo_2; however,

findings for other symptom-related outcomes were mixed and there is a lack of long-term outcomes, including hospitalization and mortality data. Thus, the existing evidence regarding how Optimizer CCM effectively manages heart failure is of insufficient quantity and/or quality.

Heart failure (HF), also referred to as congestive HF, is a chronic, progressive condition that develops due to circumstances that overwork and damage the heart, rendering the heart muscle unable to pump enough blood to meet the body's needs for blood and oxygen. The primary causes of HF include coronary heart disease, high blood pressure, and diabetes. Approximately half of heart failure cases are associated with a reduced ejection fraction (HFrEF), typically defined as a left ventricular ejection fraction (LVEF) <35% or <40%. The impact of heart failure on patient quality of life as well as its economic costs are substantial.

Treatment of HF is focused on symptom relief and typically includes lifestyle modification and oral medications that treat underling conditions including hypertension, high cholesterol, diabetes, and obesity. Treatment options for patients with severe HFrEF with inadequate response to medications include cardiac resynchronization therapy (CRT), left ventricular assist devices (LVAD), and heart transplantation. However, many patients with moderate to severe HF symptoms—including the 25% to 35% of patients who have HFrEF categorized as NYHA functional class III—do not meet established indications for these options. The Optimizer Smart System (Impulse Dynamics, Inc., Orangeburg, NY, USA) is intended for patients in this treatment "gap."

The Optimizer Smart System is a pacemaker-sized, rechargeable, implanted device intended to deliver cardiac contractility modulation (CCM) therapy to increase the strength of the heart's ventricular contraction in patients with stage III to IV HF whose LVEF is 25% to 45% despite optimal medical therapy (OMT).

The following clinical question was the subject of the review:

What is the efficacy and safety of the Optimizer Smart System for treatment of heart failure?

A comprehensive search was conducted on March 18, 2020 to identify systematic reviews, technology assessments, and randomized trials addressing the clinical question.

Based on the existing literature:

- The body of evidence on the use of Optimizer CCM for treatment of heart failure consists of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone.
- Two early trials employed a sham-control group (FIX-HF-5 Pilot) and a crossover design (FIX-CHF-4), while the 2 more recent trials used a more traditional design. The sham-controlled and crossover trials noted significant placebo effects for several outcomes.
- Moderate-quality evidence suggests that Optimizer CCM plus OMT results in clinically and statistically significant improvements in short-term clinical outcomes including QOL and peak Vo_2 compared to OMT alone.
- It is unclear if Optimizer CCM has an impact on 6-minute hall-walk (6MHW) distance, NYHA class, ventilatory threshold, hospitalizations, or mortality. The quality of evidence for these outcomes was low due to mixed findings, a lack of between-group differences, insufficient power, and/or inadequate duration of follow-up.
- Moderate-quality evidence suggests that rates of serious adverse events were relatively low and similar between CCM and OMT groups. The implantation procedure and short-term use of the device appear to be relatively safe and comparable to similar interventions (e.g., pacemakers).
- The Optimizer CCM implantation procedure takes about 3 hours to complete, although there was considerable variation across patients and the quality of this evidence is low.

- The main limitations of the included trials are their relatively small sample sizes (801 patients total), lack of long-term follow-up, mixed findings for several key outcome measures (e.g., 6MHW, NYHA class), and lack of a sham control for the 2 most recent trials.
- These promising but preliminary findings suggest that Optimizer CCM is a safe and effective treatment for patients with NYHA class III heart failure with ejection fraction between 25% and 45%. Additional randomized trials are needed to confirm these initial findings and evaluate long-term outcomes.

Among several relevant clinical practice guidelines identified in the evidence search, the European Society of Cardiology (2016) notes that CCM may be considered in selected patients with HF, and NICE (2019) notes that although there are no major safety concerns, the device should only be used in research settings due to the lack of evidence on efficacy.

The committee discussed uncertainty regarding benefits of Optimizer CCM beyond symptomatic improvement. In particular, there is a lack of mortality data. Given the determination of "insufficient evidence," the plan is to continue participation in clinical trials and to await publication of mortality data prior to considering adopting this technology.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular)
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator
0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system
HCPC Codes	**Description**
C1824	Generator, cardiac contractility modulation (implantable)
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility

	modulation generator, replacement only

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/07/2020	04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	10/26/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt new non-coverage criteria (Medicare's position)
05/26/2020	Added background from INTC review on 4/27/2020
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Coronary Artery Calcium Score with Computed Tomography (CT)

- Multidetector Computed Tomography (MDCT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	05/13/2016 Noridian retired LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. Per LCD L34137 - … Until such time as there is more evidence of the medical necessity for quantitative evaluation of coronary calcium, Medicare may not cover the procedure for coronary calcium scoring (75571).
Local Coverage Articles	None

For Non-Medicare Members

*Repeat CAC measurement not indicated within less than 5 years.

Adapted from KPWA ASCVD Primary Prevention Guideline (Oct 2020)

Coronary artery calcium scoring may be indicated for asymptomatic patients with **1 or more of the following**:

- Intermediate ASCVD risk* indicated by ALL of the following
  - Age 40-75 without DM and with LDL-C levels ≥ 70 mg/dL
  - At a 10-year ASCVD risk* of ≥ 7.5% and < 20 %
  - Risk status or decision about statin therapy is uncertain

For these patients, treatment with statin therapy may be withheld or delayed if CAC = 0, except in cigarette smokers and those with a strong family history of premature ASCVD. A CAC score of 1–99 favors statin therapy, especially in those aged ≥ 55 years. For any patient, if the CAC score is ≥ 100 or ≥ 75th percentile, statin therapy is indicated.

- May be considered in select adults age 40-75 with ALL of the following
  - Borderline elevated ASCVD risk (5-7.4% 10-year ASCVD risk*)

Back to Top

Date Sent: 4/29/24

- The presence of CAC may change decision-making with regard to statin treatment and intensity of ASCVD risk factor modification

Routine CAC measurement is not recommended for:

- Patients at low (< 5% 10-year risk) or high (≥ 20% 10-year risk) ASCVD risk
- Patients who are unlikely to initiate treatment even if CAC is identified

*ASCVD Risk Estimator Plus (American College of Cardiology)

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Documented 10-year ASCVD risk score
  - *ASCVD Risk Estimator Plus (American College of Cardiology)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Coronary heart disease (CHD) remains the leading cause of death among men and women in the United States. It is valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. The earliest detectable lesion of coronary atherosclerosis is a fatty streak, followed by crescent shaped lipid plaques, which may rupture and produce either progressive stenosis or sudden occlusion with myocardial infarction. It was previously thought that coronary artery calcification was the late result of end stage plaque degeneration. Now it is believed that calcium is present in all stages of plaque formation. Coronary artery calcification occurs in small amounts in the early lesions of atherosclerosis that appear in the second and third decades of life but is found more frequently in advanced lesions in older age (Janowitz 1993). Coronary artery calcium increases with increasing age in men, while women may experience accelerated calcification after menopause (Allison 2004).

The relation of arterial calcification to the probability of plague rupture is unknown. Some investigators postulate that calcification may actively contribute to the susceptibility of plaque rupture and subsequent events. While others believe that calcification may reflect stabilization and maturation of the plaque that would lead to fewer myocardial infarctions and CHD deaths (Lee 2002). Beckman 2001 reported that although radiographically detected coronary artery calcium can provide an estimate of total coronary plaque burden, calcium does not concentrate exclusively at sites with severe coronary artery stenosis due to arterial remodeling. Other researchers indicated that ultrafast scans cannot detect all calcium and that molecular calcium may go unnoticed. Thus calcium detected by ultrafast scans may represent only the tip of the iceberg (Rumberger 1996). Despite that, some investigators believe coronary artery calcium (CAC) detection may be able to globally define a patient's risk of CHD events.

Now that some believe that calcification can be used as a marker of the atherosclerotic process, and because calcific deposits are radio-opaque, numerous radiographic techniques have been used in the search for a noninvasive screening test for coronary artery disease. Fluoroscopy was used for decades to detect coronary artery calcium. However, its routine use for identifying patients with coronary artery disease is limited due to its low sensitivity to detect small amounts of coronary calcium that can be observed pathologically in complex atherosclerotic plaques. Conventional computed tomography (CT) have an advantage over fluoroscopy in its improved resolution, which is limited however when moving structures are imaged. This limitation has been overcome by the electron beam computed tomography (EBCT), and multidetector computed tomography (MDCT). Both technologies yield thin slice CT imaging using fast scan speeds that reduce motion artifact. 30-40 adjacent axial scans are usually obtained. The fast time scan allows the entire heart to be imaged over one or two breath holds. Images can be reconstructed to form three-dimensional or cross-sectional images. There are three methods for calcium quantification and scoring: The Agatston method, the volumetric method, and quantification of calcium mass. Agatston method is the most commonly used and is obtained by the summation of areas of the calcified lesions multiplied by a scaling cofactor; an Agatston score of zero indicates absence of coronary calcium,

Back to Top

Date Sent: 4/29/24

1-99 is considered low, 10-400 is intermediate, and 400 high (Sanz 2006). Calcium scores can be calculated for a coronary artery segment, a coronary artery, or summed for the whole coronary system.

Ultrafast CT scanners became commercially available in 1983, before the first study of their use was published in 1989. In the 1990s, another form of CT, the helical or spiral computed tomography has been developed. In helical tomography, continuous scanning is performed in combination with a continuous table feed. Thus, the x-ray beam traces a spiral path through the patient. The entire heart can be imaged with 3 mm non-overlapping slices, within one breath hold (30 sec). The initial goal of using cardiac computed tomography was to identify patients at risk of coronary artery disease based on the amount of calcium present. However, in the past 5-10 years these ultrafast scans have been used to: 1) Assist in CHD risk assessment in asymptomatic individuals, and, 2) To assess the likelihood of the presence of CHD in patients who present with atypical symptoms that could be consistent with myocardial ischemia.

The EBCT scanners currently used are produced by GE Imatron, South San Francisco California. They were approved by the FDA as Class II devices.

The use of EBCT for CAC scoring was reviewed by MTAC in 2002 and 2004 and did not meet its evaluation criteria. It is being re-reviewed due to the recent publications of studies with clinically important outcomes.

Medical Technology Assessment Committee (MTAC)

Ultrafast CT in the Screening and Diagnosis of CAD

02/11/2002: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the value of Ultrafast CT as a screening test for coronary artery disease among asymptomatic patients. In the studies reviewed, ultrafast CT and angiography were done among patients because of suspected coronary artery disease. The prevalence of CAD in these studies was high and it may not be appropriate to extrapolate these results to scans done in the population at large, or those done for screening purposes. The studies reviewed show that ultrafast CT scanning had a high sensitivity and low specificity in detecting coronary artery disease among the participants. The sensitivity increased with age and was highest for symptomatic patients older than 50 years. The specificity on the other hand, increased with the number of calcified vessels and was highest among patients with 4-vessel calcification. The majority of studies did not address clinical end-points, as their primary outcome. Detrano, et al (1996) however, followed-up the patients for a mean of 30 months, to determine the relative prognostic value of coronary calcification for predicting CHD events among symptomatic patients. They found that cardiac events and deaths tended to be more frequent in the higher quartiles of calcium score. In conclusion, the results of these studies indicate that in a population where CAD is more prevalent, the absence of coronary calcification is more helpful in ruling out CAD than is the detection of calcium in confirming the presence of CAD. Ultrafast CT seems promising, but as yet, there is no evidence that it may substitute angiography, but can be helpful in excluding or increasing the likelihood of significant CAD in certain situations.

Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. A*JR* 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

12/08/2004: MTAC REVIEW

Ultrafast CT in the Screening and Diagnosis of CAD

Evidence Conclusion: A screening test for preclinical coronary artery disease among asymptomatic individuals, and A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: There is insufficient published evidence to determine the

Back to Top

value of EBCT (Ultrafast CT) as a screening test for coronary artery disease among asymptomatic individuals. Ideally, a screening test should be highly sensitive in detecting previously undiagnosed disease and should lead to changes in management that improves outcomes. The meta-analysis and observational studies reviewed evaluated EBCT coronary artery calcium as a risk predictor of future coronary events among asymptomatic individuals. These studies suggest that coronary artery calcium detected by EBCT may be an independent predictor for coronary events and may add to the information provided by the Framingham risk score. However, the studies had some threats to validity that may limit generalization of the results. The majority is office-based and included self-referred individuals or others at high risk referred by their primary care physicians for further evaluation. Risk factors were self-reported and not measured in more than one study. Different techniques and scans were used, and there was no established cut-off level for calcium scores. The endpoints included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. The endpoint in one of the studies was all-cause mortality that might be due to other causes than coronary atherosclerotic diseases. None of these observational studies examined the influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. There is no evidence that more effective therapy or management could be provided by evaluating CAC score beyond that provided based on FRS. A recent RCT showed that the detection of coronary artery calcium among asymptomatic individuals was not associated with behavior modification or reduction of their cardiac risk scores. This RCT also had its limitations. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: The studies reviewed show that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies reviewed in the meta-analysis, and the more recent study. The sensitivity was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results.

Articles: The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See Evidence Table. Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See Evidence Table. Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. A*JR* 1996; 167:439-444. See Evidence Table.

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/02/2007: MTAC REVIEW

Ultrafast CT in the Screening and Diagnosis of CAD

Evidence Conclusion: This report focuses on the use of electron bean computed tomography for detecting calcium deposits in coronary arteries as 1. A screening test for preclinical coronary artery disease among asymptomatic individuals, and 2. A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: Ideally a screening test for predicting outcomes should not only prove to independently contribute to risk stratification, but also to provide further prognostic information beyond and above the traditional risk factors i.e. in this case, the Framingham Risk Stratification. Constructing the Receiver Operator Characteristic (ROC) curves and measuring the Area Under the ROC curve (AUC) would determine if a new marker or test has an additive benefit. An ideal screening test would also lead to changes in the management that will improve health outcomes e.g. fewer events, extended life or better quality of life. Fletcher's meta-analysis (2004), reviewed for the previous update, offered some support that there is a linear relationship between CAC and CHD events, but the analysis did not address whether CAC adds any incremental value to Framingham Risk Score (FRS) for CHD risk prediction. Greenland and colleagues (2007) pooled the results of 6 observational studies published after Fletcher's meta-analysis. There was some heterogeneity between the studies in the assessment of risk factors, cut-off levels used for calcium scores, as well as in the endpoints. The latter included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. None of the studies included in the meta-analysis examined the

Back to Top

influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. The pooled results of the studies in the meta-analysis showed that patients with any measurable calcium were at a significantly higher risk compared to those with a low-risk CAC (using a score of 0) over a 3-5 years period of observation. This analysis also showed that there was an incremental relationship between CAC and CHD risk. The authors however did not discuss if adding CAC scoring to the traditional factors would significantly increase the AUC. Arad and colleagues published two articles on the St Francis Health Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first was a prospective cohort study that investigated the accuracy of CAC scores in predicting atherosclerotic cardiovascular disease (ASCVD) events independent of standard risk factors. The second article reports on the results of an RCT embedded in the cohort study. This RCT investigated whether lipid-lowering therapy and antioxidants retard the progression of coronary calcification and prevent ASCVD events. The St Francis Health Study enrolled 4,903 mainly White, healthy men and women 50-70 years old. All participants underwent EBCT but only a subset (n=1,357) with CAC score >80th percentile for age and gender, also underwent risk factor assessment. Participants were followed up for an average of 4.3 years for a composite outcome of coronary death, nonfatal MI, surgical or percutaneous coronary revascularization, nonhemorrhagic stroke and peripheral vascular surgery. A multivariate regression analysis showed that CAC scoring predicted CAD events independent of standard risk factors, and that it was strongly predicted by age, male gender, and family history of premature coronary disease. The Receiver Operator Curve (ROC) showed that CAC score predicted CAD events more accurately than Framingham risk stratification (AUC= 0.79 vs. 0.68). It has to be noted however that this comparison was made only for participants with the highest percentiles of CAC, and that this study included all ASCVD outcomes while FRS predicts only the hard CHD outcomes. The majority of the observed events in this study were cardiovascular procedures rather than the traditional cardiac events. One other limitation of the study was low participation rate as only 2% of the eligible subjects we enrolled in the study. The RCT embedded in that study (Arad, Spadaro 2005) randomized 1,005 participants, with CAC score >80th percentile for age and gender, to receive a combination of atorvastatin, vitamin C, and vitamin E or a placebo. All participants in the two groups also received aspirin 80 mg daily. After 4.3 years of follow-up, active treatment group showed nonsignificant reduction in the primary or secondary outcomes. The results also showed no significant change in the progression of CAC. The lack of significant difference in ASCVD events might be due to the small sample size, short follow-up duration, and /or the administration of aspirin to the control as well as the active therapy group. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients:
There is no new published evidence on the use of coronary calcium scoring as a diagnostic test for CAD. The studies reviewed earlier for the last update showed that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies and was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results. *In conclusion:* There is some evidence that CAC may add a prognostic incremental value to Framingham risk score among selected asymptomatic individuals. Indirect evidence suggests that asymptomatic individuals at intermediate risk might potentially benefit from adding CAC to the risk assessment. The majority of the participants in the studies reviewed were Caucasians which may limit generalization of the results. The studies do not provide an optimal coronary calcium threshold. There is no single cutoff value that defines a high score. The coronary calcification differs according to age, sex, and race. There is no evidence to date that CAC scoring would result in an intervention that would improve CHD related health outcomes among individuals at an increased risk for CHD. The test results may lead to unnecessary invasive procedures, or overtreatment in some patients.

Articles: The search yielded around 50 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Use of EBCT for coronary artery disease screening:
The search identified a recent meta-analysis of observational studies (Greenland 2007) and several prospective cohort studies that evaluated EBCT coronary artery calcium (CAC) score as a risk marker predicting the likelihood of future coronary events among asymptomatic patients. It also revealed two articles on the St. Francis Heart Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first reported on the prospective cohort study, and the second on the RCT embedded in the cohort. The meta-analysis and the two articles on the St. Francis Heart Study were selected for critical appraisal. Use of EBCT for coronary artery disease diagnosis:
The search did not reveal any newly published large valid study on the use of CAC scoring in the detection of coronary artery stenosis among symptomatic patients. *The following articles were critically appraised:*
Greenland P, Raggi P, Harrington R, et al. ACC/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment an in evaluation of patients with chest pain. J Am Coll Cardiol. 2007; 49:378-402. See Evidence Table. Arad Y, Goodman KJ, Roth M, et al. Coronary calcification, coronary disease risk factors, C-reactive protein, and atherosclerotic cardiovascular disease events. The St. Francis Heart Study. J Am Coll Cardiol. 2005; 46:158-165. See Evidence

Back to Top

Table. Arad Y, Spadaro LA, Roth M, et al. Treatment of asymptomatic adults with elevated coronary calcium scores with atorvastatin, vitamin C, and vitamin E. The St. Francis Heart Study randomized clinical trial. J Am Coll Cardiol.2005;46:166-172. See Evidence Table.

The use of EBCT in the treatment of coronary artery calcium scoring does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

CORONARY ARTERY CALCIUM (CAC) SCORING WITH COMPUTED TOMOGRAPHY, FOR CARDIOVASCULAR DISEASE RISK ASSESSMENT

Date: 10/12/2020

Evidence Conclusion:

- There is evidence from published long-term large longitudinal population studies indicating that:
  - CAC is strongly associated and in a graded fashion with 10-year risk of incident ASCVD in asymptomatic White, Black, Hispanic and Chinese American men and women 45-84 years of age with no known history of CHD.
  - CAC scoring provides additional predictive information on ASCVD events and mortality, beyond the traditional risk factors, in men and women at different age groups, races, ethnic background, at different levels of risk, and in the presence or absence of comorbid conditions such as diabetes mellitus.
- There is insufficient published evidence, to date, from valid RCTs with long-term follow-up to determine that treatment guided by CAC scoring levels in addition to the traditional risk factors have an impact on patient management and /or health outcomes in asymptomatic adults at intermediate CV risk.

Articles: The literature search identified multiple large long-term population-based observational studies conducted in the US and Europe published over the last 20 years, that examined the association between CAC scoring and incidental CVD events and mortality in asymptomatic individual with no known coronary artery disease and its potential utility for CVD risk stratification in asymptomatic population. the largest population cohorts and/or those with longest follow-up duration were included in the review. The search did not identify any recent RCT with important clinical outcomes to determine the impact of CAC on guiding statin therapy an improving outcome in individuals at intermediate ASCVD risk.

The use of Coronary Artery Calcium (CAC) Scoring with Computed Tomography, for Cardiovascular Disease Risk Assessment does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Considered Not Medically Necessary (prior to 8/1/2021):

CPT® Codes	Description
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
12/11/2002	Established annual review for Medicare criteria 05/03/2011[MDCRPC], 09/06/2011[MDCRPC], 07/03/2012[MDCRPC], 05/07/2013[MDCRPC], 06/04/2013[MDCRPC], 03/04/2014 [MPC], 01/06/2015[MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	09/10/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
09/06/2016	Adopted retired LCD policy for Medicare members
04/24/2018	Added Medicare non-coverage language from LCD
03/02/2021	Added October 2020 MTAC Review. MPC approved criteria for Coronary Artery Calcium Scoring for non-Medicare members. The criteria are based on the KPWA ASCVD Primary Prevention Guideline. Removed Electron Beam Computed Tomography (EBCT), Helical or Spiral Computed Tomography, and Ultrafast Computed Tomography from criteria. Requires 60-day notice, effective date 08/01/2021.
09/10/2021	Added additional documentation requirements

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure

- CardioMEMS

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Implantable Pulmonary Artery Pressure Monitoring Device for Patients with Heart Failure***, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Interregional New Technologies Committee

There is insufficient evidence to determine whether CardioMEMS is a medically appropriate option for patients with NYHA functional class III heart failure. The existing evidence is of insufficient quantity and quality. Patients undergoing IRB clinical trials could be potential candidates if the IRB trial has a well-designed protocol, appropriate informed consent, and structured follow-up.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is a major public health problem in the United States and worldwide. It is estimated that more than six million Americans are currently living with heart failure, and that approximately 550,000 new cases are diagnosed in the US every year. Hospitalization for patients with chronic HF is also on the rise despite the major advances in medical and device therapies. Statistics show that HF is the primary diagnosis in over one million hospitalizations annually, and that patients hospitalized for HF are at high risk for all-cause rehospitalization with a 1-month readmission rate of 25%. The prognosis of these patients is suboptimal especially for those with serial readmissions (Hoppe 2009, Adamson 2011, Go 2013, Yancy 2013, Sandhu 2018).

More than 90% of hospitalizations for worsening HF are due to signs and symptoms of congestion leading to the decompensated state. Investigators found that increases in the intracardiac and pulmonary artery (PA) pressures are the cause of clinical congestion and that these begin several days or weeks before the onset of overt clinical signs and symptoms that are commonly used as indicators of congestion and volume overload leading to hospitalization. Thus, outpatient monitoring of markers for impending hemodynamic decompensation may allow early interventions to reduce both morbidity and hospitalization. Researchers also found that successful treatment of acutely decompensated HF patients is associated with a decrease

in diastolic pressures to values equivalent or below those present at baseline, and that continuous monitoring pressure during treatment may allow the clinicians to tailor the treatment more accurately. Based on these observations, it was hypothesized that ambulatory implantable hemodynamic monitoring (IHM) may provide information that would help avoid discharging patients from the hospital before decreasing the pressure sufficiently and returning the patient to a chronic compensated state. Continuous hemodynamic monitoring after the hospital discharge is also believed to proactively detect signs of congestion and reduce the risk of rehospitalization (Hoppe 2009, Abraham 2011, Adamson 2011, Mooney 2015, Sandhu 2018, Ayyadurai 2019).

Research has thus focused on ambulatory hemodynamic monitoring of chronic HF as a surrogate measure to guide the patients' medical therapy before the onset of acute hemodynamic decompensation. Several implantable systems have been developed to measure various cardiac pressures and tailor medical therapy accordingly "pressure guided therapy". Among these devices is the CardioMEMS HF System, which is the focus of the current review.

The CardioMEMS^{TM} HF System (Abbott [previously St Jude Medical], Inc, USA) is a leadless battery-free, permanently implantable pressure measurement system designed to directly measure systolic, diastolic, and mean pulmonary artery pressure (PAP) to help guide heart failure management in an outpatient setting. The design of the system is based on the microelectromechanical principles of resonance whereby an external antenna wand emitting radiofrequency energy can cause varying degrees of oscillations in the sensor depending on the ambient pressure The CardioMEMS HF System consists of three main components: 1. A miniaturized wireless electromechanical leadless sensor (15mm x 3mm x 2mm) that comprises a coil and capacitor encased in silicone case, with a nitinol wire loop at each end of the sensor to keep the device in place in a pulmonary artery. The capacity and coil of the sensor creates an electrical circuit that resonates at a given frequency that varies depending on the pulmonary artery pressure 2. A transverse delivery system designed to deploy the implantable sensor in the distal PA; and 3. The Champion Electronics System, which acquires and processes signals from the implantable sensor and wirelessly transfers PA pressure measurements to a secure database to be reviewed and evaluated by the treating physician (Loh 2013, Adamson 2011, Mooney 2015, Ayyaduri 2019, FDA website).

The CardioMEMS sensor is delivered during a standard right heart catheterization procedure and implanted in a descending branch of the pulmonary artery via a delivery catheter. The implanted patients are started on aspirin and clopidogrel for one month followed by aspirin monotherapy. At home, HF patients use a portable electronic unit and a special pillow containing an antenna to take daily sensor readings. The reading takes place when the antenna is held against the body or when the patients lies on the pillow. The pressure readings are then wirelessly transmitted to a secure website and accessed by the clinicians to guide treatment decisions. Automated alerts will be sent to health care providers if pressure readings fall outside of prespecified ranges (Poor Ghaz 2019).

The U.S. Food and drug Administration (FDA) premarket approval (PMA) of CardioMEMS HF System was first rejected in 2011 due to concerns on the validity of the pivotal study results. After discussing additional follow-up data and further analyses of the results provided by the investigators and sponsors, the FDA cautiously approved the system in May 2014 to *"Remotely measure and monitor PA pressure and heart rate in New York Heart Association (NYHA) functional Class III heart failure patients who have been hospitalized for heart failure in the previous yea*r". According to the FDA, the system may be used by the physician in the hospital or medical office to better manage the patients and potentially reduce HF- related hospitalizations. Continued FDA approval of CardioMEMS HF System is contingent upon the submission of periodic reports at intervals of one year (unless otherwise specified) from the date of approval of the original PMA, as well as conducting two post-approval studies (FDA Website).

The CardioMEMS HF system may not be appropriate for patients with an active infection, history of recurrent deep vein thrombosis or pulmonary embolism, are unable tolerate a right heart catherization, have congenital heart disease or mechanical right heart valve, with known coagulation disorders, hypersensitivity to aspirin or clopidogrel, with an estimated GFR <25 ml/min and not responsive to diuretics or are on chronic renal dialysis, also for patients who had undergone implantation of CRT-D within the past 3 months, or have BMI >35 kg/m^2 (Ayyaduri 2019).

Medical Technology Assessment Committee (MTAC)

Implantable Pulmonary Artery Pressure Monitoring Device (CardioMEMS HF System) For Patients with Heart Failure

Date: 01/13/2020

Evidence Conclusion

- The CHAMPION trial remains the only published RCT that evaluated CardioMEMS HF device for monitoring NYHA functional class III heart failure patients.
- There is no additional evidence from published RCTs with valid methodology and long- term follow-up that would change the conclusion of the MTAC 2016 evidence review:
    - The results of the CHAMPION study show that previously hospitalized NYHA functional class III heart failure patients who received pressure guided management in addition to the standard care, had statistically significant lower hospital admission rates compared to those managed according to standard of care alone. It is unclear if the hospitalizations prevented in the device-guided management group were among the lower risk patients, and whether it had any impact on mortality.
    - It is hard to make a firm conclusion on the safety and effectiveness of CardioMEMS HF System from one single-blinded randomized trial, with an intermediate endpoint, potential performance bias, strict inclusion/exclusion criteria, conducted under a controlled environment, with a relatively short follow- up period, and funded by the manufacturer of the device that was also responsible for data collection and analysis. In addition, the principal investigators who analyzed, interpreted, and /or wrote the report had financial ties to the manufacturer.
- More RCTs with valid methodology and long-term clinical outcomes are needed to provide stronger evidence on the safety and efficacy of CardioMEMS HF System in monitoring patients with HF.

Articles: The updated literature search on CardioMEMS HF System for patients with Heart failure did not identify any RCTs published after the pivotal CHAMPION trial. The search revealed a propensity matched retrospective study, several review articles on pulmonary artery pressure guided management of patients with heart failure, sub-analyses of data from CHAMPION trial, and case series of patients implanted with CardioMEMS. A CardioMEMS post approval study was presented by Shavelle D, MD, in the 2019 annual meeting of the American College of Cardiology but, have not been published, to date, in a peer reviewed journal. The propensity matched study (Abraham et al, 2019) as well as the results of the CardioMEMS post- approval study (Shavelle 2019) ** were reviewed and summarized. See Evidence Table.

The use of Implantable Pulmonary Artery Pressure Monitoring Device (CardioMEMS HF System) For Patients with Heart Failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
C2624	Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components
33289	Transcatheter implantation of wireless pulmonary artery pressure sensor for long-term hemodynamic monitoring, including deployment and calibration of the sensor, right heart catheterization, selective pulmonary catheterization, radiological supervision and interpretation, and pulmonary artery angiography, when performed
93264	Remote monitoring of a wireless pulmonary artery pressure sensor for up to 30 days, including at least weekly downloads of pulmonary artery pressure recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Back to Top

Date Created	Date Reviewed	Date Last Revised
07/05/2016	07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC] , 02/01/2022[MPC], 02/07/2023[MPC], 03/12/2024[MPC]	07/05/2016

[MPC] Medical Policy Committee

Revision History	Description
02/10/2021	Added MTAC review from July 2020 for CardioMems

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Carotid Intima Media Thickness (IMT or CIMT) for Coronary Artery Disease Screening and Monitoring

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Carotid Intima Media Thickness (IMT or CIMT) for Coronary Artery Disease Screening and Monitoring"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Atherosclerosis is a progressive disease that usually starts early in life. It begins with thickening of the vessel wall due to proliferation of smooth muscle cells, and progresses with the accumulation of lipids carbohydrates, calcium deposits, fibrous tissue, and blood products within the lesions resulting in hard calcified plaques (Libby 2000). Acute manifestations of atherosclerosis such as acute myocardial infarction, stroke, or sudden cardiac death are due to thrombosis following rupture of an unstable plaque. It is thus valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. Several noninvasive imaging techniques to identify and quantify atherosclerosis have evolved in the last decades. These include echocardiography, stress echocardiography with perfusion, MRI, electron beam computed tomography, carotid artery imaging, and others.

B-mode ultrasound is a well-established method to evaluate atherosclerosis of peripheral arteries, and ultrasonographic assessment of 0easily accessible arteries has been advocated as surrogate markers for less accessible vessels. To consider a test as a surrogate marker, it should have the ability to predict the risk of a disease, and to improve with the improvement of the disease process (Feinstein 2002).

Atherosclerosis predominantly affects the intima of the vessel wall; however, ultrasound imaging cannot discriminate between the intima and media, and is thus applied to the intima-media complex. Carotid artery intima-media thickness (IMT or CIMT) involves a high-resolution ultrasound imaging of the distance between the lumen-intima interface and the media-adventitia interface, reflecting the arterial wall characteristics. It can be measured at several areas along the vessel wall; at the posterior aspect of the common carotid artery, the anterior wall of the internal carotid artery or at the common carotid artery bifurcation. Researchers differ on the choice of wall or segment of the carotid artery to image. It is believed however that imaging from different segments will most likely increase the likelihood of providing more relevant information, based on the fact that atherosclerosis tends to develop in an asymmetric manner. IMT thickness measurements can be calculated as the average of arterial wall thickness, the maximal measured value, or the average of maximal values of different segments. The inter-reader variability is fairly high, and there is no clear cut-off point above which atherosclerosis can be defined. The cut-off points to determine the presence of an atherosclerotic plaque were arbitrarily chosen. It was suggested that an average thickness of the combined intima and media ranging between 0.5 and 1.2 mm is considered to be normal, and that ≥1.2 mm is used to define the presence of a plaque. It was also reported that the abnormal range of IMT is age dependent, and an IMT >1.00 mm is considered highly abnormal in younger patients and is sometimes used as the cutoff in clinical trials (Feinstein 2002).

The estimated progression of atherosclerosis per year is 0.02 to 0.05 mm (Feinstein 2002). IMT may be a potential useful marker for coronary atherosclerosis, as well as an indicator for its progression or regression, on the condition that the carotid atherosclerosis reflects coronary atherosclerosis. Still the occurrence of an acute event does not only depend on the condition of the coronaries, and carotid IMT does not visualize coronary arteries, and does not provide detailed insight into plaque composition or stability.

Medical Technology Assessment Committee (MTAC)

Carotid IMT in the Evaluation of Risk for CVD or to Monitor the Treatment Effect on CAD

04/04/2005: MTAC REVIEW

Evidence Conclusion: *Use of IMT as a screening tool, or risk predictor of CVD:* The literature search did not reveal any RCT that investigated carotid IMT as a screening tool for CHD. Ideally subjects would be randomized to receive or not receive a screening test, then followed up for a sufficient period of time, then compare the outcomes in the two groups. Carotid IMT was only evaluated in cohort studies as a risk predictor for future coronary heart disease. The ARIC study and Cardiovascular Health Study (CHS) were two large population-based cohort studies that assessed the association of IMT with coronary artery disease. ARIC study included 12,841 men and women aged 45-64 years and followed them up for 4-7 years. CHS followed 4,476 adults aged 65 years or older for 6 years. The primary outcome was the first coronary heart disease event in ARIC study, and. incidence of myocardial infarction and stroke in CHS. The Rotterdam study was a cohort study of 8,000 patients aged 55 years or older, followed up for 4.2 years. A case-control study with 374 subjects was nested in that study to determine the contribution of carotid IMT in the prediction of future coronary and cerebrovascular diseases when added to the traditional risk factors. All three studies investigated the association of the carotid IMT to the incidence of coronary heart disease (and stroke in two studies) but the added value of the carotid IMT to the predictive value of the established risk factors was only quantified in the Rotterdam's study. Carotid IMT was measured only once at baseline. Different sites of the carotid artery were imaged, and different methods of measurements were used, as well as different standards or cutoff values for the threshold thickness. The results of these studies suggest that the carotid IMT is associated with the incidence of coronary heart disease events, however the Rotterdam's study suggest that the information provided by IMT measurement does not seem to have clinically important additional predictive value over that calculated using the established risk factors. In conclusion, there is evidence for an association between carotid artery IMT and risk of coronary heart disease events, but there is no evidence that measuring carotid IMT, or treating patients based on this measurement would reduce their risk of CVD. There is also insufficient evidence to support the additive value of carotid IMT markers over the global risk assessment strategies using Framingham risk stratification. Use of carotid ITM to monitor effect of treatment on CAD: Several studies evaluated the effect of statins on the progression of atherosclerosis using imaging of carotid ITM thickness as an outcome measure. In these studies, carotid IMT was used a surrogate marker for coronary atherosclerosis. The LIPID trial randomized 522 subjects to receive pravastatin 40 mg/day or placebo in addition to a low-fat diet. Total cholesterol, triglycerides, HDL, and LDL cholesterol were measured at randomization repeatedly during follow-up. Ultrasound scans of the common carotid artery were performed before randomization, and after 2- and 4-years using B-mode ultrasonography. The study showed a regression of the common carotid artery IMT following pravastatin therapy. Carotid IMT was only an intermediate marker, and the relation between the IMT and cardiovascular events was not studied. A change in carotid intima-media thickness does not necessarily indicate a change in cardiovascular risk.

Articles: The search revealed 214 articles. The majority were review articles, opinion pieces, or dealt with specific subgroups of patients. As a screening tool/ risk predictor for coronary artery disease: The search did not reveal

Back to Top

any randomized controlled trial that evaluated the use of carotid IMT as a screening test for coronary artery disease. There were several prospective studies that investigated carotid IMT as a risk predictor for CHD including two large population based-studies conducted in the USA (ARIC study and CHS). The search also revealed few other studies conducted in Europe (e.g. Rotterdam study in the Netherlands, and KIHD study in Finland). ARIC study and CHS were selected for critical appraisal, as well as Rotterdam study that evaluated the benefit of adding carotid IMT measurement to traditional risk factors used to predict risk of CHD. Chambless LE, Heiss G, Folsom AR, et al. Association of coronary heart disease incidence with carotid artery wall thickness and major risk factors: The Atherosclerosis Risk in Communities (ARIC) Study, 1987-1993. *Am J Epidemiol.* 1997; 146:483-494. See Evidence Table. O'Leary DH, Polak JF, Kronmal RA, et al, for the Cardiovascular Health Study Collaborative Research Group. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. *N Engl J Med.* 1999; 340:14-22. See Evidence Table. Iglesias del Sol A, Moons KGM, Hollander M, et al. Is Carotid Intima-media thickness useful in cardiovascular diseases risk assessment. The Rotterdam Study. *Stroke* 2001; 32:1532-1538. See Evidence Table As a monitoring tool measure efficacy of a therapeutic intervention: The search revealed several earlier studies conducted in the 1990s to examine the effect of statins and lipid modifying therapy on the progression of atherosclerosis, using changes in the carotid IMT, measured by B-mode Ultrasonography, as their surrogate outcome. Among these studies were ACAPS, BCAPS, KAPS, LIPID, REGRESS, PLAC II as well as others. These studies did not have clinical outcomes, only the intermediate endpoint of carotid IMT. The LIPID trial with a large population size and long follow-up period of 4 years was selected for critical appraisal. MacMahon S, Sharpe N, Gamble G, et al. Effects of lowering average or below-average cholesterol levels on the progression of carotid atherosclerosis. Results of the LIPID atherosclerosis substudy. Circulation. 1998; 97:1784-1790. See Evidence Table. As a diagnostic tool for coronary artery disease: The search revealed at least six studies that investigated the potential use of carotid intima media thickness in the diagnosis of coronary artery disease. In these studies, results of carotid ultrasonography were compared to those of coronary angiography, and/ or exercise tests, or SPECT among symptomatic patients with a suspected CAD. None of these studies was critically appraised as it not the purpose of this review to evaluate the technology as a diagnostic test.

The use of carotid IMT in the evaluation of risk for CVD or to monitor the treatment effect on CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
04/04/2005	04/04/2005, 04/12/2005 MDCRPC, Initiated annual review because of Medicare criteria on 05/03/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.

05/04/2021	Updated applicable codes – removed deleted code 0126T

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cell-Free Fetal DNA Analysis

- Panorama
- MateriT21™
- Harmony™
- Verifi™
- QNatal Advanced

Criteria

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage)

Prevention and Invitae Corporation is the preferred lab for genetic testing when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae.*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions

For the genetic test(s) listed below, please use the lab specified:

- ***Cell Free Fetal DNA testing* –Any of these three labs can be used:**
  - *Ariosa Diagnostics, Inc. (81507)*
  - *Invitae (81420)*
  - *LabCorp (81420)*

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Molecular Diagnostic Tests (L36256)
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente will cover cell-free fetal DNA testing for trisomies without clinical review for pregnant women regardless of age when performed at Ariosa Diagnostics (CPT code 81507) or at Invitae (CPT code 81420) or at Labcorp (CPT code 81420).

Prior Authorization will still be required for Non-Invasive Prenatal Testing (NIPT) at any other lab in advance of submitting a claim for payment. For patients who are tested for trisomies using cell-free fetal DNA, the sequential

Back to Top

screen and nuchal translucency (NT) ultrasound (76813/76814) should no longer be routinely ordered without clinical indication.

The only codes that Kaiser Permanente will pay for Cell-Free Fetal DNA Analysis for Trisomies are 81420 and 81507.

Considered not medically necessary:

Test Name	Criteria Used	Codes
Cell-Free Fetal DNA - Microdeletion Syndromes	A-0848: This service is not covered per MCG guidelines	CPT – 81331 *not medically necessary when performed using cell-free fetal DNA*, 81422
Cell-Free Fetal DNA - Monogenic Disorders	A-0849: This service is not covered per MCG guidelines	CPT – 81479
Cell-Free Fetal DNA - Sex Chromosome Disorders	A-0850: This service is not covered per MCG guidelines.	CPT – 81479

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

***MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Fetal chromosomal abnormalities occur in approximately 1 in 160 live births. Most fetal chromosomal abnormalities are aneuploidies, defined as an abnormal number of chromosomes. The trisomy syndromes are aneuploidies involving 3 copies of 1 chromosome. The most important risk factor for trisomy syndromes is maternal age. The approximate risk of a trisomy 21 (T21; Down syndrome) –affected birth is 1 in 1100 at age 25 to 29. The risk of a fetus with T21 (at 16 weeks of gestation) is about 1 in 250 at age 35 and 1 in 75 at age 40.1

T21 is the most common chromosomal aneuploidy and provides the impetus for current maternal serum screening programs. Other trisomy syndromes include T18 (Edwards syndrome) and T13 (Patau syndrome), which are the next most common forms of fetal aneuploidy, although the percentage of cases surviving to birth is low and survival beyond birth is limited. The prevalence of these other aneuploidies is much lower than the prevalence of T21 and identifying them is not currently the main intent of prenatal screening programs. Also, the clinical implications of identifying T18 and 1T3 are unclear because survival beyond birth is limited for both conditions.

Standard aneuploidy screening involves combinations of maternal serum markers and fetal ultrasound done at various stages of pregnancy. The detection rate for various combinations of noninvasive testing ranges from 60% to 96% when the false-positive rate is set at 5%. When tests indicate a high risk of a trisomy syndrome, direct karyotyping of fetal tissue obtained by amniocentesis or chorionic villous sampling (CVS) is required to confirm that T21 or another trisomy is present. Both amniocentesis and CVS are invasive procedures and have an associated risk of miscarriage. A new screening strategy that reduces unnecessary amniocentesis and CVS procedures and increases detection of T21, T18, and T13 could improve outcomes. Confirmation of positive noninvasive screening tests with amniocentesis or CVS is recommended; with more accurate tests, fewer women would receive positive screening results.

Commercial, noninvasive, sequencing-based testing of maternal serum for fetal trisomy syndromes is now available. The test technology involves detection of cell-free fetal DNA fragments present in the plasma of pregnant women. As early as 8 to 10 weeks of gestation, these fetal DNA fragments comprise 6% to 10% or more of the total cell-free fetal DNA in a maternal plasma sample. The tests are unable to provide a result if the fetal

fraction is too low (ie, <4%). Fetal fraction can be affected by maternal and fetal characteristics. For example, fetal fraction was found to be lower at higher maternal weights and higher with increasing fetal crown-rump length.

Medical Technology Assessment Committee (MTAC)

MaterniT21

08/20/2012: MTAC REVIEW

Evidence Conclusion: Kaiser identified two observational studies that evaluated MaterniT21. The first study was a case-control study that evaluated 212 samples with by trisomy 21 matched with 1,483 euploid samples, 62 samples with trisomy 18 matched with 183 euploid samples, and 12 samples with trisomy 13 matched with 36 euploid samples. All of the samples were taken from women at high-risk for fetal aneuploidy. Before adjustment the test had a sensitivity of 98.6% and a false positive rate of 0.2% for detecting trisomy 21. After adjusting for guanine cytosine content and removing repetitive regions, the test had a sensitivity of 99.1% and a false positive rate of 0.1% for diagnosing trisomy 21. After adjustment for guanine cytosine content the test had a sensitivity of 100% and a false positive rate of 0.3% for diagnosing trisomy 18, and a sensitivity of 91.7% and a false positive rate of 0.9% for diagnosing trisomy 13 (Palomaki 2011, Palomaki 2012). The second study was a cohort study that included 480 samples from women at high-risk for fetal aneuploidy. Results from this study suggest that before adjusting for guanine cytosine content and removing repetitive regions this test has a sensitivity of 100% and a false positive rate of 0.2% (Ehrich 2011). Based on this evidence Kaiser concluded that despite a promising diagnostic performance, MaterniT21 suffers from an extremely sparse, vendor-involved body of evidence specific to a high-risk population, and lacks studies examining the prospective impact of MaterniT21 on patients' decisions of whether to purse chorionic villus sampling or amniocentesis (Kaiser 2012). *Conclusion*: Kaiser concluded that there is insufficient evidence to determine whether the MaterniT21 prenatal test to detect Down syndrome is medically appropriate for any patient.

Articles: In March 2012, Kaiser review MaterniT21 for the detection of trisomy 21. No additional studies were identified since the Kaiser review. The following technology assessment was selected for review: Kaiser Permanente. Sequenom's MaterniT21 prenatal test to detect Down syndrome. March 2012. http://cl.kp.org/pkc/national/cpg/intc/materials/MaterniT21toDetectTrisomy21(G121107).pdf.

The use of MaterniT21 does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy

Considered Not Medically Necessary when performed using cell-free fetal DNA:

CPT® Codes	Description
81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
81403	Molecular Pathology Procedure Level 4
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81479	Unlisted molecular pathology procedure

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS

Back to Top

codes, descriptions, and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 02/05/2013[MDCRPC], 1, 03/01/2022[MPC] 2/03/2013[MPC], 01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC],03/07/2023[MPC]	10/07/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34101
07/05/2016	Adopted GHC-0724
04/08/2020	Added temporary change for code 81507 due to COVID-19 pandemic
06/02/2020	Extended temporary change until September 15, 2020 for code 81507 due to COVID-19 pandemic
08/04/2020	Extended temporary change until November 1, 2020 for code 81507 due to COVID-19 pandemic
12/07/2020	Extended temporary change until February 15, 2021 for code 81507 due to COVID-19 pandemic
03/08/2021	Extended temporary change until May 15, 2021 for code 81507 due to COVID-19 pandemic
05/04/2021	Extended temporary change until June 15, 2021 for code 81507 due to COVID-19 pandemic
06/01/2021	Extended temporary change until August 15, 2021 for code 81507 due to COVID-19 pandemic
08/03/2021	MPC approved to permanently eliminate age restrictions on cell-free fetal DNA (NIPT) testing for trisomies for commercial members (81507 and 81420). Prior authorization is still required for this testing at labs other than Ariosa. Requires 60-day notice, effective date January 1, 2022. Extended temporary change until December 31, 2021 for code 81507 due to COVID-19 pandemic.
03/01/2022	Updated applicable codes.
08/16/2022	MCG* A-0847 was removed from the 26th edition; removed from criteria
10/7/2022	Added labcorp as preferred vendor for Cell Free Fetal DNA testing. Noted Prevention as preferred lab for genetic testing.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chronic Cerebrospinal Venous Insufficiency Treatment

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **Chronic Cerebrospinal Venous Insufficiency Treatment**, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Multiple sclerosis is an autoimmune inflammatory disease of the central nervous system that affects approximately 250,000 to 500,000 people in the United States. Although the cause of multiple sclerosis is unknown, evidence suggests it may be caused by the interplay of genetic and environmental factors. However, it has recently been hypothesized that a phenomenon known as chronic cerebrospinal venous insufficiency (CCSVI) may also play a role in the etiology, pathogenesis, and/or disease progression of multiple sclerosis. This theory suggests that abnormal drainage of venous blood due to stenosis or malformation of the internal jugular and/or azygous veins may be a cause of multiple sclerosis (Ghezzi 2011, Khan 2010, Vedantham 2010).

The evidence pertaining to the association between CCSVI and multiple sclerosis is inconsistent. Depending on the study, the frequency of CCSVI in patients with multiple sclerosis ranged from 0 to 100%. The frequency of CCSVI in controls ranged from 0 to 23%. Different methods of assessing CCSVI may explain some of the variability among these studies. Doppler sonography, venous MRI, and venous angiography have all been used to assess CCSVI; however, it is not clear which is the gold standard (Ghezzi 2011). Additionally, it is not clear if CCSVI is a cause of multiple sclerosis, an effect of multiple sclerosis, or an unrelated finding (Singh 2009, Vedantham 2010). Based on the CCSVI hypothesis balloon angioplasty has been proposed as a treatment for multiple sclerosis patients with CCSVI.

Medical Technology Assessment Committee (MTAC)

Chronic Cerebrospinal Venous Insufficiency Treatment

Back to Top

06/10/2011: MTAC REVIEW

Evidence Conclusion: A recent open-label, prospective case-series evaluated the safety of CCSVI endovascular treatment and its influence on clinical outcomes in 65 consecutive patients with multiple sclerosis. No operative or postoperative complications were recorded. After the endovascular treatment, disease severity significantly improved for patients with relapse remitting multiple sclerosis, but not for patients with primary progressive or secondary progressive multiple sclerosis. In patients with relapse remitting multiple sclerosis, significantly more patients were relapse free during the 18 months posttreatment compared to the year proceeding endovascular treatment; however, there was no significant difference in annualized relapse rate. Quality of life improved significantly for subjects with relapse remitting and primary progressive multiple sclerosis, but not for subjects with secondary progressive multiple sclerosis. Results from this study should be interpreted with caution as this is a small, open-label study with no comparison group (Zamboni 2009). Another prospective case-series evaluated the safety of endovascular treatment for CCSVI in 331 patients with multiple sclerosis. Overall, three patients experienced major complications. Two patients (1.2% of implanted stents) experienced stent thrombosis and one patient (0.3%) required surgical opening of the femoral vein to remove the angioplastic balloon. Minor complications included: local bleeding from the groin (4 patients, 1.2%), minor gastrointestinal bleeding (1 patient, 0.3%), transient cardiac arrhythmia (2 patients, 0.6%), difficulty removing the angioplastic balloon or delivery system (4 patients, 1.2%), problems with proper placement of the stent (4 patients, 2.3% of implanted stents), unsuccessful catheterization of the stenosed internal jugular vein (4 patients, 1.3%). Long-term complications were not addressed (Ludyga 2010). *Conclusion:* Currently, there is insufficient evidence to determine the safety and efficacy of balloon angioplasty for the treatment of CCSVI in patients with multiple sclerosis. In a recent position statement, the Society of Interventional Radiology also concluded that the current published literature was inconclusive on whether CCSVI is a clinically important factor in the development and/or progression of multiple sclerosis and on whether balloon angioplasty is clinically effective in patients with multiple sclerosis (Vedantham 2010).

Articles: To determine the safety and efficacy of balloon angioplasty for the treatment of multiple sclerosis patients with CCSVI. No randomized controlled trials were identified that assessed the safety or efficacy of balloon angioplasty for the treatment of multiple sclerosis patients with CCSVI. The best evidence came from an observational study. This study was selected for review. The following study was critically appraised:
Zamboni P, Galeotti R, Menegatti E, et al. A prospective open-label study of endovascular treatment of chronic cerebrospinal venous insufficiency. *J Vasc Surg 2009;* 50:1348-1358. See Evidence Table.

The use of chronic cerebrospinal venous insufficiency treatment for multiple sclerosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered not medically necessary for Multiple Sclerosis:

CPT® or HCPC Codes	Description
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure)
37248	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; initial vein
37249	Transluminal balloon angioplasty (except dialysis circuit), open or percutaneous, including all imaging and radiological supervision and interpretation necessary to perform the angioplasty within the same vein; each additional vein (List separately in addition to code for primary procedure)
With diagnosis code	
G35	Multiple sclerosis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Back to Top

Date Created	Date Reviewed	Date Last Revised
07/05/2011	07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 03/05/2013[MDCRPC], 01/07/2014[MDCRPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	09/08/2015

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Cervical Fusion (Anterior or Posterior)

- **Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cervical Fusion (Anterior or Posterior)"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

**All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.*

NOTE: Any operative candidate should be nicotine-free for at least 6 weeks prior to elective surgery (unless there is evidence of cord compression, infection, malignancy, or progressive neurologic deficit). For persons with recent nicotine use, documentation of nicotine cessation should include a lab report (not surgeon summary) showing blood or urine nicotine level of 0, drawn within 6 weeks prior to surgery)

NOTE: BMI > 40 is a relative contraindication to fusion in patients without progressive neurologic deficit or cord compression

I. ANTERIOR CERVICAL FUSION FOR DEGENERATIVE DISEASE

Single or multilevel anterior cervical discectomy and fusion (ACDF) is considered medically necessary for treatment of symptomatic degenerative disease when **EITHER of the following** criteria are met:

A. Radiculopathy, must meet **ALL of the following**:

1. Clinical diagnosis of unremitting cervical radiculopathy** (see below), resulting in disability and/or neurological deficit
2. Refractory to at 3 months of standard conservative physician supervised medical management *** (see below)
3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
    - Herniated nucleus pulposus
    - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
    - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
    - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:
    1. Clinical diagnosis of myelopathy*(see below)
    2. Complex imaging studies (i.e., CT, MRI, Xray, Myelogram) demonstrate structural cord compression associated with cord signal change/myelomalacia on MRI imaging
    3. Physical examination findings and imaging studies correlate with each level being considered for the fusion

II. CERVICAL FUSION FOR INSTABILITY

Single or multilevel cervical fusion is considered medically necessary for **ANY of the following** indications when there is an associated spinal instability:

- Acute spinal fracture and/or dislocation
- Neural compression after spinal fracture
- Traumatic ligamentous disruption
- Epidural compression, fracture or vertebral destruction from spinal tumor or cyst
- Spinal decompression or debridement for infection (e.g., discitis, osteomyelitis, epidural abscess, TB)
- Spinal decompression for myelopathy associated with subluxation in rheumatoid arthritis
- Cervical spinal deformity associated with neurological symptoms of myelopathy* or radiculopathy** (e.g., sagittal plane angulation of more than 11 degrees between adjacent segments, subluxation of >3.5 mm)
- As an adjunct to cyst excision of synovial facet cysts in the cervical spine
- Atlantoaxial instability (e.g., atlas and axis fracture, nonunion)
- Treatment of cervical spine fracture/dislocation associated with acute cervical radiculopathy** or myelopathy*
- Multilevel spondylotic myelopathy with kyphosis, when symptoms of myelopathy are present and
- Imaging studies correlate with symptoms and demonstrates cord compression

- Cervical instability from any **ONE of the following**:
  - Klippel-Feil syndrome
  - Down's syndrome
  - Skeletal dysplasia or connective tissue disorder

III. CERVICAL FUSION FOR IATROGENIC INSTABILITY

Cervical fusion is considered medically necessary for anticipated intraoperative iatrogenic spinal instability of the level or levels involved resulting from **ANY of the following** surgical procedures:

- Removal of 50% or more of the facets bilaterally
- Removal of 75% or more of a single facet
- Following cervical corpectomy*, as part of a stabilization procedure

***Note:** Corpectomy is a procedure in which the at least 50% or more of the body of the vertebrae is removed.

IV. POSTERIOR CERVICAL FUSION: SPINAL STENOSIS

Posterior cervical fusion is considered medically necessary for the treatment of spinal stenosis with laminectomy when **EITHER of the following** criteria are met**:**

A. Radiculopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of unremitting cervical radiculopathy**(see below) resulting in disability and/or neurological deficit
   2. Refractory to at 3 months of standard conservative physician supervised medical management ***
   3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
      - Herniated nucleus pulposus
      - Spondylosis such as foraminal stenosis due to an osteophyte causing nerve root compression
      - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
      - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
   4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of myelopathy*
   2. Radiographic evidence of **ANY of the following**:
      - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
      - Sagittal plane angulation of more than 11 degrees between adjacent segments
      - Structural cord compression associated with cord signal change/myelomalacia on MRI

3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

V. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY:

Cervical fusion is considered medically necessary for treatment of symptomatic adjacent or same segment stenosis following prior cervical surgery, when **EITHER of the following** criteria have been met:

A. Radiculopathy, must meet **ALL of the following**:
   1. Clinical diagnosis of unremitting cervical radiculopathy** resulting in disability and/or neurological deficit
   2. Refractory to at 3 months of standard conservative physician supervised medical management ***
   3. Complex imaging studies (i.e., CT, MRI, X-ray, Myelogram) demonstrate at least **ONE of the following** at each impacted level being considered for the fusion:
      - Herniated nucleus pulposus
      - Spondylosis/ foraminal stenosis due such as an osteophyte causing nerve root compression
      - ligamentous hypertrophy causing impingement (either cord compression or foraminal stenosis)
      - Visible loss of disc height compared to adjacent levels with resultant foraminal stenosis
   4. Physical examination findings and imaging studies correlate with each level being considered for the fusion

OR

B. Myelopathy, must meet **ALL of the following:**
   1. Clinical diagnosis of myelopathy*
   2. Radiographic evidence of **ANY of the following**:
      - Subluxation or translation of more than 3.5 mm on static lateral views or dynamic radiographs
      - Sagittal plane angulation of more than 11 degrees between adjacent segments
      - Structural cord compression associated with cord signal change/myelomalacia on MRI
   3. Complex imaging studies s (e.g., radiographs, magnetic resonance imaging [MRI], computerized tomography [CT], myelography) that correlates with the clinical symptoms and/or signs

VI. CERVICAL FUSION FOLLOWING PRIOR SPINAL SURGERY: PSEUDOARTHROSIS

Cervical fusion is considered medically necessary for the treatment of pseudoarthrosis (i.e., nonunion of prior fusion) of the cervical spine at the same level(s) when it has been at least 12 months from the prior surgery and **ALL of the following criteria** are met:

- Mechanical neck pain that correlates to the level of the pseudoarthrosis
- Imaging studies (e.g., radiographs, CT) confirm evidence of a pseudoarthrosis (e.g., lack of bridging bone, dynamic motion on flexion-extension radiographs)

- Failure of three (3) consecutive months of physician-supervised conservative*** management which includes exercise, nonsteroidal and/or steroidal medications (unless contraindicated), physical therapy **AND**

- Activity lifestyle modification

VII. CERVICAL FUSION NOT MEDICALLY NECESSARY

Cervical fusion is considered not medically necessary for the following indications:

- anterior or posterior cervical fusion for chronic axial neck pain
- posterior cervical fusion performed with laminectomy in the absence of kyphosis (e.g., degenerative spine) or subluxation/translation of more than 3.5 mm

Isolated cervical facet fusion, with or without instrumentation, including facet joint implants and/or bone graft substitutes used exclusively as a stand-alone stabilization device is considered experimental, investigational, or unproven.

***Cervical Myelopathy:** signs suggestive of *spinal cord* involvement:

- Upper limb weakness in more than a single nerve root distribution
- Lower limb weakness
- Loss of dexterity (e.g., clumsiness of hands)
- Bowel or bladder incontinence
- Frequent falls
- Hyperreflexia
- Hoffmann sign (overreaction to flick of the fingernail)
- Increased extremity muscle tone or spasticity
- Spastic Gait/ataxic Gait
- Positive Babinski

****Radicular pain/suspected radiculopathy** defined as:

- Pain in a *nerve root* distribution (e.g., C6, C7)
- Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) *OR*
- EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms

*****Physician-supervised conservative medical management** defined as: Patients must have three months of non-operative treatment as demonstrated by a trial of **one or more of the following** medications:

- Non-steroidal anti-inflammatory drugs (oral or topical)
- Acetaminophen
- Epidural steroid injection of corticosteroids as appropriate

AND

- A trial of **All** of the following physical measures:

- Supervised Physical therapy, attendance at >75% of sessions, minimum of 3 visits
- Flexibility and muscle strengthening exercises
- Reasonable restriction of activities
- If conservative therapy is not appropriate, the medical record must clearly document why such an approach is not reasonable.
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present

Procedure	Criteria
Percutaneous Posterior Cervical Fusion (w/ CAVUX® Cervical Cage, DTRAX® Spinal System, Corus™ Spinal System)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Neck pain occurs in many people and typically involves more than one component of the spine, such as the vertebrae, intervertebral discs, spinal nerves, other anatomic structures such as ligaments, muscles, and joints. Conditions that frequently result in neck pain include soft tissue injury, trauma, infection, herniated disc, degenerative spine conditions, neoplastic conditions, and deformities such as kyphosis. While the cause of neck pain is often multifactorial (e.g., originating from the vertebrae, discs, ligaments, tendons and muscles) the location of pain varies. Axial neck pain occurs along the spine, is of musculoskeletal or soft tissue origin, and is a non-radiating type of pain. The most common cause of axial neck pain is degenerative change to the cervical spine, which occurs as a natural consequence of aging. Radicular pain involves a nerve root, is due to nerve root compression, follows the nerve root distribution, and radiates to one or both upper extremities, and/or into the shoulder area. Radicular pain can include varying degrees of sensory, motor, and/or reflex changes related to nerve root(s) without evidence of myelopathy (North American Spine Society, [NASS], 2013). Myelopathy is a term that describes any neurological deficit related to the spinal cord and is often used to describe loss of function in the upper or lower extremities (NASS, 2013). Depending on the cause of neck pain associated symptoms may include numbness, tingling, weakness, and other types of neurologic dysfunction in the presence of spinal cord compression. Conservative measures for treatment of neck pain include analgesics, muscle relaxants, local injections, physical therapy, cervical bracing and home exercise. Conservative treatment is often effective for alleviating symptoms and typically lasts six to eight weeks. However, conservative therapy is not recommended in the presence of progressive neurological deficits, in the presence of unstable spinal fractures or dislocations, or for progressive spinal deformity. In the absence of progressive neurologic compromise, or when conservative management has been attempted and fails to relieve pain and disability, surgery may be required for conditions with underlying pathology confirmed by physical examination and radiological imaging. When spinal cord compression is present surgical methods to relieve the pressure on the nerves is often necessary and is referred to as decompression surgery.

Decompression typically includes surgical procedures such as discectomy (removal of the disc), laminectomy (removal of the lamina), corpectomy (removal of the vertebral body), or osteotomy (removal of a piece of bone). When performed, these procedures may result in spinal instability. As such, decompression is often performed as part of cervical fusion in order to regain stability of the spine. For example, anterior cervical fusion is usually performed with decompression. Posterior cervical fusion is typically performed with stabilization (using rods, screws) although may be performed with decompression in some instances (NASS, 2014). Instability of the cervical spine can also result from trauma and/or disease, or a combination of all (White, Panjabi, 1980), which may or may not require a decompression. Instability of the cervical spine has been defined by White, Panjabi (1980) and is well-accepted in the medical literature as sagittal plane translation of >3.5 mm, and/or rotation between motion segments of 11˚, in addition to other notable factors such as destruction of elements or inability to function, a positive stretch test, spinal cord or nerve root damage, and abnormal disc narrowing (White, Panjabi, 1980). In the absence of instability, evidence in the published peer-reviewed scientific literature does not provide strong support that when used for this indication cervical fusion is clinically effective for reducing pain and disability. 2011; Persson, et al., 1997). Psychological assessment and treatment as part of a multidisciplinary approach to conservative pain management is recommended. Risk factors, such as drug or alcohol abuse and depression may act as a barrier to recovery following spinal fusion (Washington State Department of Labor and Industries, 2002; Hanley, David, 1999; Tang, et al., 2001). Authors have recommended psychological screening, and treatment if applicable, of patients with neck and/or back pain prior to surgery for identification of risk factors that may be associated with chronic disability. Cervical spinal fusion is in many situations an elective surgery, therefore it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery. Modifiable risk factors and the influence on outcomes of spine surgery has been studied, modification of such risk factors can assist with improved patient selection for spine surgery and better postoperative management (Shahrestani, et al., 2021). Along with alcohol and opioid use, tobacco/nicotine increases the risk of perioperative complications, cardiopulmonary complications, pseudoarthrosis and infection (Shahrestani, et al., 2021) furthermore it is well-established that smoking is a preventable cause of morbidity and mortality. Tobacco use in particular is considered a risk factor for poor healing and has been associated with nonunion. Particularly with spinal fusion, tobacco use has been associated with increased risk of pseudoarthrosis (Brown, et al., 1986). The American Academy of Orthopedic Surgeons (AAOS) supports avoidance and cessation of all tobacco products and cigarette smoking due to the harmful impact on musculoskeletal health, as well as overall health (AAOS, 2016).

Medical Technology Assessment Committee (MTAC)

Percutaneous posterior cervical fusion with the CAVUX Cervical Cage-I or DETRAX System

BACKGROUND

Date: 10/17/2017

Evidence Conclusion: The literature was limited for single-level cervical radiculopathy and studies comparing posterior cervical fusion using DTRAX with standard practice (anterior cervical discectomy and fusion, total disc replacement) were scarce. However, two studies were reviewed. These studies were prospective in design. The aims of these studies were to assess clinical and radiographic outcomes of DTRAX on patients with single level cervical radiculopathy. Patients were enrolled consecutively and underwent surgery using DTRAX. Follow-up occurred at one and two-year post-surgery. Clinical as well as imaging evaluations were also performed. Patients who failed conservative management were recruited and a total of 60 patients were enrolled. Patients' mean age was 53 years with a range of 40 to 75years. The most common level treated was C5-C6 followed by C6-C7. Clinical outcomes have improved at one and two-year after the surgery. First, neck and arm pain, assessed by VAS, have significantly decreased (P<0.0001 in one study; P-value not reported in the second study). Second, the neck disability index has significantly decreased (P<0.0001). Third, quality of life, measured by both mental and physical component, has improved (P<0.0001). Radiographic assessments were equivocal and not consistent. Segmental lordosis did not significantly change 2 years after the surgery; at 1-year post-surgery, this outcome was not reported. In addition, no change was reported for posterior disc height 1 year after surgery, but at 2 years post-surgery, a small decrease was reported (P=0.001). Anterior disc height has decreased 1-year post-surgery (P<0.01). Fusion rate was high. No major complications were reported; however, the most common procedure-related adverse events were postoperative pain, nausea, pain from the bone graft harvest site. Limitations included the non-randomized nature of the

study, consulting relationship between surgeons and study sponsor, the small sample size, and the short follow-up. For these reasons, the quality of evidence is deemed low. **Other studies and conclusion** (See Evidence Table 1): Bilateral cervical cage with a posterior approach can increase foraminal area and decompress nerve roots; but studies showing correlation between increased in foraminal area and clinical outcomes are warranted. (See Evidence Table 1)): Posterior bilateral cervical cage led to 6% (N=53) of adjacent segment degeneration 2 years after surgery; 12% of existing degeneration showed moderate progression and long-term adjacent segment degeneration incidence was unknown.
A retrospective study (See Evidence Table 2) of 10 patients with one-year follow-up, on whom cervical fusion using bilateral posterior cervical cages was performed reported favorable improvements in pain and function in patients with single-level cervical radiculopathy. See Evidence Table 1 & 2
Conclusion:

- Studies were scarce; two studies were reviewed; studies comparing posterior cervical fusion using DTRAX with standard practice (anterior cervical discectomy and fusion, total disc replacement) were not identified
- The quality of evidence is low
- Clinical outcomes have improved at one and two-year post-surgery
- Radiographic findings were not consistent and ambiguous at one and two-year after the procedure
- Adverse events were minimal
- The available evidence is insufficient to recommend for or against the effectiveness and safety of posterior cervical fusion with DTRAX in patients with single level cervical radiculopathy who failed conservative management.

Articles: The literature revealed 7 articles, however 4 were relevant, but 2 studies with the largest sample size were extensively reviewed.

The use of Percutaneous posterior cervical fusion with the CAVUX Cervical Cage-I or DETRAX System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Cervical Fusion: Anterior

CPT® or HCPCS Codes	Description
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments

Cervical Fusion: Posterior

CPT® or HCPCS Codes	Description

22590	**Arthrodesis, posterior technique, craniocervical (occiput-C2)**
22595	**Arthrodesis, posterior technique, atlas-axis (C1-C2)**
22600	**Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment**
22614	**Arthrodesis, posterior or posterolateral technique, single interspace; each additional vertebral segment (List separately in addition to code for primary procedure)**
22800	**Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments**
22802	**Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments**

Considered Experimental, Investigational or Unproven when used to report isolated cervical facet fusion, including facet joint implants and/or bone graft substitutes used exclusively as stand-alone stabilization devices for treatment of facet joint pain:

CPT® or HCPCS Codes	Description
22899	**Unlisted procedure, spine**
0219T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical**
0222T	**Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure**

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/05/2022	07/05/2022[MPC], 07/11/2023[MPC]	12/15/2022

[MPC] Medical Policy Committee

Revision History	Description
07/05/2022	MPC approved to adopt criteria for Cervical Fusion for non-Medicare members. Requires 60-day notice, effective date 12/01/2022.
10/04/2022	MPC approved to include quantifying number of 3 visits for conservative treatment. 60-day notice required.
10/28/2022	Merged criteria set with Percutaneous Cervical Fusion.
12/15/2022	Standardized approach to clinical myelopathy to remove conservative treatment as a prerequisite for surgery.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chelation Therapy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Effective until August 1st, 2024

Kaiser Permanente has elected to use the Edetate (EDTA) Chelation (KP-0297) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Effective August 1st, 2024

Edetate (EDTA) Chelation Therapy will be reviewed using the Medically Necessary Services medical policy.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Chelation is a process to remove certain heavy metals from the blood. In this treatment, a chemical solution is injected into the bloodstream or taken by mouth. Molecules then bind to heavy metals and/or minerals. The heavy metals are then cleared out of the body through urination. Chelation therapy has been studied and approved by the Food and Drug administration to treat certain conditions. This includes removing dangerously high levels of iron, as well as lead or mercury. Thinking that the process of chelation could also remove the buildup of some other substances in the body, some doctors have tried to use it to try to treat other conditions. Examples of these other conditions include Alzheimer disease, autism, diabetes, and plaque inside of arteries (atherosclerosis). Scientific research has not proven that using chelation therapy treatment for these or other conditions is effective. For this reason, chelation therapy for many conditions is considered investigational (unproven).

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
M0300	IV chelation therapy (chemical endarterectomy)
J3520	Edetate disodium, per 150 mg
J0600	Injection, edetate calcium disodium, up to 1,000 mg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/04/2020	02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/02/2023[MPC], 03/12/2024[MPC]	03/12/2024

[MPC] Medical Policy Committee

Revision History	Description
05/05/2020	Updated MCG guideline name
03/12/2024	MPC approved to archive criteria & move to Medically Necessary Services, effective August 1st, 2024. Requires 60-day notice.

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Substance Use Disorder – General

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Inpatient Hospital Stays for Treatment of Alcoholism (130.1) Outpatient Hospital Services for Treatment of Alcoholism (130.2) Chemical Aversion Therapy for Treatment of Alcoholism (130.3) Excluded Service: Electrical Aversion Therapy for Treatment of Alcoholism (130.4) Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic (130.5) Treatment of Drug Abuse (Chemical Dependency) (130.6) Withdrawal Treatments for Narcotic Addictions (130.7)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
American Society of Addiction Medicine (ASAM)	Kaiser Permanente uses ASAM criteria as a supplement to the above NCDs or LCDs for medical necessity review of residential, inpatient, and detoxification treatment for Medicare members.

For Non-Medicare Members

Service	Criteria
Methadone Treatment (H0020)	**Effective until March 1, 2024** Send all cases to MD for review. **Effective March 1, 2024** No prior authorization required for opioid use disorder.
For all other SUD treatments The following services may be considered medically necessary when criteria are met using ASAM® Criteria: • Outpatient Services • Intensive Outpatient/Partial Hospitalization Service • Residential/Inpatient Services • Sub-Acute Detoxification	Kaiser Permanente uses criteria from the American Society of Addiction Medicine (ASAM) to review for residential, inpatient, and detoxification services for adults and adolescents. ASAM criteria were created to improve access to and quality of care in the treatment of substance use disorders. These criteria match individual patients with the appropriate services to help patients succeed in their recovery. This policy describes which types of substance use disorder treatment may be considered medically necessary when using ASAM criteria.

***The ASAM criteria are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed by our

Date Sent: 4/29/24

Behavioral Health department, you may request a copy of the criteria that is being used to make the coverage determination. Call the Behavioral Health Unit for more information regarding the case under review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Kaiser Permanente Mental Health and Wellness Services has adopted American Society of Addiction Medicine (ASAM) criteria to define medical necessity for substance use disorder treatment and to define substance use disorder level of care.

ASAM placement criteria for both adult and adolescents

Washington State requires the use of ASAM criteria by State-certified chemical dependency treatment providers, when determining placement of patients with substance use disorders (criteria includes placement recommendations related to residential treatment). Clinical recommendations must be documented in writing and must contain objective clinical information. Clinical criteria do not factor in family, employer or legal mandates or requests for treatment. Clinical criteria are intended to evaluate the impact of the substance use disorder on the affected individual (via a bio-psychosocial assessment) and to guide decision making related to care strategies.

ASAM placement criteria for both adult and adolescents

Washington State requires the use of ASAM criteria by State-certified chemical dependency treatment providers, when determining placement of patients with substance use disorders (criteria includes placement recommendations related to residential treatment). Clinical recommendations must be documented in writing and must contain objective clinical information. Clinical criteria do not factor in family, employer or legal mandates or requests for treatment. Clinical criteria are intended to evaluate the impact of the substance use disorder on the affected individual (via a bio-psychosocial assessment) and to guide decision making related to care strategies.

Evidence and Source Documents

References:

The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions, Third Edition (2013)
Copies of the criteria can be obtained at www.asam.org.
Revised Code of Washington (RCW) 41.05.528

Applicable Codes

Methadone for Opioid Use Disorder

Medical Necessity Review not required:

CPT® or HCPC Codes	Description
H0020	Alcohol and/or drug services; methadone administration and/or service (provision of the drug by a licensed program)

Substance Use Disorder

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes	

Date Sent: 4/29/24

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/09/2006	07/02/2013[MDCRPC],10/01/2013[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 09/06/2016[MPC], 07/11/2017[MPC], 05/01/2018[MPC], 05/07/2019[MPC], 05/05/2020[MPC], 05/04/2021[MPC], 05/03/2022[MPC], 05/02/2023[MPC]	10/24/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
01/05/2016	Online version of criteria has been updated with editorial changes
07/11/2017	Minor changes to criteria to note ASAM criteria, 3rd edition
12/31/2020	Adopted ASAM Criteria for non-Medicare per mandated Washington state requirement, effective January 1,
05/26/2021	Adopted ASAM criteria for Medicare members. Requires 60-day notice, effective October 1, 2021.
09/17/2021	Updated Background and References with current information.
10/03/2023	MPC should approve updates to the criteria in order to stop requiring prior-authorization of office-based methadone treatment (H0020) for opioid use disorder. 60-day notice required, effective March 1, 2024.
10/24/2023	Merged all criteria sets that utilize ASAM Criteria: Outpatient Services, Intensive Outpatient/Partial Hospitalization Service, Residential/Inpatient Services, Sub-Acute Detoxification

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Spinal Manipulations – Chiropractic and Osteopathic

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 15 Section 30.5 - Chiropractor's Services and Section 240 Chiropractic Services - General
National Coverage Determinations (NCD)	Manipulation (150.1)
Local Coverage Determinations (LCD)	Chiropractic Services (L34009) 12/31/2019 Noridian retired LCD Chiropractic Services (L34009). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34009 for determining medical necessity.
Local Coverage Article	Billing and Coding: Chiropractor Services (A57914)

For Non-Medicare Members

When considering clinical information submitted for medical necessity review, the following data elements and corresponding details are evaluated to ensure correlation to the presenting diagnosis and proposed care plan*:

- Chief Complaint(s)
- Past Medical History
- Mechanism of Onset
- Duration of Symptoms (acute or chronic)
- Evaluation and Re-evaluation findings
- Results of Diagnostic Testing
- Diagnostic Impression
- Complicating Factors (conditions or circumstances that may affect the patient’s response to care)
- Prior and/or Concurrent History of Treatment
- Prognosis and Provider Comments

Manipulative Therapy*

In establishing a fundamental need for manipulation, the treating provider must maintain a clinical record that includes an appropriate new and/ or established patient history and physical examination, and a goal-oriented care plan with measurable treatment goals. This collectively will be considered the key components of an evaluation and management service.

Examples of clinically significant improvement include, but are not limited to:

- Corresponding reduction and/or mitigation in subjective symptoms;

Back to Top

Date Sent: 4/29/24

- Measured improvement in objective findings (i.e., orthopedic tests, neurologic signs, joint specific and region specific ranges of motion, musculoskeletal asymmetry at rest, palpation of tender and sensitive zones, tissue texture changes, muscle strength metrics); and
- A qualitative and/or quantifiable improvement in the patient's ability to perform specific functional tasks and/or activities of daily living as measured by the Patient-Specific Functional Scale (PSFS) or similar validated patient reported clinical outcome measure. For example, a clinically relevant improvement in the PSFS can be indicated by a change of at least 2 points in the average score of all activities or at least a 3-point change in a single activity over the reported baseline within a 4-week period.

  For Manipulative therapy services, Medicare requires the primary diagnosis to be a spinal subluxation diagnosis code, followed by a secondary neuro-musculoskeletal diagnosis code. Medicare mandates that the physical exam must demonstrate a causal relationship between the spine and the patient's presenting complaint, which demonstrates medical necessity for spinal manipulation.

  Medical necessity for manipulative therapy services should be supported by three elements of documentation:
  ▪ Presence of a spinal subluxation;
  ▪ Evidence of the subluxation by X-ray or physical examination; and
  ▪ Documentation of the initial and subsequent visits.

  Medicare requires the acronym P.A.R.T. (Pain, Asymmetry, Range of Motion, and Tissue/Tone) must be used to describe the examination components indicating that a patient is suffering from a spinal condition amenable to manipulation. At least 2 of the 4 P.A.R.T. criteria must be met, with a least one of them being the "A" or "R" component.

*Excerpted from Tivity WholeHealth Network Clinical Criteria to Determine Medical Necessity: Physical Medicine Services (reviewed and updated January, 2021)

Take home equipment and supplies must follow Kaiser Permanente coverage rules and guidelines.
See Devices, Equipment and Supplies
See Compression Garments
See Magna Bloc

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Spinal manipulation is defined by chiropractors as "a specific form of direct articular manipulation utilizing a short lever and characterized by a dynamic, forceful, high velocity thrust of controlled amplitude" (Janse, 1975, as cited by Coulehan. 1985, p. 355). Chiropractors distinguish between chiropractic adjustments and spinal manipulation. Spinal manipulation is a generic term that refers to techniques used by osteopathic physicians, physiatrists (rehabilitation specialists), physiotherapists, or orthopedic surgeons. Spinal adjustment therapy usually involves more frequent visit than medical treatment for the same condition. (Coulehan, 1985).
Manual manipulation of the spine is composed of four elements: patient positioning, location of applied load, peak velocity of the load that is achieved, and peak load developed. The total displacement of the body segments is believed to be properly controlled by a combination of patient positioning and peak load. Techniques used by chiropractors to augment the manipulation may include mobilization, manual traction, soft-tissue massage, and pressure-point techniques (Haldeman, 1983).
Spinal manipulation and adjunct therapies (physical therapy) have been demonstrated to be effective when delivered alone, but no therapy has been consistently demonstrated to be more effective than the other modalities. A 2011 Cochrane Back Group review of 26 randomized controlled trials with 6070 participants (9 studies with low bias) found high quality evidence that spinal manipulative therapy for low back pain indicates provides clinically relevant, statistically significant short-term effect on pain relief as compared to other interventions, including exercise therapy, standard medical care or physical therapy. (Rubinstein, 26Feb2011)

Back to Top

The reviewers note that spinal manipulation appears to be no better or no worse than other existing therapies for pain relief. This review affirms the 2008 Cochrane Database Review of Spinal Manipulative Therapy for low-back pain results indicating no evidence that spinal manipulative therapy is superior to other standard treatments (physical therapy, exercises, back school, general physician care) for pain relief or improved functional outcomes. (Assendelft, et al., Cochrane Library Review, 8Oct2011)
There is mixed evidence on the clinical effectiveness of adjunct modalities, including physical therapy and rehabilitative services and durable medical equipment and supplies, when delivered concurrently with spinal manipulation.
An April 2010 Cochrane Back Group Review of combined chiropractic interventions demonstrated slightly improved pain and disability for patients with acute and subacute back pain in the short term. No difference was demonstrated for combined chiropractic interventions for chronic lower back pain and for studies that had a mixed population of lower back pain. Any demonstrated differences were small and were only seen in studies with a high risk of bias. For acute and subacute LBP, chiropractic interventions improved short- and medium-term pain (SMD -0.25 (95% CI -0.46 to -0.04) and MD -0.89 (95%CI -1.60 to -0.18)) compared to other treatments, but there was no significant difference in long-term pain (MD -0.46 (95% CI -1.18 to 0.26)). Short-term improvement in disability was greater in the chiropractic group compared to other therapies (SMD -0.36 (95% CI -0.70 to -0.02)). However, the effect was small and all studies contributing to these results had high risk of bias. There was no difference in medium- and long-term disability. (Walker, 14APR2010)
In a randomized controlled trial of chiropractic care (flexion distraction) or physical therapy (exercise program), Cambron found that subjects in both groups had decreased pain and disability regardless of which therapy was utilized (p<.002). During the year after care, chiropractic subjects had significantly lower pain scores (p=.002) and received fewer visits but experienced no difference in timing of care following intervention when compared to than those in physical therapy treatment. Physical therapy subjects attended significantly more health care visits than subjects who received chiropractic care only. (Cambron, Cochrane Register of Controlled Trials, Chiropractic care vs medical care for low back pain: Assessment of long-term follow-up data, 2005).

Evidence and Source Documents

Hayes Report, Chiropractic Treatment of Low Back Pain, May 26, 1999
Spinal Manipulative Therapy for Chronic Low Back Pain, The Cochrane Library. Rubinstein, SM, van Middelkoop, M, Assendelft, WJJ, de Boer, MR, vanTulder, MW. 8 Oct 2011 online publication.
Walker B, French S, Grant W, Green S, Cochrane Library Review of Combined Chiropractic Interventions for Low Back Pain, 14APR2010 online publication.
Cambron JA, Cochrane Register of Controlled Trials, Chiropractic care vs medical care for low back pain: Assessment of long-term follow-up data, 2005.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
98925	Osteopathic manipulative treatment (OMT); 1-2 body regions involved
98926	Osteopathic manipulative treatment (OMT); 3-4 body regions involved
98927	Osteopathic manipulative treatment (OMT); 5-6 body regions involved
98928	Osteopathic manipulative treatment (OMT); 7-8 body regions involved
98929	Osteopathic manipulative treatment (OMT); 9-10 body regions involved
98940	Chiropractic manipulative treatment (CMT); spinal, 1-2 regions
98941	Chiropractic manipulative treatment (CMT); spinal, 3-4 regions
98942	Chiropractic manipulative treatment (CMT); spinal, 5 regions
98943	Chiropractic manipulative treatment (CMT); extraspinal, 1 or more regions

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Back to Top

Date Created	Date Reviewed	Date Last Revised
02/10/2000	10/05/2010[MDCRPC], 08/02/2011[MDCRPC], 06/05/2012 [MDCRPC], 10/02/2012 [MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC] ,09/04/2018[MPC] , 09/03/2019[MPC] , 09/01/2020[MPC] , 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC]	12/21/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/05/2015	The chiropractic policy was modified. The Healthways Clinical Criteria for Chiropractic Services was adopted as GHC policy.
09/08/2015	Revised LCD L34009
09/07/2021	Updated Tivity criteria reference for manipulative therapy.
12/21/2023	Added NCD Manipulation (150.1)

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Chromoendoscopy
Narrow Band Imaging for Colonoscopy

- Barrett's Esophagus
- Colorectal Cancer
- Inflammatory Bowel Disease (IBD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"Chromoendoscopy, Narrow Band Imaging for Colonoscopy"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Chromoendoscopy: • Barrett's Esophagus • Colorectal Cancer Screening	There is insufficient evidence in the published medical literature to show that these procedures provide better long-term outcomes than current standard services/procedures during endoscopy.
Chromoendoscopy: • Inflammatory Bowel Disease	Medical necessity review is no longer required. **Please refer to Kaiser Permanente payment policy *Chromoendoscopy and Narrow Band Imaging* for reimbursement clarification (Not separately reimbursed).**

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Background

Chromoendoscopy (also known as chromoscopy or chromocolonoscopy) is an image-enhanced endoscopic technique that has the potential of providing detailed contrast enhancement of the surface of gastrointestinal mucosa. It can be used during any endoscopic examination to improve detection and characterization of subtle mucosal abnormalities, circumscribed dysplastic lesions and malignant changes in the gastrointestinal tract. Chromoendoscopy however, requires optimal bowel preparation in order to provide adequate visualization (Bisschops 2019, Buchner 2017, Clarke 2019, Shukla 2017).

Types of chromoendoscopy:

1. Dye-based chromoendoscopy. This involves actual spraying of absorptive stains or contrast stains directly onto the GI mucosa, through a spray catheter inserted into the endoscope. Dye spraying, or chromoscopy techniques, were first described in the 1970s to provide visualization of the mucosal surface with more clarity and sharpness. It has been used to aid in the detection and evaluation dysplastic changes in the esophagus, stomach, small intestine, and large intestine. Several stains have been described and can broadly be categorized into three groups:
    - Contrast stains (e.g., indigo carmine) that permeate through mucosal crevices and highlights surface topography and mucosal irregularities. Indigo carmine is the most commonly used stain with colonoscopy to enhance the detection of colorectal neoplasms.
    - Absorptive stains (e.g. methylene blue and Lugol's solution) that diffuse or are preferentially absorbed across specific epithelial cell membranes. The normal epithelial cells absorb the methylene blue dye and stain blue while dysplastic and cancerous lesions remain unstained. Methylene blue has been used to detect colonic neoplasia and to aid in the detection of intraepithelial neoplasia in individuals with chronic ulcerative colitis. It has also been used for the detection of Barrett's esophagus and associated dysplasia and/or early cancer, and for the diagnosis of early gastric cancer.
    - Reactive stains (e.g., Congo red and phenol red) undergo chemical reactions with specific cellular constituents, resulting in a color change. These are primarily used to identify gastric abnormalities and are not used with colonoscopy.

    The stains used in chromoendoscopy are transient in contrast to endoscopic tattooing that involves the use of a long-lasting pigment for future localization of lesions (Bisschops 2019, Brown 2016**,** Buchner 2017, Clarke 2019, Shukla 2017).
2. Virtual chromoendoscopy, also called electronic chromoendoscopy (EC), involves imaging enhancements with endoscopy systems using a computer algorithm to simulate different colors of light resulting from dye or stain spraying. The EC techniques depend on finding lesion first with WLE and then using EC function to characterize it (Desai 2019)

    Electronic chromoendoscopy includes:
    - Narrow-band Imaging (NBI) (Olympus Medical Systems Tokyo, Japan),
    - Flexible spectral imaging color enhancement (FICE) (Fujinon, Fujifilm Medical Co, Saitama, Japan),
    - i-SCAN (PENTAX Endoscopy, Tokyo, Japan).

    Selective light transmittance is accomplished by optical filtering of white light in NBI, and by software driven post-image processing in FICE and i-SCAN (Buchner 2017)

    Narrow-band Imaging technology is the most studied in clinical trials. It is a blue light technology that enhances visualization of superficial mucosal structures, especially superficial microcapillaries. The technology is based on the penetration properties of light that is directly proportional to wavelength. Short wavelengths penetrate only superficially into the mucosa, whereas longer wavelengths are capable of penetrating more deeply in the mucosa. In contrast to conventional white-light endoscopy (WLE) that uses the full visible wavelength range (400-700 nm) to produce a red-green-blue image, NBI illuminates the tissue surface using special filters that narrow the red-green-blue bands and simultaneously increase the relative intensity of the blue band. The resulting narrow-band blue-green light improves visualization of mucosal patterns due to the limited optical scattering and shallow penetration depth; therefore, the color contrast is enhanced between the neoplastic lesions and adjacent normal mucosa. The blue light is also absorbed by hemoglobin for optimal detection of mucosal, glandular, and vascular patterns as well as the presence of abnormal blood vessels that are associated with the development of dysplasia. It is hypothesized that as adenomas have increased vascularity and look brown with NBI against a blue-green normal background mucosa, this increased

Back to Top

contrast might improve visualization in wide-field observation (Thosani 2016, Buchner 2017, Atkinson 2019).

Chromoendoscopy has been evaluated for its use with or without standard white light colonoscopy for screening, diagnosis, and/or surveillance of gastrointestinal dysplasia or cancer including the following:

- As an adjunct to colonoscopy for colorectal cancer (CRC) screening to increase the sensitivity of the procedure by facilitating the identification of mucosal abnormalities. The traditional colonoscopy using white light is considered the gold standard method for screening the general population for colon cancer, detection of precursor lesions, and for the diagnosis of colorectal neoplasia in symptomatic patients. However, it is not a perfect imaging test and has been found to miss polyps in 1 of 5 cases with an estimated polyp miss rate of up to 22% especially with very small adenomas. This may lead to an increase in the interval CRC rates. Potential explanations for these missing lesions include the small size or flatness of lesions, difficulty in finding lesions such as those hidden behind folds or flexures, shorter withdrawal time, and poor bowel preparation Over the years, several modifications have been made in the imaging modalities to enhance the traditional colonoscopy and improve its sensitivity in polyp detection. The introduction of High-definition (HD) imaging in the last decade have improved the detection of more adenomas and sessile lesions that may have been missed with the standard colonoscopy. Chromoendoscopy is another technique introduced to potentially improve polyp detection and characterization particularly the flat or nonpolypoid colonic adenomas. The technology can be used for the whole colon (pan-colonic chromoendoscopy) or directed to a specific lesion or lesions (targeted chromoendoscopy). Chromoendoscopy however may to be time consuming and labor intensive (Buchner 2017, Desai 2019, Kim 2020).
- Endoscopic surveillance of patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease) with the goal of early detection of dysplasia and identification of mucosal abnormalities for targeted biopsy as an alternative to multiple random biopsies (Shukla 2017, Clarke 2019).
- Endoscopic surveillance of Barrett's esophagus to potentially improve the image quality and the diagnostic accuracy of white light endoscopy. It can also potentially allow visualization of advanced esophageal neoplasms and identifying any subtle changes in the esophageal mucosa that may correspond to early stages of the disease or abnormalities that may not be seen in upper gastrointestinal endoscopy (Morita 2017, Cerrone 2019).

Medical Technology Assessment Committee (MTAC)

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus

Date: 01/11/2021

Evidence Conclusion:

- The published literature suggests that using acetic acid chromoendoscopy or NBI electronic endoscopy for BO surveillance may have a higher diagnostic yield compared to WLE and standard Seattle protocol when performed by experienced endoscopists (considering all limitations discussed earlier).
- There is insufficient published evidence on the long-term benefit of the using chromoendoscopy and targeted biopsy as a replacement to or in adjunct to the current standard of WLE and Seattle protocol on reducing the rate of biopsy, improving patient QoL or reducing the BO-related morbidity and mortality.

Articles: The literature search for recent of studies and meta-analyses of studies evaluating the accuracy and /or efficacy of chromoendoscopy versus WLE in detecting and characterizing dysplastic lesions and reducing the rate of unnecessary biopsies identified three meta-analyses published in the last 5 years, as well as the protocol and feasibility study for the ABBA trial on the use of acetic acid targeted biopsies in Barrett's surveillance. The search did not reveal ant recently published RCTs or prospective longitudinal studies that compared the efficacy of chromoendoscopy versus WLE in the detection and characterization of dysplastic lesions during surveillance of BO. The more recent and /or relevant meta-analysis comparing chromoendoscopy versus WLE and the standard surveillance protocol were selected for critical appraisal. See Evidence Table

The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Barrett's Esophagus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance

Back to Top

Date: 01/11/2021
Evidence Conclusion:

- The overall results of the published trials and meta-analyses suggest that dye-based chromoendoscopy marginally improves the detection of the adenoma as well as small polyps and flat lesions per subject when compared to standard colonoscopy. There were no significant differences between the two imaging modalities in the detection rate of advanced adenomas, advanced neoplasia, or cancer. The duration of withdrawal time is known to be directly associated with the adenoma detection rate (ADR), and thus the higher detection rates of adenomas, flat, and diminutive lesions with chromoendoscopy may be attributed to the increased withdrawal time with the dye-spray techniques.
- Electronic chromoendoscopy using NBI may modestly improve the adenoma detection rate compared with standard white-light colonoscopy, but the observed difference was only significant with optimal bowel preparation and use of NBI second generation. There were no significant differences in polyp or adenoma detection was observed between high definition white-light colonoscopy and high definition NBI.
- There is a lack of long-term studies to determine whether the use of chromoendoscopy would reduce rates of colorectal interval cancers.
- There is a lack of published studies comparing the effect of chromoendoscopy versus standard or high definition white light endoscopy in reducing the incidence of CRC or the associated morbidity and mortality.
- There is no published evidence, to date, to determine the effects of technology on net health outcome.

Articles: The literature search identified over 40 RCTs and more than 20 meta-analyses (dating back to the year 2012) that examined the impact of different dyes or electronic chromoendoscopy modalities on increasing the detection rate of colonic lesions when compared to one another or to white light colonoscopy.
Due to the large number of published studies and meta-analyses, the most recent meta-analyses of RCTs, that were more inclusive of trials, and had valid methodology were selected for the current review as well as recently published RCTs that compared neoplasia detection rates with chromoendoscopy (dye -based or NBI) versus standard white light (WL) of high-definition white light (HDWL) colonoscopy used for screening or diagnosis of colorectal cancer. The use of chromoendoscopy for the surveillance of Barrett's esophagus and the surveillance of irritable bowel disease will be reviewed separately in different reports. See Evidence Table**.**

The use of Chromoendoscopy Imaging (Dye-Based Chromoendoscopy & Virtual Electronic Chromoendoscopy) for Colon Cancer Screening, Diagnosis and Disease Surveillance does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD)
Date: 01/11/2021
Evidence Conclusion:

- There is strong evidence that dye chromoendoscopy (DCE) is superior to standard white light endoscopy (SD-WLE) in detecting dysplastic lesions in patients with IBD.
- There is moderate to high strength evidence indicating that DCE does not provide any additive benefit over HD-WLE in the overall ability to detect dysplasia in patients with IBD. Randomized controlled trials, meta-analyses of RCT, and a recent US-based case control sturdy (Clarke et al 2020) showed no significant difference in dysplasia detection rate between DCE and HD-WLE. The studies that showed higher dysplasia detection rate with of DCE were mainly observational studies (with the exception of Alexandersson et al's 2020 RCT).
- Narrow band imaging (NBI) is not superior to SD or HD-WLE. Other technologies such as i-scan and Fujifilm Intelligent Chromoendoscopy have not been sufficiently studied in dysplasia surveillance.
- There is insufficient evidence to determine the safety of dye-chromoendoscopy.
- There are no published long-term longitudinal studies to date, to determine the impact of chromoendoscopy on treatment decisions for patients with IBD, patient health outcomes, e.g. reducing colectomy, reducing interval cancer and CRC-related morbidity and mortality, improving the quality of life and other patient-oriented outcomes.

Articles: The literature search identified four RCTs published in the last two years, one case control study , and nine meta-analyses of RCTs and /or prospective studies that examined the impact of dye or electronic chromoendoscopy modalities on increasing the dysplasia detection rates when compared to one another or to the standard or high definition white light colonoscopy. Three of the meta-analyses were network meta-analyses, two MAs compared dye chromoendoscopy versus white light endoscopy, and five compared different modalities of WLE and chromoendoscopy. See Evidence Table

Back to Top

The use of Chromoendoscopy (Dye-Based & Electronic Chromoendoscopy) for the Surveillance of Patients with Inflammatory Bowel Disease (IBD) does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes-*commonly submitted with CPT code 43499 or 45399*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
7/10/2020	08/03/2021 MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC	10/03/2023

MPC Medical Policy Committee

Revision History	Description
08/04/2020	MPC approved to adopt non-coverage policy. Requires 60-day notice, effective date 01/01/2021.
05/04/2021	Added MTAC reviews for BE, CRC, and IBD. MPC approved to adopt MTAC's recommendation of non-coverage for chromoendoscopy for Barrett's Esophagus (BE) and Colon Cancer Screening (CRC). MPC approved to adopt MTAC's recommendation of coverage for chromoendoscopy for Inflammatory Bowel Disease (IBD). Criteria align with Kaiser Permanente payment policy (not separately reimbursed). Requires 60-day notice, effective date August 15, 2021.
10/03/2023	MPC approved to eliminate the chromoendoscopy clinical criteria for use in CRC screening of patients with IBD and instead point to KPWA payment policy. Requires 60-day notice, effective date March 1, 2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cochlear Implant

- Cochlear Implant Device
- Hybrid Cochlear Implant

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cochlear Implantation (50.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Service	Criteria Used
Cochlear Implant	Kaiser Permanente has elected to use the Cochlear Implant Effective 12.01.2022 (KP-0177 12012022) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Most recent audiogram/hearing test • Most recent clinical notes from requesting provider &/or specialist (otolaryngology, ENT)
Cochlear implantation with a hybrid cochlear implant/hearing aid device that includes the hearing aid integrated into the external sound processor of the cochlear implant, including but not limited to the Nucleus® Hybrid™ L24 Cochlear Implant System	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

***MCG Manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Date Sent: 4/29/24

Background

A cochlear implant is an electronic device that can enable patients with severe to profound hearing loss to perceive sound. Cochlear implants have two main parts:

1) An internal device that is implanted under the skin behind the ear; and
2) A speech processor that is worn or carried (externally) by the individual.

Sounds are detected by a microphone and transformed into an electrical signal. The speech processor codes the signals into a particular pattern of electrical pulses. The pulses are sent to the implant, which in turn transmits them via the auditory nerve to the brain, which recognizes them as sound. Use of a cochlear implant requires both a surgical procedure to implant the device, and substantial post-implantation therapy to learn or re-learn the sense of hearing. In the United States, approximately 22,000 adults have cochlear implants and about 15,000 children have received them (NIDCD, 2006).

Provision of unilateral cochlear implants is currently standard practice. Although results are often positive, particularly in the ability to understand speech in a quiet situation, normal hearing is not restored. There is increasing interest in bilateral cochlear implants to further improve the ability to patients to detect sound. Potential advantages of bilateral implantation include improvements in:

- Hearing in noise, due to the ability to benefit from a “head shadow effect
- Speech perception, due to the availability of sound information from both ears;
- Sound localization, the ability to correctly identify the directional location of sounds surrounding the listener (Litovsky et al., 2006; Tyler et al., 2003).

A potential problem with bilateral cochlear implants is that bilateral coordination of pulsed signals is not yet possible. Instead, the two implants function independently. This is not likely to be as effective as normal binaural hearing which takes advantages of the integration of binaural acoustical cues. In addition, patients with severe hearing loss may have different patterns of loss on each side, and also may have developed abnormal binaural brain maps (Tyler et al., 2003). Response to bilateral cochlear implants, especially localization ability, may also depend on previous experience with hearing. Adults who have had exposure to binaural stimulation early in life appear to perform better with bilateral cochlear implants than adults who were born without hearing or lost hearing at a very young age (Litovsky et al., 2006).

Experts have pointed out that a challenge in studying the effectiveness of bilateral cochlear implants is that learning may influence an individual’s ability to detect aural cues, either unilateral or bilateral. Studies that evaluate users of bilateral implants without comparing them to experienced users of unilateral users may be limited because they do not include patients who have been able to adapt to listening through one device.

Medical Technology Assessment Committee (MTAC)

Bilateral Cochlear Implants

10/13/2004: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine the effect of bilateral cochlear implants on health outcomes compared to unilateral cochlear implants, in patients with severe to profound hearing loss.
Articles: The search yielded 19 articles. The empirical studies were small (sample sizes ranged from one to 20 patients) and laboratory based. They consisted of conducting speech tests of patients with bilateral cochlear implants, sometimes comparing results to one-ear only in the same patients. There were no studies that compared bilateral cochlear implants to experienced users of unilateral implants. There were also no studies that examined functional outcomes with bilateral vs. unilateral implants, such as the ability to use the telephone or perceive speech in a real-world setting.

The use of bilateral cochlear implants for severe to profound hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Bilateral Cochlear Implants

10/02/2006: MTAC REVIEW

Evidence Conclusion: The evidence base consists of small laboratory-based case series and one small randomized controlled trial. The RCT (Summerfield et al., 2006) compared quality of life outcomes in adults who received a second cochlear implant to a delayed treatment group. All participants were successful users of unilateral implants. The study found statistically significant improvement in spatial hearing and quality of hearing

subscales of a QOL questionnaire in the bilaterally implanted group compared to the control group. However, there were no significant differences on six other quality of life measures and if the p-values had been corrected for multiple comparisons, none of the between-group comparisons would have been statistically significant. The study suggests that bilateral cochlear implants may be beneficial for improving some aspects of hearing in experienced adult users of unilateral implants, but findings are inconclusive. There is insufficient evidence on the effectiveness of bilateral cochlear implants compared to unilateral implants in children.
Articles: The evidence base consists of small laboratory-based case series and one small randomized controlled trial. The RCT (Summerfield et al., 2006) compared quality of life outcomes in adults who received a second cochlear implant to a delayed treatment group. All participants were successful users of unilateral implants. The study found statistically significant improvement in spatial hearing and quality of hearing subscales of a QOL questionnaire in the bilaterally implanted group compared to the control group. However, there were no significant differences on six other quality of life measures and if the p-values had been corrected for multiple comparisons, none of the between-group comparisons would have been statistically significant. The study suggests that bilateral cochlear implants may be beneficial for improving some aspects of hearing in experienced adult users of unilateral implants, but findings are inconclusive. There is insufficient evidence on the effectiveness of bilateral cochlear implants compared to unilateral implants in children.

The use of Bilateral Cochlear Implants in the treatment of severe hearing loss does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hybrid Cochlear Implant

BACKGROUND

Sensorineural hearing loss (SHL) is the most common form of hearing loss occurring when there is damage to the inner ear or the nerve pathway from the inner ear to the brain. Causes are variable and range from aging and heredity, all the way to exposure to loud noises and drugs toxic to the inner ear. SHL typically results in difficulty hearing faint sounds, understanding people with higher-pitched voices, hearing certain speech sounds, and in some cases, hearing high-pitched emergency vehicle sirens or common safety alarms, such as smoke detectors. Any type of hearing loss can be debilitating and can affect people in various ways.
Conventional treatment options for hearing loss are dependent on the type and source of hearing loss. While hearing loss cannot be fully restored, a wide variety of technologies are currently available to improve hearing. These technologies utilize either air or bone conduction to transmit sound. Air conduction hearing aids (ACHA), for example, receive sound waves through a microphone which are then converted to electrical signals and amplified through a speaker in the ear. Alternatively, bone anchored hearing aids (BAHA) transmit sound vibrations directly to the inner ear through the skull, bypassing the outer and middle ear completely. In any case, both technologies come with strengths and limitations.
The Nucleus® Hybrid™ L24 Cochlear Implant System, developed by Cochlear® (Centennial, CO), combines the functions of both ACHA and BAHA in a single device. The device specifically uses acoustic amplification to amplify low frequency hearing, while taking advantage of cochlear implant technology to restore access to the high-frequency hearing allowing a near normal hearing experience. The hybrid technology requires surgical implantation, similar to that of a standard cochlear implant with the main difference being that the array is shorter and therefore not inserted as far into the cochlear.
The United States Food and Drug Administration (FDA) approved the first hybrid cochlear implant in March of 2014. The Medical Technology and Assessment Committee (MTAC) has not previously assessed hybrid cochlear implants and is currently reviewing the topic to support a coverage decision.

08/17/2015: MTAC REVIEW

Hybrid Cochlear Implant

Evidence Conclusion: *Effectiveness*: A multi-centered European study, carried out by Lenarz and colleagues, investigated hearing conservation in 66 patients with significant low-frequency residual hearing using the Nucleus Hybrid L24 cochlear implant. The investigators compared pre- and post-operative performance in speech recognition scores in both quiet and noisy environments were significantly improved for 65% and 73% of subjects, respectively. In addition, the mean speech spatial and quality subscale ratings were significantly improved by 1.2, 1.3 and 1.8 points, respectively ($p<0.001$). Ultimately, the investigators concluded that the hybrid cochlear implant preserved low-frequency residual hearing and improved speech perception (Lenarz, James et al. 2013). [Evidence Table 1] A similar study, conducted by Roland et al. in multiple centers across the US, included 50 individuals with severe to profound high-frequency hearing loss. In the same way as the European trial, pre- and post-operative performance was measured on consonant-nucleus-consonant words, AzBio sentence noise as well as self-assessment. At six months, the investigators reported that a majority of the patients had statistically significant improvements in word and sentence recognition leading the investigators to conclude that the Nucleus Hybrid L24 cochlear implant provides significant improvements to hearing (Roland, Gantz et al. 2015). [Evidence Table 2]

Back to Top

Safety: The safety profile on these devices is not entirely clear. Both of the included studies detail a number of adverse effects including dizziness, irritation and tinnitus to name a few. Beyond that, the literature reports risk of permanent damage to residual hearing fibers from the surgery and placement of the electrode itself. A larger long-term concern is associated with future changes in hearing in the implanted ear. Specifically, should the patient experience additional hearing loss, will they need additional surgery using a longer standard electrode. Collectively, the evidence is limited by small sample sizes, lack of randomization and inadequate comparison groups. To add to this, neither of the studies provide a sufficient follow-up period. Finally, both of the studies are sponsored by the device manufacturer leaving the studies open to potential bias. Ultimately, the evidence does not adequately support the safety and effectiveness of the hybrid cochlear implant. The evidence base would benefit from large RCTs with extended follow-up to establish long-term performance and safety.
Conclusions: There is insufficient evidence to support the effectiveness of a hybrid cochlear implant with external hearing aid compared with a standard cochlear implant. There is insufficient to establish the safety of hybrid cochlear implant with standard cochlear implant.
Articles: The search returned a small variety of publications including retrospective analyses, small single arm prospective studies and one cross-sectional study (Golub, Won et al. 2012; Nguyen, Mosnier et al. 2012; Reiss, Turner et al. 2012; Szyfter, Wróbel et al. 2013; Jurawitz, Büchner et al. 2014). The literature was specifically screened for randomized controlled trials (RCTs) with the overall aim to compare hybrid cochlear implants with conventional cochlear implants. In the absence of RCTs with appropriate comparators, the best available evidence came from two prospective, single arm studies (one of which supported the 2014 FDA approval) were selected for critical appraisal. The following articles were selected for review: Lenarz T, James C, Cuda D, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. *International Journal of Audiology*. 2013; 52:838-848. See Evidence Table 1. Roland JT, Gantz BJ, Waltzman SB, et al. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. *Laryngoscope.* 2015. See Evidence Table 2.

The use of hybrid cochlear implants does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Cochlear Implant - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
69930	Cochlear device implantation, with or without mastoidectomy
HCPC Codes	**Description**
L8614	Cochlear device, includes all internal and external components
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement

Hybrid Cochlear Implant - Considered Not Covered:

Same as listed above and billed with HCPC Code	Description
L8614	Cochlear device, includes all internal and external components

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised

Back to Top

03/20/1995	09/07/2010 MDCRPC, 10/05/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013 MDCRPC, 01/07/2014 MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC, 02/07/2023MPC	07/05/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt updates to the Cochlear Implant criteria (KP-0177) Specific changes include but not limited to: • No longer indicates a need to place one implant at a time and that evidence supports concurrent bilateral implants specifically for adults • Added “replacement exclusion” language from commercial contracts Removed non-applicable CPT codes: 69714, 69715, 69717, 69718
03/02/2021	MPC approved the updated recommendations to the current hybrid criteria for Cochlear Implant to include indications for unilateral sensorineural hearing loss for ages 5 years old and older. Requires 60-day notice, effective date 08/01/2021.
07/05/2022	MPC approved to update the hybrid criteria (KP-0177) to include indications for single-sided deafness and include clarifying language for obsolescence/warranty. Requires 60-day notice, effective date 12/01/2022.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Combined Hydrogen/Methane Breath Test

- Diagnosing Small Intestinal Bacterial Overgrowth (SIBO)
- Fructose or Lactose Intolerance

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Diagnostic Breath Analyses (100.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Services	Criteria used
Diagnosing Small Intestinal Bacterial Overgrowth (SIBO)	Hydrogen/methane breath test covered only when ordered by Gastroenterologist for possible SIBO
Fructose or Lactose Intolerance	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Small intestinal bacterial overgrowth (SIBO) is characterized by a malabsorption syndrome due to abnormally large amounts of bacteria within the small intestine (Gasbarrini, et al. 2007). Symptoms include diarrhea, abdominal pain or cramps, nausea, constipation, acid reflux, bloating, flatulence, dehydration and fatigue. SIBO can also cause more severe symptoms including steatorrhea, anemia, bleeding or bruising, night blindness, bone pain, fractures, leaky gut syndrome, autoimmune reactions, weight loss and “failure to thrive”. Due largely to uncertainty with regard to definition and detection, the true prevalence of SIBO and its relationship to a number of clinical disorders remains unclear (Dukowicz, et al. 2007).

Direct aspiration and culture of jejunal fluid have traditionally been considered the “gold standard” for SIBO diagnosis. With results expressed as colony-forming units per milliliter of jejunal fluid (cfu/ml), a SIBO diagnosis is

Back to Top

most commonly defined as >105 cfu/ml, however, the thresholds vary throughout the literature (Abu-Shanab and Quigley 2009; Dukowicz, et al. 2007). To add to this, aspiration and culture is expensive, invasive and difficult to perform requiring the passage of a tube under fluoroscopic guidance through the nose, throat, esophagus and stomach. Breath tests, on the other hand, escape these limitations and have been proposed as a simple tool for diagnosing SIBO. Based on the fact that only bacteria in the gastrointestinal tract can ferment unabsorbed carbohydrates and metabolize them into hydrogen and/or methane, the gases are absorbed into the bloodstream and subsequently excreted in the breath (Levitt, et al. 2006; Simren and Stotzer 2006). Put simply, breath tests measure the levels of hydrogen and/or methane gas in a breath (Ghoshal, et al. 2006).

Breath tests can be performed at home or in a clinic and require that the patient fast for 12 hours prior to testing, after which, the patient provides a baseline sample breath. After establishing a baseline measurement, the patient ingests a small amount of substrate, either lactulose or glucose, and subsequently, provides breath samples every 15 minutes for three to five hours. At this time, hydrogen/methane breath tests have not been standardized with protocols differing in dose and concentration of the test substrate, and duration of test time intervals (Bures, et al. 2010). In the same way, there have been no accepted criteria for what constitutes a positive result.

Hydrogen/methane breath tests have not been approved by the Food and Drug Administration (FDA).

Medical Technology Assessment Committee (MTAC)

Combined Hydrogen/Methane Breath Test

6/16/2014: MTAC REVIEW

Evidence Conclusion: Evidence on the validity of the lactulose breath test for the diagnosis of SIBO is conflicting. In 1990, Corazza and colleagues performed complete microbiological analyses of jejunal aspirates in 77 patients thought to have SIBO. Those results were then compared to glucose and lactulose breath tests. In the results, the investigators reported sensitivities of 62% and 68% for glucose and lactulose, respectively and specificities of 44% and 83% (Corazza, et al. 1990). See Evidence Table More recently, however, Ghoshal and colleagues performed both glucose and lactulose breath tests on 83 patients on two separate days and reported that, when compared to culture of small bowel aspirate, both glucose and lactulose breath tests had lower sensitivities (glucose 44%, lactulose 31%) and higher specificities (glucose 80%, lactulose 86%). The authors propose several theories to explain the low sensitivities, including non-hydrogen producing patients, and patients with high basal breath hydrogen levels despite adequate preparation (Ghoshal, et al. 2006). See Evidence Table While none of the studies measured safety outcomes or recorded adverse events, most of the literature identifies breath tests as simple, safe, and lacking invasiveness (Dukowicz, et al. 2007). Despite these advantages, there is a lack of uniformity regarding their protocol and interpretation. Furthermore, hydrogen and methane levels are affected by a number of factors including smoking, exercise, chewing gum, breath mints, and antibiotic use. Above all else, differences in bacterial flora among patients can determine responses to breath testing with about 10-15% of patients lacking bacteria capable of producing hydrogen. Ultimately, the absence of an established interpretation of the gold standard, limits the ability to firmly establish the diagnostic accuracy of breath tests for diagnosing SIBO leaving the validity of the test in question. Conclusion: There is insufficient evidence to establish the diagnostic accuracy of the combined hydrogen/methane breath test for diagnosing SIBO. There is insufficient evidence to conclude that the hydrogen breath test is not harmful to patients. There is insufficient evidence to determine the impact of the test on patient management.

Articles: There is extensive literature on the use of breath testing to diagnose SIBO with many publications addressing the prevalence of SIBO among patients with irritable bowel syndrome. Generally speaking, there is a greater body of published literature on the use of hydrogen breath testing with less literature specifically addressing the use of methane breath tests and combination hydrogen and methane breath tests. Two studies were identified that assess the utility and accuracy of SIBO. The following studies were selected for critical appraisal: Corazza GR, Menozzi MG, Strocchi A, et al. The diagnosis of small bowel bacterial overgrowth: reliability of jejunal culture and inadequacy of breath hydrogen testing. Gastroenterology. 1990;98(2):302-309. See Evidence Table Ghoshal UC, Ghoshal U, Das K et al. Utility of hydrogen breath tests in diagnosis of small intestinal bacterial overgrowth in malabsorption syndrome, and its relationship with oro-cecal transit time. Indian J Gastroenterology. 2006;25(1):6-10. See Evidence Table.

The use of Combined Hydrogen/Methane Breath Test for Diagnosing Small Intestinal Bacterial Overgrowth (SIBO) does not meet the *Kaiser Permanente Medical Technology Testing Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
91065	Breath hydrogen or methane test (eg, for detection of lactase deficiency, fructose intolerance, bacterial overgrowth, or oro-cecal gastrointestinal transit)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/01/2014	07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC] , 09/03/2019[MPC] , 09/01/2020[MPC] , 09/07/2021[MPC] , 09/06/2022[MPC], 09/05/2023[MPC]	12/06/2016

[MPC] Medical Policy Committee

Revision History	Description
12/06/2016	Added language to cover test if ordered only by GI for possible SIBO

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Complications of Non-Covered Services

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Benefit Manual Chapter 16, 180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

All services related to the non-covered services are excluded from coverage. However, certain contracts, but not all, have provisions to cover specific complications of non-covered services for acute medical complications. Contracts that have coverage may allow for coverage of specific medically necessary interventions to resolve an acute, potentially life threating medical complication (not necessarily covering non-acute issues). Refer to the member specific contract language to determine the benefit coverage for non-covered services. Coverage does not include complications that occur during or immediately following the non-covered service. Additional surgeries or other medical services to resolve other acute medical complications resulting from non-covered services shall not be covered.

Examples of -Non-covered complications may include but are not inclusive of the following possible situations:

- A nasal obstruction after cosmetic rhinoplasty
- Desired cosmetic outcomes not achieved
- Scarring of surgical wounds arising from a cosmetic procedure
- Request for removal of breast implants due to contracture or leakage, when placed for cosmetic purposes

All requests that appear to involve complications of a non-covered services, or any from dental services should be sent to the clinical review physicians for review.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Most Kaiser Permanente contracts state “Excluded: non-covered surgical services.” In applying this exclusion guidance was requested by staff making coverage determinations. The above criteria were developed to provide guidance.

Creation Date	Review Dates	Date Last Revised
09/24/2007	04/06/2010[MDCRPC], 02/11/2011[MDCRPC], 02/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018 [MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	08/03/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Revised LCD L34886 and L35008 Non-Covered Services.
11/12/2018	Updated KPWA criteria for Non-Medicare Members
12/5/2018	Revised ALL reviews must go to Medical Director Review
05/07/2019	MPC approved to adopt criteria for complications of non-covered services
08/04/2020	Added Medicare LCA A57642
08/03/2021	Removed retired Medicare LCD L35008 and LCA A57642.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Compression Garments – Stockings/Sleeves

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Surgical Dressings (L33831) Lymphedema Compression Treatment *(Must have diagnosis of I89.0, I97.2, I97.89, Q82.0)*
Local Coverage Article	Surgical Dressings (A54563) External Breast Prosthesis (A52478)- (Addresses L8010 *A mastectomy sleeve (L8010) is denied as noncovered, since it does not meet the definition of a prosthesis)* Lymphedema Compression Treatment Items—Correct Coding and Billing *(Must have diagnosis of I89.0, I97.2, I97.89, Q82.0)* Standard Documentation Article (A55426)
MLN Matters Article	Lymphedema Compression Treatments Items: Implementation

For Non-Medicare Members

Kaiser Permanente has elected to use the Graduated Compression Stockings/Sleeves (KP-0336) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Elastic stockings are generally stockings of 18-20 mm or less and can be purchased over the counter.

***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 12 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

Background

Compression garments are usually made of elastic material and are used to promote venous or lymphatic circulation. Compression garments worn on the legs can help prevent deep vein thrombosis and reduce edema and are useful in a variety of peripheral vascular conditions. Compression garments can come in varying degrees of compression. The higher degrees require a physician's prescription.

Evidence and Source Documents

2/12/1986: LITERATURE SEARCH

Articles: The use of JOBST products for the treatment of burns is medically appropriate.

12/31/1999: LITERATURE SEARCH

Articles: Effective Health Care, NHS Centre for Reviews and Dissemination, University of York, August 1997, Volume 3:4, ISSN: 0965-0288.

Twenty randomized controlled trials evaluated different forms of compression bandaging on venous ulcer healing in a wide range of age groups. Two of these incorporated economic evaluations, 2 compared compression stockings with compression bandages and 2 evaluated intermittent pneumatic compression. Overall, the quality of trials is poor. Six RCT's assessed whether compression therapy was better than no compression. These showed that compression provided by either Unna's boot, 2-layer, 4 layer or short stretch bandages improve healing rates compared to treatment using no compression. One study showed that compression was more cost effective because of faster healing rates saving nursing time. High compression showed the best healing rates. A combination of 2 compression stockings has been shown to increase the rate of healing compared to a short stretch bandage.

Compression stockings have been found to be more effective than drug therapy in the prevention of recurrence of leg ulcers.

White Paper - Kaiser on Benefits of Compression Therapy:

Venous ulcers can be healed, and recurrence prevented through the use of compression therapy (not TED hose). Recommend coverage of two pair a year and patients must wear all day every day. Compression therapy can prevent serious complications of venous insufficiency and reduce treatment costs.

Federal Post-Mastectomy Reconstructive Surgery Mandate: December 21, 1998 AAHP memo:

The Federal post-mastectomy reconstructive surgery mandate was contained in the Women's Health and Cancer Rights Act of 1998 that was included in the FY99 omnibus appropriations act (P.I., 105-277, enacted October 21, 1998). Under the new law most plans and insurers that provide coverage for medical and surgical benefits in connection with a mastectomy are required to provide reconstructive surgery benefits. Coverage includes reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce symmetrical appearance, and prostheses and treatment of physical complications at all stages of the mastectomy, including lymphedemas.

Yasuhara MD, Hiroshi et al., A Study of the Advantages of Elastic Stockings for Leg Lymphedema, *International Angiology,* Vol 15:3, 272-277, September 1996 See Evidence Table

G. Bertelli, et al, An analysis of prognostic factors in response to conservative treatment of postmastectomy lymphedema, Surgery, Gynecology and Obstetrics, Volume 175: 455-460, November 1992 See Evidence Table

Bunce, Ian H et al, Post-mastectomy Lymphedema Treatment and Measurement, *Medical Journal of Australia,* Vol 161: 125-128, July 18, 1994 See Evidence Table

Applicable Codes

Compression Burn Garments

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A6501	Compression burn garment, bodysuit (head to foot), custom fabricated
A6502	Compression burn garment, chin strap, custom fabricated
A6503	Compression burn garment, facial hood, custom fabricated
A6504	Compression burn garment, glove to wrist, custom fabricated
A6505	Compression burn garment, glove to elbow, custom fabricated
A6506	Compression burn garment, glove to axilla, custom fabricated
A6507	Compression burn garment, foot to knee length, custom fabricated
A6508	Compression burn garment, foot to thigh length, custom fabricated

Back to Top

A6509	Compression burn garment, upper trunk to waist including arm openings (vest), custom fabricated
A6510	Compression burn garment, trunk, including arms down to leg openings (leotard), custom fabricated
A6511	Compression burn garment, lower trunk including leg openings (panty), custom fabricated
A6512	Compression burn garment, not otherwise classified
A6513	Compression burn mask, face and/or neck, plastic or equal, custom fabricated

Surgial Dressing Compression Garments

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
A6531	Gradient compression stocking, below knee, 30-40 mmhg, used as a surgical dressing, each
A6532	Gradient compression stocking, below knee, 40-50 mmhg, used as a surgical dressing, each
A6545	Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, used as a surgical dressing, each

Compression Garments

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

† not covered by Medicare

CPT® or HCPC Codes	Description
A6520	Gradient compression garment, glove, padded, for nighttime use, each
A6521	Gradient compression garment, glove, padded, for nighttime use, custom, each
A6522	Gradient compression garment, arm, padded, for nighttime use, each
A6523	Gradient compression garment, arm, padded, for nighttime use, custom, each
A6524	Gradient compression garment, lower leg and foot, padded, for nighttime use, each
A6525	Gradient compression garment, lower leg and foot, padded, for nighttime use, custom, each
A6526	Gradient compression garment, full leg and foot, padded, for nighttime use, each
A6527	Gradient compression garment, full leg and foot, padded, for nighttime use, custom, each
A6528	Gradient compression garment, bra, for nighttime use, each
A6529	Gradient compression garment, bra, for nighttime use, custom, each
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each
A6535	Gradient compression stocking, thigh length, 40 mmhg or greater, each
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each
A6538	Gradient compression stocking, full length/chap style, 40 mmhg or greater, each
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each
A6541	Gradient compression stocking, waist length, 40 mmhg or greater, each
A6544	Gradient compression stocking, garter belt
A6549	Gradient compression garment, not otherwise specified
A6552	Gradient compression stocking, below knee, 30-40 mmhg, each
A6553	Gradient compression stocking, below knee, 30-40 mmhg, custom, each
A6554	Gradient compression stocking, below knee, 40 mmhg or greater, each
A6555	Gradient compression stocking, below knee, 40 mmhg or greater, custom, each
A6556	Gradient compression stocking, thigh length, 18-30 mmhg, custom, each
A6557	Gradient compression stocking, thigh length, 30-40 mmhg, custom, each
A6558	Gradient compression stocking, thigh length, 40 mmhg or greater, custom, each
A6559	Gradient compression stocking, full length/chap style, 18-30 mmhg, custom, each
A6560	Gradient compression stocking, full length/chap style, 30-40 mmhg, custom, each
A6561	Gradient compression stocking, full length/chap style, 40 mmhg or greater, custom, each
A6562	Gradient compression stocking, waist length, 18-30 mmhg, custom, each
A6563	Gradient compression stocking, waist length, 30-40 mmhg, custom, each
A6564	Gradient compression stocking, waist length, 40 mmhg or greater, custom, each
A6565	Gradient compression gauntlet, custom, each

Back to Top

A6566	Gradient compression garment, neck/head, each
A6567	Gradient compression garment, neck/head, custom, each
A6568	Gradient compression garment, torso and shoulder, each
A6569	Gradient compression garment, torso/shoulder, custom, each
A6570	Gradient compression garment, genital region, each
A6571	Gradient compression garment, genital region, custom, each
A6572	Gradient compression garment, toe caps, each
A6573	Gradient compression garment, toe caps, custom, each
A6574	Gradient compression arm sleeve and glove combination, custom, each
A6575	Gradient compression arm sleeve and glove combination, each
A6576	Gradient compression arm sleeve, custom, medium weight, each
A6577	Gradient compression arm sleeve, custom, heavy weight, each
A6578	Gradient compression arm sleeve, each
A6579	Gradient compression glove, custom, medium weight, each
A6580	Gradient compression glove, custom, heavy weight, each
A6581	Gradient compression glove, each
A6582	Gradient compression gauntlet, each
A6583	Gradient compression wrap with adjustable straps, below knee, 30-50 mmhg, each
A6584	Gradient compression wrap with adjustable straps, not otherwise specified
A6585	Gradient pressure wrap with adjustable straps, above knee, each
A6586	Gradient pressure wrap with adjustable straps, full leg, each
A6587	Gradient pressure wrap with adjustable straps, foot, each
A6588	Gradient pressure wrap with adjustable straps, arm, each
A6589	Gradient pressure wrap with adjustable straps, bra, each
A6593	Accessory for gradient compression garment or wrap with adjustable straps, not-otherwise specified
A6594	Gradient compression bandaging supply, bandage liner, lower extremity, any size or length, each
A6595	Gradient compression bandaging supply, bandage liner, upper extremity, any size or length, each
A6596	Gradient compression bandaging supply, conforming gauze, per linear yard, any width, each
A6597	Gradient compression bandage roll, elastic long stretch, per linear yard, any width, each
A6598	Gradient compression bandage roll, elastic medium stretch, per linear yard, any width, each
A6599	Gradient compression bandage roll, inelastic short stretch, per linear yard, any width, each
A6600	Gradient compression bandaging supply, high density foam sheet, per 250 square centimeters, each
A6601	Gradient compression bandaging supply, high density foam pad, any size or shape, each
A6602	Gradient compression bandaging supply, high density foam roll for bandage, per linear yard, any width, each
A6603	Gradient compression bandaging supply, low density channel foam sheet, per 250 square centimeters, each
A6604	Gradient compression bandaging supply, low density flat foam sheet, per 250 square centimeters, each
A6605	Gradient compression bandaging supply, padded foam, per linear yard, any width, each
A6606	Gradient compression bandaging supply, padded textile, per linear yard, any width, each
A6607	Gradient compression bandaging supply, tubular protective absorption layer, per linear yard, any width, each
A6608	Gradient compression bandaging supply, tubular protective absorption padded layer, per linear yard, any width, each
A6609	Gradient compression bandaging supply, not otherwise specified
A6610	Gradient compression stocking, below knee, 18-30 mmhg, custom, each
L8010†	Breast prosthesis, mastectomy sleeve

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Back to Top

Date Sent: 4/29/24

Date Created	Date Reviewed	Date Last Revised
12/31/1999	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC] , 06/04/2013[MDCRPC],12/13/2013 [MPC], 10/07/2014[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 01/09/2024[MPC]	12/27/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Date Last Revised	Description
07/28/2015	Codes added and description of elastic stockings
08/26/2015	Added new LCD link
01/27/2016	Added Medicare coverage article
10/03/2017	Revised criteria to include indication: *Documented history of venous stasis ulcer within the last 2 years*
07/20/2023	Added Medicare Coverage article for External Breast Prostheses as this addresses mastectomy sleeve non-coverage.
12/27/2023	Updated Medicare links related to new DME benefit category for Lymphedema Compression Treatment Garments. Updated coding section with new applicable codes effective 1/1/2024 and description updates.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Continuous Glucose Monitor (CGM)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Home Blood Glucose Monitors (40.2)
Local Coverage Determinations (LCD)	Glucose Monitors (L33822) Implantable Continuous Glucose Monitors (I-CGM) (L38659)
Local Coverage Article	Glucose Monitor – Policy Article (A52464) Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) (A58138)

For Non-Medicare Members

Kaiser Permanente has elected to use the Continuous Glucose Monitoring (KP-0126 01012024) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> **MCG* are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed for heart transplant eligibility, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

*Note – Requests for an insulin infusion pump used with continuous glucose sensing (HCPCS code E0787 or E0784 + E2103 for Medicare) will only be authorized if the patient meets both criteria for continuous glucose monitor as outlined in this criteria and all criteria outlined in the Insulin Pump clinical review criteria including that current device is no longer under warranty.

Documentation requirements to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (endocrinology, primary care)
- Last 6 months of lab work
- Last 1-2 months of legible home monitoring logs or a printout of CGM results

ORDER FORM

Request for Approval of Patient-Use Continuous Glucose Monitoring System (CGMS)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Background

Diabetes mellitus is one of the leading causes of death in the United States. If poorly controlled, it causes accelerated both large and small artery diseases that predispose patients to a number of late secondary complications including heart disease, stroke, renal, disease, peripheral vascular disease, retinal damage, peripheral nerve damage, and others. Management of diabetes involves maintaining blood glucose levels close to the normal range. Currently, self-monitoring of capillary blood glucose (SMBG), and laboratory testing of HbA1c, to measure longer term glycemic control, are the standard methods for glucose testing. Blood glucose values are influenced by a number of changing variables, including food choices and portions, stress, insulin doses, physical activity, and rate of nutrient absorption. SMBG is important for monitoring and treating fluctuations in blood glucose level, but it provides only a snapshot of glucose status at a given moment, and even compliant diabetics do not do perform it frequently enough to identify all the fluctuations in the blood glucose level, especially those that occur at night (Evert 2009).

In hopes of gaining a more complete picture of blood glucose level, researches have thus developed technologies for monitoring blood glucose concentrations on a continuous basis. Among these are the continuous glucose monitoring systems (CGMS) which are capable of monitoring interstitial glucose levels every 1-5 minutes. These systems consist of a small needle which is inserted in the abdominal subcutaneous fat. On the tip of the needle there is a glucose sensor that measures the glucose levels in the fluid surrounding the fatty tissue. There are two types of CGMS: retrospective systems and real-time systems. Both systems measure glucose concentration during a certain time span; however, these systems differ with regards to when the information is accessed. With the retrospective system data is stored in a monitor to be downloaded for later use while the real-time system continuously provides the actual glucose concentration on a display. It is thought that CGMS may help diabetic patients reach a near normal blood glucose pattern, assist in preventing hypoglycemic events, reduce emergency room visits, and decrease long-term complications by improving glycemic control (Cemeroglu 2010, Chetty 2008, De Block 2008, Girardin 2009, Langendam 2012).

Early generations of CGMS e.g. the GlucoWatch Biographer, and the physician use device MiniMed Continuous Glucose Monitoring System were uncomfortable and difficult to use. In addition, their results could only be determined in a physician's office and when graphed provided useful, but retrospective information about within- and between-day blood glucose variations and the frequency of unrecognized hypoglycemia. When compared with venous plasma glucose values, the interstitial fluid glucose sensor yielded lower values when blood glucose concentrations were rapidly rising. More recent devices were developed to overcome some of the earlier limitations, and several products that provide real-time information on glucose levels to patients rather than requiring data download in a providers' office are now available. These newer systems, however, still measure glucose in the interstitial space, and it takes time for interstitial glucose to achieve equilibrium with blood glucose (Reach, 2008, Cox 2009).

All continuous glucose monitoring devices consist of the same basic components: 1. A disposable short-term glucose sensor (a fine wire about the diameter of two hairs) which is placed under the skin and is worn for 3-7 days depending on the system (3 days for Guardian RT, 5 days for FreeStyle Navigator, or 7 days for DexCom Seven), 2. A reusable transmitter that is wirelessly attached to the sensor and conveys data to a receiver within a 5-10 foot range of the sensor, and 3. A pager-size receiver that displays current glucose values and recent trends. The receiver can be worn on the belt or carried in a pocket or purse. The process is very fast with measurements made every 10 seconds and then aggregated to give a value on the glucose monitor every 1-5 minute. High and low glucose value thresholds can be customized for individual patients and fed into the system. When these thresholds are exceeded, an alarm will sound. The receiver displays directional arrows to show the rate of change in glucose levels, allowing the patient to predict and possibly prevent hypoglycemic episodes. CGMS can be used continuously, as long as the sensors are replaced according to manufacturer recommendations. Continuous readings over a 24-hour period for up to seven days allow the user to detect variations and identify trends. Patients must initialize and calibrate the system whenever a new glucose sensor is inserted. They also need to calibrate it every 8-12 hours and before adjusting insulin therapy (Peters 2009).

Continuous glucose monitors are intended to be used as an adjunct, not a replacement, for self-monitoring of blood glucose. They should not be used to make therapeutic decisions; any readings that indicate hypo-or hyperglycemia events must be verified by SMBG before taking action. CGM systems have several limitations including:

1. They are not suitable for use by all patients and those who are likely to benefit from them are the motivated patients who know the importance of strict metabolic control, participate in the care of their diabetes, and are able to use the technology. Those who have poor control because of reluctance to perform SMBG would not comply with CGMS and will not benefit from its use.

Back to Top

Date Sent: 4/29/24

2. Patients need to learn how to use the large amount of data generated by the real-time CGMS.
3. The patients also need to be aware of the limitations of the systems as regards the lag time and calibration issues, and check with a standard blood glucose meter before making medication adjustments. They also need to understand the time of onset and peak of their insulin so that they make appropriate adjustments.
4. The insertion of the sensor under the skin is at times painful, and if it fails to calibrate another one has to be placed. Moreover, it needs to be firmly attached to the skin using tape, which may cause skin irritation or infection, and may become loose especially with sweating and exercise.
5. The functional operability of CGMS is limited to 2-7 days which might not be sufficient to detect recurrent glycemic patterns throughout the day or night.
6. Providers will have to find ways to incorporate the technology into their already busy clinical practice (De Block 2008, Hrabchak 2010, Ives 2010).

As of the current review the FDA-approved CGM real-time systems include:

- Medtronic Guardian Real Time Glucose Monitoring System that records glucose values for up to 3 days.
- Medtronic MiniMed Paradigm Real-Time System which integrates real-time CGM with an insulin delivery device and records glucose values for up to 3 days.
- DexCom SEVEN PLUS records glucose values for up to 7 days.
- Abbott FreeStyle Navigator provides continuous measurement for up to 5 days.
- The iPro Continuous Glucose Monitor (Medtronic, Inc) used only by the health provider and provides an average blood sugar measurement every 5 minutes for 3 days at a time.

The SEVEN PLUS and the FreeStyle Navigator are FDA approved for adults only. Pediatric versions of MiniMed Paradigm and Guardian systems are approved for use in patients 7-17 years. All systems require a prescription.

Medical Technology Assessment Committee (MTAC)

Continuous Glucose Monitoring

06/07/2001: MTAC REVIEW

Evidence Conclusion: The published evidence is insufficient to draw conclusions about the effect of continuous glucose monitoring on health outcomes. According to MiniMed, a multicenter outcome study is underway.
Articles: The literature search yielded 20 articles. Excluding review articles and opinion pieces, articles on other types of glucose monitoring or other aspects of diabetes control, there were two empirical articles, both of which were case series. One article had a sample size of 11 children and the other had a sample size of 9 adults. Due to the small sample sizes, evidence tables were not created.

Continuous Glucose Monitoring for the management of unstable diabetes is approved by the FDA, but does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/11/2004: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: *Pediatric population* - Three studies with the pediatric population were reviewed. The DirecNet study, a relatively large study with nearly 100 patients, evaluated the accuracy of the CGMS in children during a 24-hour hospital stay. It did not specifically include children with diabetes management problems. The authors found a relatively low accuracy. According to Clarke error grid, 61% of the decisions using the CGMS would lead to clinically correct treatment decisions (Zone A). Newer modified sensors appeared to be more accurate (78% of measurements were in Zone A compared to 58% with older original sensors). The newer sensors were also more reliable than the original sensors, but measurement taken by two new sensors differed from one another by more than 20% about one-fourth of the time. The Ludviggson study, a randomized cross-over design, focused on changes in HbA1c during three months with the benefit of data from the CGMS and three months without CGMS data. Eligibility included an initial HbA1c ³6.8%. When each time period was examined separately, there was not a statistically significant benefit from having CGMS data available. When data from both periods were combined, there was a significant decrease in mean HbA1c in the study arm using CGMS data, but not the other arm. The authors did not compare the change in HbA1c in the arm using CGMS data versus the other arm and had several threats to validity including lack of a wash-out period. The Kaufman study included patients with glucose management problems. The study found that data from the CGMS leads to changes in the recommendation for patient management. However, the authors did not discuss the impact of these changes on health outcomes. In summary, the limited evidence suggests that the accuracy of the CGMS in children may not be sufficiently high. The evidence is insufficient to determine the effect of continuous glucose monitoring on improving health outcomes. *Adult population* - There is less published empirical evidence in the adult population and no high-quality studies on accuracy. The best available study (Yogev) was on pregnant women with type 1 diabetes (not on patients with uncontrolled diabetes). In this sample, continuous glucose monitoring detected

Back to Top

hyperglycemia that was not detected by self-blood glucose monitoring in all 34 patients and nocturnal hypoglycemia in 26 (76%) patients. Recommendations to change insulin treatment were made for 24 out of the 34 (70%) patients. However, the authors did not present data on how the change in recommendations affected maternal or neonatal outcomes.
Articles: The Medline search yielded 52 articles, some of which were reviews or opinion pieces, were on technical aspects of glucose monitoring or had outcomes unrelated to the accuracy of the glucose monitor e.g. changes in blood glucose with a low glycemic diet. *Pediatric population* - The search yielded 5 empirical articles. One had a sample size of only 9 patients (Caplin, 2003). Another was a case series with 28 patients and appeared to be relatively weak methodologically (e.g. only included 28 out of the 44 children who used the monitor in the analysis, did not discuss management changes following use of the monitor) (Salardi, 2002). The remaining 3 studies, one of which was a randomized cross-over trial, were critically appraised: Diabetes Research in Children Network (DirecNet) Study Group. The accuracy of the CGMS in children with type 1 diabetes: Results of the diabetes research in children network (DirecNet) accuracy study. Diabetes Technol Ther 2003; 5: 781-789. See Evidence Table. Kaufman FR, Gibson LC, Halvorson M. A pilot study of the continuous glucose monitoring system. Diabetes Care 2001; 24: 2030-2034. See Evidence Table. Ludvigsson J, Hanas R. Continuous subcutaneous glucose monitoring improved metabolic control in pediatric patients with type 1 diabetes; A controlled crossover study. Pediatrics 2003; 111: 933-938. See Evidence Table. *Adult population* - The search yielded 4 empirical articles. One was specifically on diabetic patients needing dialysis and included only 8 patients. Two other studies each included only 18 patients. The remaining study, which studied pregnant women with type 1 diabetes, was critically appraised: Yogev Y, Chen R, Ben-Haroush A. Continuous glucose monitoring for the evaluation of gravid women with type 1 diabetes mellitus. Obstet Gynecol 2003; 101: 633-638. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/30/2005: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: The new studies published after our last review of 2/11/2004 were evaluated. There was only one RCT with just over 100 patients (Tanenberg 2004), that compared the hemoglobin A1c values between patients who used the CGMS to those who underwent self-monitoring. The difference between the two groups in the HBA1c was not statistically significant.
Articles: Tanenberg R, Bode B, Lane W et al. Use of the continuous glucose monitoring system to guide therapy in patients with insulin-treated diabetes: A randomized controlled trial. Mayo Clin Proc 2004; 79: 1521-1526. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: There are no published studies to date that evaluate the impact of real-time glucose monitor use on diabetic complications. There are also no published studies evaluating the accuracy or effectiveness of the Medtronic MiniMed Guardian RT device, or the consistency of measurements of either the Guardian RT or DexCom STS when multiple devices are worn. One published empirical study on the DexCom STS system was identified. The study evaluated both device accuracy compared to self-monitoring of glucose measurements and impact on short-term glycemic control. In 47 patients, 95% of paired sensor-home monitoring data points over nine days were in Clarke error grid regions A (clinically accurate) or B (acceptable). In addition, compared to a control group (n=44) that used devices but did not receive display information, there was a statistically significant improvement in glycemic control (more time in target glucose range, less time in hypoglycemic and hyperglycemic ranges). Conclusions cannot be drawn about the intermediate or long-term impact of the DexCom STS on glycemic control-- patients were only followed during the nine days devices were worn. Another remaining issue is the 15-30-minute lag time between interstitial glucose readings and blood glucose levels when the blood glucose is rising or falling quickly.
Articles: No published empirical studies evaluating the Guardian RT were identified. One published empirical study on the subcutaneous DexCom STS was identified. This was a randomized controlled trial with 91 patients and was critically appraised: Garg S et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor. Diabetes Care 2006; 29: 44-50. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

08/04/2008: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion: *Accuracy/Reliability* the Garg et al. (2006) study, previously reviewed by MTAC, found that the DexCom STS device was reasonably accurate compared to self-monitoring of blood glucose. >95% of 6,767 paired sensor-SMBG data points were in Clarke error grid regions A or B (clinically accurate or acceptable, respectively). An issue identified was the 15-30-minute lag time between interstitial glucose readings and blood glucose levels when the blood glucose is rising or falling quickly. Weinstein et al. (2007) also found >95% of paired sensor-venous blood sample data points were in Clarke error grid regions A or B when the FreeStyle Navigator was tested in an inpatient setting in adults. A smaller study of the FreeStyle Navigator in children (Wilson et al., 2007) identified a lag time, with Navigator readings lagging behind reference values during times of rapid rates of change in glucose levels. Impact: There is insufficient evidence on the impact of real-time continuous glucose monitor use on diabetic complications, hospitalizations and ER visits. There is fair evidence from one RCT (Deiss et al., 2006) that there are greater improvements in HbA1C levels of children and adults when a Guardian RT is worn continuously, but not intermittently, compared to self-monitoring of blood glucose. Limitations of the RCT were that it was sponsored by Medtronic, the device manufacturer, and the process for using glucose monitor data to make changes to patient treatment was not well described. There is insufficient evidence that other commercially available real-time continuous glucose monitors, the DexCom STS or Seven, and the Abbott FreeStyle Navigator, impact glycemic control. Only case series were available. A series of 140 patients (Bailey et al., 2007) found a significant reduction in HbA1c level after 12 weeks of continuous glucose monitoring with the DexCom STS. Significant reductions in HbA1c over 13 weeks were also found in small case series with children who were managed with the FreeStyle Navigator. The available evidence is insufficient to evaluate the impact of real-time continuous glucose monitors on detection of hypoglycemic episodes, larger sample sizes and longer follow-up are required.
Articles: No published empirical studies evaluating the Guardian RT were identified. One published empirical study on the subcutaneous DexCom STS was identified. This was a randomized controlled trial with 91 patients and was critically appraised: Garg S et al. Improvement in glycemic excursions with a transcutaneous, real-time continuous glucose sensor. Diabetes Care 2006; 29: 44-50. See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/21/2010: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion: There is insufficient evidence to determine the accuracy and reliability of the 7-day continuous glucose monitoring systems. There is fair evidence that the use of CGMSs including the 7 day is associated with a significant reduction in HbA1c levels among highly selected motivated 25 years of age or older patients with type 1 diabetes. There is insufficient evidence to determine whether use of the 7-day real-time continuous glucose monitoring systems leads to better patient-oriented health outcomes (e.g. hospitalizations, ER visits, and microvascular and macro vascular diabetic complications).
Long-term studies are needed to confirm the potential benefits of CGMS in preventing hypo-and hyperglycemic episode, improving the patient's quality of life and potentially reducing the likelihood of complications that may develop.
Articles: Accuracy/Reliability of CGMS: The literature search revealed the STAR 1 trial (2008) evaluating the MiniMed Paradigm Real-Time System which is sensor augmented insulin pump, the Real Trend study (2009) on the Medtronic MiniMed Paradigm Real-Time System, the MITRE trial (2009) that used the MiniMed CGMS and GlucoWatch which is no longer available commercially and a small study (N=14) by Garg and colleagues (2010) that compared the SEVEN and FreeStyle Navigator CGMS, as well as a meta-analysis of studies published up to March 2007. Impact of CGMS on health outcomes:
The ideal study would be a randomized trial comparing health outcomes in patients managed using a real-time CGMS compared to standard self-monitoring. The literature search did not identify any published RCTs that evaluated the impact of CGMS on hospitalizations, ER visits, microvascular or microvascular diabetic complications. There was a relatively large trial by the Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Group (2008) that used change in the HbA1c as a surrogate outcome for diabetes control. This study was selected for critical appraisal. The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Group. Tamborlane WV, Beck RW, Bode BW, et al. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med 2008;359:1464176 See Evidence Table.

The use of continuous glucose monitoring in the management of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

08/20/2012: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion: For CGM to be considered a useful technology, it needs to be accurate, reliable, and reproducible for reflecting a patient's plasma glucose values, especially in the lower glucose range to help avoid hypoglycemia and allow patients to achieve lower HbA1c with less hypoglycemia. However, current data do not allow this conclusion. Even when taking the average of four sensors worn simultaneously (an impractical approach for everyday use) results vary from the true plasma glucose value by 25 – 50% almost 20% of the time when patients true blood glucose values were less than 70 mg/dL. Additionally, most studies show no or only trivial improvement in HbA1c, that is not sustained overtime. Results from current data suggest that it is unlikely that everyday use of CGM will result in decreased hypoglycemia or lower HbA1c.
Articles: No studies were identified that addressed patient-oriented health outcomes. Several meta-analyses and three randomized controlled trials (RCTs) published after the meta-analyses were identified that addressed the effects of CGMS on glycemic control. The most recent meta-analysis, two RCTs, and an observational study published after the meta-analysis were selected for review. The other RCT was not selected for review due to methodological limitations (i.e., not stated if an intent-to-treat analysis was performed, power was not assessed, and baseline characteristic were not similar). The following studies were selected for critical appraisal:
Langendam MW, Luijf YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. *Cochrane Database Syst Rev.* 2012;1:CD008101. See Evidence Table
Riveline JP, Schaepelynck P, Chaillous L, et al. Assessment of patient-led or physician-driven continuous glucose monitoring in patients with poorly controlled type 1 diabetes using basal-bolus insulin regimens: a 1-year multicenter study. *Diabetes Care.* 2012; 35:965-971. See Evidence Table**.** Castle JR, Pitts A, Hanavan K, et al. The accuracy benefit of multiple amperometric glucose sensors in people with type 1 diabetes. *Diabetes Care.* 2012; 35:706-710. See Evidence Table. Mauras N, Beck R, Xing D, et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. *Diabetes Care.* 2012; 35:204-210. See Evidence Table

The use of continuous glucose monitoring in the diagnosis of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/20/2017: MTAC REVIEW
Continuous Glucose Monitoring
Evidence Conclusion:
Conclusion:

- Moderate evidence shows that the Continuous Glucose Monitoring system with the use of multiple daily insulin injection may be more effective in HbA1c and glycemic variability in adults with type 1 Diabetes Mellitus than self-monitoring blood glucose on the short term; no major adverse events were reported
- Moderate evidence shows that continuous Glucose Monitoring with the use of insulin pump may be more effective on HbA1c in adults with T1DM than self-monitoring blood glucose on the short term; no statistically significant difference in time spent in hypoglycemia was found
- In patients with T2DM, Hayes conclusion can be adopted: there is conflicting evidence concerning efficacy
- The technology is safe. Studies with longer follow-up are warranted.

Articles: Beck, R. W., Riddlesworth, T., Ruedy, K., Ahmann, A., Bergenstal, R., Haller, S., Polonsky, W. (2017). Effect of Continuous Glucose Monitoring on Glycemic Control in Adults with Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA, 317(4), 371-378. Benkhadra, K., Alahdab, F., Tamhane, S., Wang, Z., Prokop, L. J., Hirsch, I. B., Murad, M. H. (2016). Real Time Continuous Glucose Monitoring in type 1 diabetes: A Systematic review and Individual Patient Data Meta-Analysis. Clinical Endocrinology. Gu, W., Liu, Y., Chen, Y., Deng, W., Ran, X., Chen, L. Mu, Y. (2017). Multicentre randomized controlled trial with sensor-augmented pump vs multiple daily injections in hospitalized patients with type 2 diabetes in China: Time to reach target glucose. Diabetes Metab. doi: 10.1016/j.diabet.2016.12.009
Lind, M., Polonsky, W., Hirsch, I. B., Heise, T., Bolinder, J., Dahlqvist, S., Wedel, H. (2017). Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults with Type 1 Diabetes Treated with Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA, 317(4), 379-387. van Beers, C. A., DeVries, J. H., Kleijer, S. J., Smits, M. M., Geelhoed-Duijvestijn, P. H., Kramer, M. H., . . . Serne, E. H. (2016). Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. Lancet Diabetes Endocrinol, 4(11), 893-902. doi:10.1016/s2213 8587(16)30193-0.

Applicable Codes

Back to Top

Continuous Glucose Monitor (not implanted)

Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Non-Medicare: Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM), one unit = 1 day supply
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver

Implantable Continuous Glucose Monitors (I-CGM)

Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare – Considered not medically necessary

CPT® or HCPC Codes	Description
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

Date Created	Date Reviewed	Date Last Revised
06/07/2001	07/06/2010[MDCRPC],04/05/2011[MDCRPC],07/05/2011[MDCRPC],05/01/2012[MDCRPC], 09/04/2012 [MDCRPC],07/02/2013[MDCRPC],08/06/2013[MPC],12/03/2013[MPC],10/07/2014[MPC], 11/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 01/09/2024[MPC]	09/22/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Back to Top

Revision History	Description
08/04/2015	• Removal of with a negative C peptide an indication • "Criteria for current users and for annual evaluation" was changed to "For ongoing approvals of supplies and/or replacement of current CGM"
04/03/2018	MPC approved to revise indication to criteria: *Patient is motivated, and has monitored and documented blood glucose 4 or more times per day for 2 months (change to 1 month)*
08/27/2018	Added Free Style Libre non-coverage language
09/13/2018	Removed Medicare from the Free Style Libre language
03/11/2019	Clinical review is no longer required for 72-hour evaluation
12/03/2019	MPC approved to revise criteria to address pediatric population and avoid delays in receiving a continuous glucose monitor when a pediatric patients' condition warrants.
11/03/2020	MPC approved to revise hybrid criteria to remove specific qualifiers for hypoglycemia and type I diabetes, removed statement that Freestyle Libre not on formulary for non-Medicare members, updated CGM order form (link in criteria), and added note about combined insulin pump/CGM device
02/16/2022	Updated applicable codes
04/05/2022	MPC approved to update CGM criteria to remove the 4x/day blood glucose checks, added indications for patients with dexterity or visual impairments. Requires 60-day notice, effective date 09/01/2022. Updated applicable codes.
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
01/09/2023	Added new HCPC codes A4239 and E2103 effective 1/1/2023.
03/13/2023	Removed reference to code K0554 in the criteria as this code was replaced with code E2103 effective 1/1/23.
08/08/2023	MPC approved changes to the existing CGM criteria to allow providers managing a members diabetes to place this order (including but not limited to primary care, internal medicine, etc.) and relieve the excessive demands on the Diabetes Population care nurses. Requires 60-day notice, effective date 01/01/2024.
09/22/2023	Updated code descriptions and deleted inappropriate codes from I-CGM.

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Restorative and Cosmetic Procedures

- Abdominoplasty
- Lipectomy
- Panniculectomy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 16 - General Exclusions from Coverage, Section 120
National Coverage Determinations (NCD)	Plastic Surgery to Correct "Moon Face" 140.4
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article	Billing and Coding: Plastic Surgery (A57222)

For Non-Medicare Members

Cosmetic Surgery is performed to reshape normal structures of the body in order to improve appearance in the absence of a specific functional improvement. Surgery performed to improve on "natural" appearance or performed purely for the purpose of enhancing one's normal appearance is not considered reasonable and necessary.

Reconstructive Surgery is performed to restore bodily function or to correct a deformity resulting from disease, injury, trauma, birth defects, congenital anomalies, infections, burns, or previous medical treatment, such as surgery or radiation therapy. The primary goal is to restore function. Reconstructive surgery is reasonable and necessary to improve the functioning of a malformed body part. Please refer to member's contract for specific coverage regarding congenital anomalies.

I. Abdominoplasty
1. Abdominoplasties are not covered as they are considered cosmetic.
2. Diastasis recti treatment - Treatment of diastasis recti is considered cosmetic as the separation/laxity of the muscles of the abdominal wall is not considered a true hernia and the treatment does not address a physical functional condition.

II. Panniculectomy: is covered when **ALL of the following** criteria are met:
1. Panniculus hangs below the level of the pubis (documented by photographs)
2. Documentation in the medical record of the presence of significant complications including one or more of the following, requiring at least two office visits for treatment:
    a. The excess skin is the primary cause of at least one episode of cellulitis requiring systemic (oral or intravenous) antibiotics

OR

    b. Transdermal skin ulcerations in the skin folds that are recurrent or refractory to medical treatment.

3. If the procedure is being performed following significant weight loss, in addition to meeting the criteria noted above, there should be evidence that the individual has maintained a stable weight for at least six

Back to Top

months. If the weight loss is the result of bariatric surgery, procedure should not be performed until at least 18 months after bariatric surgery.
4. There is a functional deficit (interference with activities of daily living) due to a severe physical deformity or disfigurement resulting from the excess skin.
5. The surgery is expected to restore or improve the functional deficit.
6. BMI must be < 35
7. No diabetes, or diabetes with HbA1c < 7.5
8. Members who use nicotine/tobacco must be actively involved in a nicotine cessation program and must be nicotine/tobacco-free for a minimum of 30 days prior to surgery
9. Not covered when performed in conjunction with abdominal or gynecological procedures (e.g., abdominal hernia repair, hysterectomy, obesity surgery) unless criteria for panniculectomy are met separately
10. Not covered to minimize the risk of hernia formation or recurrence

III. Liposuction for Lipedema
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

IV. Procedures to remove excess skin in the arms, buttocks, hips, legs, thighs, or torso are considered cosmetic as these procedures do not address any physical functional condition.

V. Dental/orthodontic procedures for craniofacial anomalies – for baseline policy for all plans, click here to view the policy.

See individual links below for the following potentially cosmetic procedures:
- Blepharoplasty
- Dermatology Services
- Dermal Fillers for Facial Lipoatrophy (Sculptra/Radiesse)
- Reduction Mammoplasty
- Rhinoplasty
- Breast Reconstruction
- Skin Lesions
- Vein Procedures

The following are considered cosmetic in nature and non-covered under member's contract:
- Cervicoplasty ("neck lift")
- Collagen injection
- Hair Transplant
- Canthoplasty ("outer eyelid lift surgery") except in the setting of skin cancer excision

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Kaiser Permanente coverage contracts exclude cosmetic procedures. However, some procedures may be medically necessary when certain clinical criteria have been met. This document has been created to provide guidance to physician's reviewers when reviewer requests to cover potentially cosmetic services.

Evidence and Source Documents
Member contract

References

Back to Top

Liposuction for Lipedema
April 27, 2020: INTC Review

Evidence Conclusion: There is insufficient evidence regarding the efficacy and safety of liposuction compared to conventional treatments (compression therapy, exercise, or massage) for lipedema. The existing evidence is of insufficient quantity and quality.
The existing body of evidence on the surgical management of lipedema is sparse and limited to six low-quality observational studies, a majority of which were conducted in Germany, among 575 patients and included in two technology assessments. The low-quality evidence reported positive improvements in pain, mobility, bruising, sensitivity to pressure, appearance and quality of life with no report of major complications following liposuction. The diagnostic criteria for the condition is contested and remains unclear.
Articles: Liposuction for Lipedema: Technology Assessment (kp.org)

Liposuction for the Treatment of Lipedema
April 19, 2022: Hayes Technology Assessment

Clinical studies: A review of full-text clinical studies suggests minimal support for using liposuction for lipedema.
systematic reviews: A review of full-text systematic reviews suggests no/unclear support for using liposuction for lipedema.

Insights
Evidence from 3 very poor-quality studies suggests that liposuction leads to clinically significant improvements in quality of life, disability, and pain and reduced need for conservative treatment in women with lipedema at 2 to 3 years of follow-up. Patients enrolled sought treatment at specialized healthcare centers, increasing risk of selection bias in cases reported. No other treatments for lipedema were identified in the literature beyond traditional conservative care with congestive therapy. Nonserious complications were common (e.g., bruising and postoperative bleeding). All 3 studies in this report are retrospective in design and do not compare liposuction treatment to any other intervention. One clinical study comparing the efficacy and safety of liposuction with conservative care is in progress. Clinical practice guidelines and payer policies appear generally supportive of the use of liposuction to treat lipedema.

Hayes. Hayes Technology Assessment. Liposuction for the Treatment of Lipedema. Dallas, TX: Hayes; April 19, 2022. Retrieved October 11, 2023, from https://evidence.hayesinc.com/report/eer.liposuction4059

Applicable Codes

Panniculectomy - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy

Excision of Excess Skin
Considered Not Medically Necessary

CPT® Codes	Description
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

Abdominoplasty

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Back to Top

Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)

Lipectomy

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity

Cervicoplasty - Considered Not Medically Necessary:

CPT® Codes	Description
15819	Cervicoplasty

Canthoplasty - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
67950	Canthoplasty (reconstruction of canthus)

Otoplasty - Considered Not Medically Necessary:

CPT® Codes	Description
69300	Otoplasty, protruding ear, with or without size reduction

Hair Transplant

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts

Tissue Expanders - Considered Not Medically Necessary:

CPT® Codes	Description
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion

Back to Top

Date Sent: 4/29/24

11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant

Wrinkle Removers - Considered Not Medically Necessary:

CPT® Codes	Description
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap

Collagen Injections - Considered Not Medically Necessary:

CPT® Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

Date Created	Dates Reviewed	Date Last Revised
07/01/2005	07/01/2005[MDCRPC], 05/30/2006[MDCRPC], 11/20/2006[MDCRPC], 12/22/2006[MDCRPC], 10/15/2007[MDCRPC], 06/09/2008[MDCRPC], 04/13/2009[MDCRPC], 02/2/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 07/02/2013[MDCRPC], 03/04/2014[MPC], 01/06/2015 [MPC], 11/03/2015 [MPC], 09/06/2016[MPC], 07/11/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC] , 06/07/2022[MPC] 06/06/2023[MPC]	12/21/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
11/01/2015	Changed Medicare links
05/03/2016	Added definitions for Cosmetic vs. Reconstructive Surgery. Added a list of non-covered cosmetic services
12/19/2017	Added LCD 37020
05/18/2020	Added clarifying language to canthoplasty “except in the setting of skin cancer excision”
06/01/2021	Removed reference to retired LCD Cosmetic vs. Reconstructive Surgery (A52729) for Medicare as it was replaced with the Plastic Surgery LCD/LCA. Updated applicable codes.
09/07/2021	MPC approved to adopt updates to the clinical indications for panniculectomy and updated excess skin removal from the arms, buttocks, hips, legs, thighs, or torso to cosmetic/not medically necessary for Non-Medicare members. Requires 60-day notice, effective date February 1, 2022.
11/06/2021	Added clarifying language to Reconstructive Surgery definition “Please refer to member’s contract for specific coverage regarding congenital anomalies.”
11/07/2023	Make the current policy more explicit and provide a summary of medical evidence justifying a position of non-coverage (no 60-day notice). No Vote Required.
12/21/2023	Added NCD Plastic Surgery to Correct "Moon Face" 140.4

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Collagen Cross-Linking for the Treatment of Keratoconus

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Collagen Cross-Linking for the Treatment of Keratoconus"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

A. To qualify for photochemical cross-linkage using riboflavin and Ultraviolet A light **ALL** of the following must be met:
   1. Has a diagnosis of keratoconus
   2. Patient is not older than 50 years old
   3. Treatment is limited to a once in a lifetime

Notes:
Kaiser Permanente considers epithelium-off photochemical collagen cross-linkage using riboflavin and ultraviolet medically necessary for keratoconus. For any other diagnosis, such as keratectasia, collagen cross-linking is considered experimental and investigational, as the effectiveness has not been established. Epithelium-on (transepithelial) collagen cross-linkage and performance of photochemical collagen cross-linkage in combination with other procedures (CXL-plus) (e.g., intrastromal corneal ring segments, PRK or phakic intra-ocular lens implantation) is considered experimental and investigational.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Back to Top

Keratoconus is a disease of the cornea that is characterized by a gradual thinning and protuberance of the cornea resulting in visual damage. The cause of keratoconus is not known; its prevalence varies from 50 to 230 per 100,000 (Kennedy, Bourne et al. 1986, Heidecke, Burkert et al. 2008) and the association between African Americans and Latinos and keratoconus has been described (Woodward, Blachley et al. 2016). Several risk factors have been identified; these include eye-rubbing, contact lens use, systemic disorders (Down syndrome, Ehlers-Danlos syndrome, and osteogenesis imperfecta), family history, and environment (asthma, atopic disease) (Gasset, Houde et al. 1978, Rabinowitz 1998, Sugar and Macsai 2012, Woodward, Blachley et al. 2016).

Clinical characteristics include bilateral or unilateral visual impairment, sudden decrease in visual acuity, and/or astigmatism. Patient may also present with difficulty with visual correction and protrusion of the cornea with an indentation of the lower eyelid on downgaze. Disease progression is marked by corneal hydrops. Diagnosis can be done by slit lamp examination when the disease progresses. The mainstay of treatment is the correction of the vision which can be performed with spectacle correction, contact lens, surgical treatments or intrastromal corneal ring, keratectomy, keratoplasty (corneal implantation) and collagen crosslinking (CXL).

Corneal collagen crosslinking aims to slow the progression of keratoconus by increasing covalent bonds in the cornea. During the corneal crosslinking treatment, riboflavin drops saturate the cornea, which is then activated by ultraviolet light. In laboratory and clinical studies this procedure has been shown to strengthen the cornea. CXL is not a cure for keratoconus. The goal of this treatment is to stop the progression of keratoconus and prevent further deterioration in vision. The procedure consists of applying riboflavin every 3-5 minutes for 25-30 minutes and irradiating the cornea with UVA light after removal of the corneal epithelium. Then bandage lens is applied, and assessment of re-epithelialization is performed about one week after the treatment. The intervention lasts one hour to 90 minutes. Although no approval statement was found on the Food and Drug Administration website, Avedro, the manufacturer of Photrexa® Viscous, Photrexa® and KXL® System indicated that in 2016, the US Food and Drug Administration approved corneal collagen cross-linking using riboflavin and UV for progressive keratoconus (Avedro 2016). Collagen crosslinking is believed to flatten the cornea and improve vision.

Medical Technology Assessment Committee (MTAC)

Collagen Cross-Linking for the treatment of Keratoconus

09/19/2016: MTAC REVIEW

Evidence Conclusion: Two randomized trials were critically appraised. These studies assessed the efficacy and effectiveness of CXL. Comparison was made between CXL and no treatment or between CXL and riboflavin only. Baseline characteristics were similar between the groups and patients were followed up for one year. The results showed that CXL led to positive outcomes by reducing corneal steepness and asphericity. Adverse events were reported, and these include corneal opacity, eye pain, punctate keratitis, blurry vision, corneal striae and corneal epithelial defect. However, the open label nature of the design, the lack of clarification on how the sequence generation was performed, the lack of information of allocation concealment, the short follow-up (1 year), the small sample size, and the fact that the sponsor of one of the trials was the manufacturer compromise the validity of the studies. The body of evidence is also constituted of prospective and observational studies. The sample size in these studies varied from 13 to 97 and a reduction in keratoconus progression was globally observed. It is worth noted that the follow-up period varied from 6 to 24 months. No meaningful conclusion can be reached because these studies are non-comparative studies.

Conclusion:
The body of evidence is of low quality and there is insufficient evidence to determine whether CXL is effective and safe in stopping the progression of keratoconus as compared to the use of alternative treatments.

Articles:
The literature revealed a number of articles; the following articles were selected for critical appraisal:
Safety and Effectiveness of the UV-X System for Corneal Collagen Cross-Linking in Eyes with Progressive Keratoconus (NCT00647699)
https://clinicaltrials.gov/ct2/show/results/NCT00647699?term=corneal+collagen+crosslinking&rank=19&sect=X016 See Evidence Table 1 (not peer reviewed). Corneal collagen crosslinking for progressive keratoconus in Saudi Arabia: One-year controlled clinical trial analysis (Khattak, Nakhli et al. 2015) See Evidence Table 2.

The use of Collagen Cross-Linking for the treatment of Keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Back to Top

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium and intraoperative pachymetry, when performed (Report medication separately)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/04/2016	10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC] , 07/11/2023[MPC]	07/07/2020

[MPC] Medical Policy Committee

Revision History	Description
10/04/2016	Created document & added MTAC review
11/01/2016	MPC approved criteria of medical necessity for collagen cross linking for the treatment of keratoconus
07/09/2019	MPC approved to change age indication from 40 years old to 50 years old
07/07/2020	Removed LCD L35008 and added Kaiser Permanente Medical Policy statement for Medicare

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Cryosurgery

- Cryosurgical Ablation (CSA) for Breast Cancer and Benign Lesions
- Cryosurgical Ablation (CSA) for Liver Tumors
- Cryosurgical Ablation (CSA) for Prostate Cancer
- Cryosurgical Ablation (CSA) for Renal Tumors
- Cryosurgical Ablation (CSA) for Lung Cancer

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Cryosurgery of Prostate (230.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	**For Breast Cancer and Benign Lesions*:*** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cryosurgery"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Indication	Criteria Used
Breast Cancer and Benign Lesions	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Cryosurgical Ablation (CSA) for Liver Tumors Cryosurgical Ablation (CSA) for Lung Cancer Cryosurgical Ablation (CSA) for Prostate Cancer Cryosurgical Ablation (CSA) for Renal Tumors	Medical necessity review no longer required.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Background

Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance.

It is reported that the critical temperature that leads to cancer cell destruction is approximately –40°C. Normal and neoplastic tissues are ablated and rendered necrotic at temperatures of –20°C (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of –185° to-195°C, the temperature will be approximately 0°C at outer edge of the ice ball, –20°C at a distance of 4mm, and –40°C at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of –40°C or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually performed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge.

The size of the cryolesion depends on several factors, including the temperature at the tip of the cryoprobe, area of tissue contacts, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992).

Evidence/ Source Documents

Breast Cancer/Lesions

Medical Technology Assessment Committee

Cryoablation for Breast Cancer or Benign Fibroadenomas of the Breast

BACKGROUND

Cryoablation has been used to treat liver and prostate tumors. It is also proposed a treatment for small breast cancers and benign fibroadenomas of the breast. Cryoablation kills tumor cells by alternately freezing and thawing a target tissue. Freezing injures individual cells at the time of treatment. In addition, the tissue as a whole is affected because microcirculation is damaged. Cell necrosis during cytoablation depends on the lowest temperature achieved and the hold time at subzero temperatures. It is believed that uniform ablation can be achieved when tissue is exposed to at least -40oC during two consecutive freeze thaw cycles (Whitworth & Rewcastle, 2005). The procedure for using cryoablation to treat breast tumors is as follows: Using ultrasound guidance, a cryoprobe is inserted through a 3mm skin incision into the center of the tumor. Ultrasound is used to guide the cryoprobe, and also to monitor the treatment. Once appropriate placement of the cryoprobe is confirmed, the machine it turned on “high.” When set to “high,” argon gas, the cooling agent, is allowed to flow continuously through the cryoprobe. The probe is cooled to -160oC which freezes the tumor, forming an “ice ball” around it. After the iceball is formed, the cryoablation unit set on “low” setting which allows argon gas to flow intermittently into the cryoprobe for 1 of every 10 seconds to preserve freezing temperatures. Generally, two freeze-thaw cycles are used. Helium is used as the warming agent between freezing cycles (Nurko et al., 2005; Visica, manufacturer’s Web site). Benign breast fibroadenomas are common, especially among young women. Approximately 10% of women will experience a breast fibroadenoma during their lifetime. Currently accepted treatments include excisional biopsy and conservative management. Conservative management may be a reasonable choice for this benign condition, particularly smaller fibroadenomas. Moreover, women may choose to avoid immediate intervention since an estimated 30% of breast fibroadenomas resolve spontaneously within several years. Excisional biopsy provides a definitive diagnosis, but a disadvantage is morbidity including possible cosmetic and/or ductal damage. Cryoablation is less invasive than excisional biopsy and is done on breast fibroadenomas after confirmation that the tumor is benign, generally with needle biopsy (Whitworth & Rewcastle, 2005; Houssami et al. 2001). A minimally invasive procedure, such as cryoablation, may also be useful for treating early breast cancers treated with breast-conserving therapy rather than mastectomy. Other thermal methods have been used to treat breast tumors. These include radiofrequency ablation, interstitial laser therapy and highly intensive focused ultrasound (Pfleider et al., 2005).

08/07/2006: MTAC REVIEW

Cryosurgery – Breast Cancer

Evidence Conclusion: There is insufficient evidence to permit conclusions the efficacy of cryoablation for treating benign breast tumors including fibroadenomas. No studies were identified that compared cryoablation to

Back to Top

conservative management, an accepted approach for managing fibroadenomas. The available studies were case series. A limitation of the published series was that there was likely overlap among patients in the studies. The degree of overlap could not be determined. In addition, two of the three studies reviewed (not the registry) were funded by the manufacturer of the cryoablation system. The Kaufman et al. and Caleffi et al. studies found that a higher proportion of larger (>2.5cm) fibroadenomas than smaller fibroadenomas were palpable at 12 months. This suggests that the usefulness of cryoablation may be limited because there is likely more demand for intervention, rather than conservative management, with larger fibroadenomas. There is insufficient evidence to permit conclusions on the efficacy of cryoablation for treating early breast cancer. No studies were identified comparing cryoablation to other treatments such as radiofrequency ablation or interstitial laser therapy. The available studies were relatively small case series with sample sizes of 30 or fewer patients. In the series, cryoablation was followed by surgery 1-4 weeks later, at which time the tumor cells were evaluated. In one study, there was residual DCIS in 5 out of 30 patients and in the other study, there was residual invasive cancer or DCIS in 6 out of 27 patients. In the latter study, cryoablation was successful in all of the 10 patients with tumors <1.5 cm and with ductal or medullary cancer and no extensive intraductal component. Number of patients were too small to draw conclusions about sub-groups that might benefit from cryoablation for early breast cancer.
Cryoablation appears to be safe, although data on adverse effects are limited. No major complications were reported in any of the series that were reviewed.
Articles: No randomized controlled trials or other controlled trials were identified. Empirical studies were all case series. Three series on benign breast tumors, including fibroadenomas, were identified. Findings from one of the series, written by Kaufman and colleagues, were reported in three articles. Sample sizes were 63 patients in the Kaufman study and 102 and 29 in the other series. In addition, a registry of fibroadenomas treated by cryoablation was identified. The registry included 444 fibroadenomas (the number of patients was not reported, some patients contributed more than one fibroadenoma). The registry study and the two largest case series were critically appraised. All of the Kaufman et al. studies were included in the same evidence table. Four studies on cryoablation for breast cancer were identified. All included patients with small breast tumors ≤2.0 cm. Sample sizes in the studies were n=30, n=29, n=15 and n=9. The two larger case series were critically appraised. The series with n=15 appeared to report preliminary data for one of the larger studies. The studies reviewed were as follows: Kaufman CS, Bachman B, Littrup PJ et al. Cryoablation treatment of benign breast lesions with 12-month follow-up. Am J Surg 2004; 188: 340-348. (Kaufman CS, Littrup PJ, Freeman-Gibb LA et al. Office-based cryoablation of breast fibroadenomas with long-term follow-up. Breast J 2005; 11: 344-350. Kaufman CS, Littrup PJ, Freeman-Gibbs LA et al. Office-based cryoablation of breast fibroadenomas: 12-month follow-up, J Am Coll Surg 2004; 198: 914-923) v See Evidence Table. Caleffi M, Filho DD, Borghetti K et al. Cryoablation of benign breast tumors: Evolution of technique and technology. The Breast 2004; 13: 397-407. See Evidence Table
Nurko J, Mabry CD, Whitworth P et al. Interim results from the FibroAdenoma Cryoablation Treatment Registry. Am J Surg 2005; 190: 647-652. See Evidence Table. Pfleiderer SOR, Marx C, Camara O et al. Ultrasound-guided, percutaneous cryotherapy of small (≤15mm) breast cancers. Invest Radiol 2005; 40: 472-477. See Evidence Table
Sabel MS, Kaufman CS, Whitworth P et al. Cryoablation of early-stage breast cancer: Work-in-progress report of a multi-institutional trial. Ann Surg Oncol 2004 11: 542-549. See Evidence Table.

The use of Cryoablation in the treatment of breast cancer or benign fibroadenomas of the breast does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Cryosurgical Ablation (CSA) for Liver Tumors

BACKGROUND

The liver is a common site for primary and secondary malignancies. Hepatocellular carcinoma (HCC), the most common primary tumor, is the fifth most common cancer in the world, and the third most common cause of cancer-related mortality. It is responsible for more than half a million deaths across the globe each year. Treatment options for patients diagnosed with primary and secondary malignancies are limited. Less than 15% are candidates for surgical resection at presentation because of inadequate liver functional reserve, extrahepatic disease, anatomic constraints of the tumor, or medical co morbidities. The use of external beam radiation is limited due to the intolerance of normal liver parenchyma to tumoricidal radiation doses (the dose required to destroy solid tumors (>70 Gy) is much higher than the liver tolerance dose of 35 GY). In addition, systematic chemotherapy was found to have little impact on survival, and negative impact on the health-related quality of life due to the toxicity to other organs and systems. These limitations have led to the emergence of other therapies, such as radiofrequency ablation (RFA), cryosurgical ablation (CSA), percutaneous ethanol injections (PEI), hepatic arterial infusion chemotherapy, transarterial chemo-embolization (TACE), and selective intraarterial radioembolization therapy (Steel 2003, Salem 2005, Ibrahim 2008, Bult 2009, Riaz 2009, Bhardwaj 2010). Ablative techniques, such as RFA and CSA, improve the ability to treat patients with unresectable hepatic tumors. Thermal ablative techniques destroy tumors via a source that changes temperature to levels that are associated with cell death while causing minimal damage to adjacent, normal tissue. The choice of technique depends on

Back to Top

equipment availability and physician preference. The most commonly used ablative technique in the United Stated is RFA. RFA causes tumor destruction through the use of alternating high-frequency electric current in the radiofrequency range (460-500 kHz). This current is delivered through an electrode placed in the center of a lesion. Ions within the cell follow the alternating current creating frictional heat producing local tissue temperatures that can exceed 100°C. This ionic agitation leads to tissue destruction via tissue boiling and creation of water vapors. Once temperatures greater than 60°C are reached, protein denaturation, tissue coagulation, and vascular thrombosis result in a zone of complete ablation. Partial tissue destruction can occur up to 8 mm in diameter from the zone of complete ablation. RFA can be delivered either percutaneously, laparoscopically, or through open approaches (laparotomy). Complications from RFA include: pleural effusion, hepatic abscess, biliary injury, liver failure, intra-abdominal hemorrhage, pneumothorax, and hypoxemia. The most troubling complications arise when a probe is placed too close to the diaphragm or intra-abdominal organ, resulting in ablation of the surrounding viscera with the accompanying complications of perforation, diaphragmatic injury, or pulmonary damage. Limitations of RFA include: treating lesions in perihilar areas or near large vascular structures, and real time monitoring of the ablative zone is difficult due to air released during heating (Yamane 2009, Arciero 2006). CSA is another ablative technique. CSA uses repetitive freezing and thawing to produce irreversible tissue destruction. One or more cryoprobes are inserted at the site of the diseased tissue and liquid nitrogen or argon gas is delivered through the probe to freeze the tissue. Rapid freezing of the tissue results in the formation of intercellular ice crystals. At temperatures of about -40°C lethal ice crystals begin to form in the cell. Ice crystals also form in the fluid outside the cell leading to cell dehydration. The combination cause tumor cells to burst. Additionally, ice crystals form in small vessels and block blood supply to the tumor. Normally, two freeze-thaw cycles are used. CSA is easy to monitor, and the area treated can be accurately visualized with ultrasound. This allows for accurate real-time visualization; however, it does not guarantee that there has been cell death. Two devastating complications that are associated with CSA are cryoshock, a complex of severe coagulopathy and multi-organ failure, and intra-operative hypothermia. Other complications include: hemorrhage from cracking of the frozen liver, subphrenic abscesses, bilomas, and biliary fistulae (Bhardwaji 2010, Arciero 2006). The cryoprobe that is used in CSA has received FDA approval for ablation of cancerous or malignant tumors, benign tumors, and as a palliative intervention. RFA has received FDA approval for generic tissue ablation and the ablation of unresectable colorectal cancer metastases. This technology is being reviewed based on a request from gastroenterology.

06/21/2010: MTAC REVIEW
Cryosurgery – Liver Tumors
Evidence Conclusion: It is difficult to compare the results of CSA with surgery or other ablative techniques, as most authors report data from studies where a variety of different treatment modalities were used in conjunction with CSA. Differences in patient selection, follow-up duration, types of tumors, and treatment approaches also make studies difficult to compare.
CSA vs. RFA: The empirical evidence comparing CSA to RFA consists of nonrandomized, case series, and cohort studies that examined multimodal therapies rather than CSA alone. The Pearson study was selected for critical appraisal as it was the largest prospective study (N=146). The objective of this study was to compare complication and local recurrence rates in patients treated with RFA or CSA. Patients with either primary or secondary hepatic malignancies were included in the study. Compared to patients treated with RFA, patients treated with CSA appeared to have higher local recurrence rates (22% vs. 3%). However, data was not adjusted for confounding factors that may influence the rate of recurrence. With regard to complications, a total of 27 complications occurred in 22 CSA patients, while a total of 3 complications occurred in 3 RFA patients. Patients treated with CSA had a higher incidence of intrahepatic abscess and symptomatic pleural effusion than patients treated with RFA. It is not clear who these results are generalizable to as only very limited demographic information is presented. There is a high probability of selection bias in the study, as it is not stated how patients were recruited for the study and treatment choice was based on preference and training of the individual surgeon. Additionally, a subset of patients underwent resection in combination with CSA or RFA.
CSA vs. CSA + resection: The Niu study was selected for critical appraisal as it was a large prospective study (N=315) that compared long-term results of resection combined with CSA with resection alone in patients with colorectal liver metastases. The study found that the combined treatment group (CSA + resection) had higher recurrence rate, but survival rates were not statistically different between the two groups. Results from this study should be interpreted with caution as treatment groups were not comparable at baseline, more patients in the combined treatment group were treated with chemotherapy, and results were not controlled for confounding factors. It is not clear who these results are generalizable to as only very limited demographic information is presented. Conclusion: There is insufficient evidence to determine the relative safety and efficacy of CSA compared to RFA. There is insufficient evidence to determine whether CSA combined with hepatic resection will improve recurrence and survival rates compared to resection alone in patients with liver metastases from colorectal carcinomas.

Back to Top

Articles: No published randomized controlled trials or meta-analyses were found pertaining to the use of cryosurgical ablation for liver cancer. The literature consisted mainly of case series and cohort studies. Two prospective cohort studies were selected for critical appraisal. One study (Pearson 1999) assessed the relative safety and efficacy of CSA versus RFA and one study (Niu 2007) evaluated recurrence and survival rates of CSA combined with resection versus resection alone in patient with liver metastases from colorectal carcinomas.
The following studies were critically appraised:
Pearson SA, Izzo FI, Declan RY, Delrio P et al. Intraoperative radiofrequency ablation or cryoablation for hepatic malignancies. Am J Surg 1999; 178:592-599. See Evidence Table. Niu R, Yan TD, Zhu JC et al. Recurrence and survival outcomes after hepatic resection with or without cryotherapy for liver metastases from colorectal carcinoma. Ann Surg Oncol 2007; 14:2078-2087. See Evidence Table.

Cryosurgery for Prostate Cancer

BACKGROUND

Radical prostatectomy and external beam radiation therapy are considered standard treatments for localized prostate cancer. Both can result in significant morbidity such as incontinence and impotence. There is interest in other treatments that are of similar or greater effectiveness and have less morbidity. Cryosurgery (also known as cryoablation) was first used to treat prostate cancer in the last 1960s. Originally, clinicians used an open perineal approach that had high morbidity. The procedure was re-introduced in 1993 by Onik and colleagues using transrectal ultrasound (Onik, 1993). The technique continued to evolve and is now performed with modifications to the procedure introduced by Onik. In the basic modern technique, six to eight 3.4 mm diameter cryoprobes are inserted transperineally into the prostate guided by transrectal ultrasound. Temperature probes are placed in the right and left neurovascular bundles and the apex of the prostate gland to ensure that temperatures reach optimal levels in the margins of the gland. In addition, temperature probes are placed in the Denonvilliers' fascia and the external sphincter and are used to make sure that sensitive areas adjacent to the prostate are not frozen. A urethral warming catheter is used to prevent the urethra from being frozen. Patients are treated with one or two freeze-thaw cycles (two is used more often in recent procedures) using a target temperature of –40°C. When the target temperature is attained, the ice ball is maintained at a static size for up to 10 minutes if this is possible without endangering the rectal wall (Bahn et al., 2002). Cryosurgery is also used as salvage therapy to treat recurrent prostate cancer after radiation therapy. Salvage prostatectomy is the standard treatment, but about half of patients have positive surgical margins and there is significant associated morbidity (Cespedes et al., 1997).

06/11/2003: MTAC REVIEW

Cryosurgery – Prostate Cancer

Evidence Conclusion: Primary treatment of clinically localized prostate cancer - Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the case series did not evaluate a standard intervention; instead, the procedure changed over time. Both case series reported an intermediate outcome, biochemical success, as their primary health outcome. Conclusions about the effectiveness of cryosurgery compared to standard treatments for prostate cancer (e.g. radical prostatectomy, external beam radiation therapy) or no treatment can be drawn. Randomized controlled trials testing cryotherapy as primary treatment for prostate cancer should be feasible. The case series data suggest that cryosurgery is associated with a high-rate of impotence. Among men potent before surgery, in Bahn, 95% became impotent after cryosurgery and 90% remained so at follow-up (a mean of 5.4 years) and in Donnelly, 100% became impotent after cryosurgery and 53% remained so at 3 years, even with the use of sildenafil.
Salvage treatment for recurrent prostate cancer- Only case series data were available, the lowest grade of evidence because there is no control or comparison group. In addition, the procedure was inconsistent and changed over time. In a series of 131 patients (Izawa), 5-year disease-specific survival was 79% and 5-year disease-free survival was 40%. The long-term post-cryosurgery incontinence rate was 29%. Conclusions about the effectiveness of cryosurgery as salvage therapy after radiation treatment for patients with recurrent prostate cancer, or associated morbidity, compared to an alternate treatment such as salvage prostatectomy cannot be drawn.
Articles: *Primary treatment of clinically localized prostate cancer:* There were no randomized or non-randomized controlled trials. The only empirical data were from case series. The two largest case series that had data both on outcomes and adverse effects were critically appraised: Bahn DK, Lee F, Badalament R et al. Targeted cryoablation of the prostate: 7-year outcomes in the primary treatment of prostate cancer. *Urology* 2002 (Suppl 2A): 3-11. See Evidence Table. Donnelly BJ, Saliken JC, Ernst S et al. Prospective trial of cryosurgical ablation of the prostate: Five-year results. *Urology* 2002; 60: 645-649. See Evidence Table.
Salvage treatment for recurrent prostate cancer: Three case series were identified. Two were from the same institution and reported different outcomes on virtually the same group of patients. These studies were critically appraised. The other case series, which had a smaller sample size and a shorter follow-up, was excluded. Cespedes RD, Pisters LL, von Eschenbach AC et al. Long-term follow-up of incontinence and obstruction after salvage cryosurgical ablation of the prostate: Results in 143 patients. J Urol 1997; 157: 237-240. See Evidence

Back to Top

Table. Izawa JI, Madsen LT, Scott SM et al. Salvage cryotherapy for recurrent prostate cancer after radiotherapy: Variables affecting patient outcome. J Clin Oncol 2002; 20: 2664-2671. See Evidence Table.

The use of cryosurgery in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Cryoablation of Renal Tumors

BACKGROUND

With the widespread use of body imaging techniques as magnetic resonance imaging (MRI) and computed tomography (CT), there is an increasing number of incidentally detected small renal masses or lesions with unclear clinical significance. The standard treatment for renal masses is radical nephrectomy. Other available treatment options include watchful waiting or partial nephrectomy. Recently, with the current trend of minimally invasive surgery, nephron-sparing approaches have gained more acceptance. Open, percutaneous, and laparoscopic renal cryoablation, radiofrequency ablation, and high intensity focused ultrasonography (HIFU) have been performed but are still under development. These techniques only target selected, small renal tumors with a diameter of 4 cm or less. Cryosurgery has been known for years, but the recent changes in the technology and the development of improved cryosurgery units are permitting its clinical use. Cryoablation is a technique that uses liquid nitrogen or argon gas to freeze and ablate tissues. Cryoablation is mainly performed laparoscopically under real time ultrasound guidance. It is reported that the critical temperature that leads to cancer cell destruction is approximately –40oC. Normal and neoplastic renal tissues are ablated and rendered necrotic at temperatures of –20oC (Chosy, 1996). During cryosurgery, the temperature is lowest at the center of the iceball with an incremental increase towards the periphery. Thus, with a cryoprobe tip temperature of –185o to-195oC, the temperature will be approximately 0oC at outer edge of the ice ball, –20oC at a distance of 4mm, and –40oC at a distance of 6mm towards the center of the iceball. It is important that the edge of the cryolesion be 1 cm beyond the margin of the tumor to make sure that a lethal temperature of –40oC or less was achieved throughout the tumor. The effect of cryosurgery occurs in two phases, freezing and thawing. The freezing phase is performed rapidly, and passive thawing is performed more slowly for a maximum effect. A double freeze-thaw cycle is usually preformed to ensure the extension of the iceball to approximately 1 cm beyond the tumor edge. The size of the cryolesion depends on several factors including the temperature at the tip of the cryoprobe, area of tissue contact, freeze time, and tissue vascularity. The response of a tumor to cryoablation depends on its biological characteristics e.g. density, specific heat, thermal conductivity, and rate of blood flow (Gage 1992). Potential complications of renal cryosurgery include post-thaw hemorrhage, urine leakage due to caliceal cryoinjury, and fistula formation.

04/09/2003: MTAC REVIEW

Cryosurgery – Renal Tumors

Evidence Conclusion: There is insufficient published evidence to determine the efficacy, safety, and long-term outcome of cryoablation for the treatment of renal tumors. No randomized controlled trials or non-randomized comparative studies were conducted to compare the procedure to surgery or other alternatives and assess its long-term benefits. All studies were either case reports or case series with very small sample sizes. The case series reviewed included small numbers of patients, were subject to selection and observation biases, and had short follow-up durations. These series showed that after a mean follow-up of 9 months in Shingleton's study, 14 months in Lee's study and 16 months in Gill's study the ablated renal tumor was no longer detectable in 25-40% or reduced in size in 20-75% of the patients with available follow-up data. Large randomized controlled studies with long-term follow up duration will be needed to compare cryoablation to other alternatives, and to determine its efficacy, safety, and long-term benefits.

Articles: The search yielded 48 articles. Many were reviews or tutorials that dealt with the technical aspects of the procedure. There were no meta-analyses or randomized controlled trials. There were 13 case reports (with 1-9 patients), and 9 case series with a small number of patients (10 to 32 patients). The 3 largest series were selected for critical appraisal: Gill IS, Novick AC, Meraney AM, et al. Laparoscopic renal cryoablation in 32 patients. Urology 2000; 56:748-753. See Evidence Table. Lee DI, McGinnis DE, Feld R, et al. Retroperitoneal laparoscopic cryoablation of small renal tumors: intermediate results. Urology 2003;61: 83-88. See Evidence Table. Shingleton WB and Sewell PE. Percutaneous renal tumor cryoablation with magnetic resonance imaging guidance. J Urol 2001; 165:773-776. See Evidence Table.

The use of cryoablation in the treatment of renal tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Back to Top

Applicable Codes

Breast Cancer and Benign Lesions - Considered Not Medically Necessary:

CPT® Codes	Description
19105	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma

Prostate Cancer –

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Medical Necessity Review not required

CPT® Codes	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

Renal Tumors - Medical Necessity Review not required:

CPT® Codes	Description
50250	Ablation, open, 1 or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy

Liver Tumors - Medical Necessity Review not required:

CPT® Codes	Description
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical
47381	Ablation, open, of 1 or more liver tumor(s); cryosurgical

Lung Cancer - Medical Necessity Review not required:

CPT® Codes	Description
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/30/2003	08/03/2010[MDCRPC], 03/01/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Back to Top

Date Sent: 4/29/24

Revision History	Description
08/04/2020	Added Kaiser Permanente Medical Policy statement under Medicare for Breast Cancer and Benign Lesions.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Coronary CT Angiography

- Cardiac CT Angiography
- Cardiovascular Computed Tomography (CVCT)
- Cardiovascular Multislice CT (MSCT)
- Contrast Enhanced Computed Tomographic Angiography
- Fractional Flow Reserve CT
- Multidetector Row Spiral Computed Tomography (MDCT Scan)
- Multislice Detector Computed Tomography
- Multislice Tomography

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	**(CPT codes 75572, 75573, 75574)** Noridian has retired LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search. LCD Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease L38615) **(CPT 75580)**
Local Coverage Article (LCA)	LCA Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease A58097

For Non-Medicare Members

Cardiac CT Angiography (CTA) CPT 75574	Kaiser Permanente has elected to use the MCG* Care Guideline: Cardiac CT Angiography (CTA) (A-0483) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

Back to Top

Fractional Flow Reserve CT CPT 75580	FFR-CT is considered medically necessary when **ALL** of the following criteria are met: • Patient has symptoms consistent with myocardial ischemia • CCTA has been performed in the preceding 90 days • There is at least one 40%-90% coronary stenosis located in the proximal or middle segment of a major native coronary artery or a named branch thereof which is of uncertain functional significance.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (cardiology)

For screening see:
Coronary Artery Calcium Score with Computed Tomography (CT) - CPT 75571

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Coronary artery disease (CAD) is one of the leading causes of morbidity and mortality worldwide. Currently invasive coronary angiography is the gold standard for coronary artery lumen assessment. It provides high spatial resolution and accurately determines the location, extent, and severity of coronary obstructive lesions. It also allows immediate intervention if needed. Coronary angiography, however, is an invasive procedure, has a small risk of serious complications, and requires a period of observation for several hours in a monitoring unit. Moreover, it was reported that nearly 40% of these procedures result in normal findings. This has led to a growing interest in the development less invasive methods for evaluating coronary anatomy, especially in stable patients at low to moderate risk of disease (Vembar 2006, Miller 2008).

Numerous anatomic and functional noninvasive tests for detecting CAD have emerged and are rapidly developing. Among these are stress echocardiography, nuclear perfusion studies, SPECT, magnetic resonance angiography, and others. More recently, computed tomography has been used for the evaluation of CAD. Electron beam computed tomography (EBCT) was initially used to assess coronary artery calcium as a marker of atherosclerosis. The first generation of multislice computed tomography (MSCT), also known as multidetector computed tomography (MDCT) scanners were introduced in the 1990s. The 4-slice scanner was developed to provide noninvasive direct visualization of the coronary arteries and led to significant improvements in spatial resolution compared to EBCT. However, it had motion artifacts, low resolution, long acquisition time, and up to 22% of the segments were non-assessable. The 4-slice CT thus rapidly evolved to16, 32, 40, and 64-slice CT scanners. The 16-slice scanner has better spatial resolution, faster gantry rotation, and larger coverage resulting in significantly shorter breath hold and less motion artifacts than those with 4-slice. The 64-slice scan generation, introduced in 2004, further improved the resolution, decreased the slice thickness, and reduced the acquisition time to less than 10 seconds. The entire procedure can be performed in approximately ten minutes. Systems with 256 and 320 slices and others with 64 slices but with 2 x- ray tubes (dual –source CT or DSCT) have recently been introduced (Gertz 2006, Vembar 2006, Berman 2006, Min 2009).

With the newer scanners, electrocardiographically synchronized images can be taken through the entire heart in the time of one breath hold. Synchronizing the location of the peak of QRS complex in the ECG with the projection data allows the reconstruction and visualization of anatomy at various phases of the cardiac cycle thus making functional imaging possible (Cademartiri 2005, Vembar 2006, Budoff 2008).

Back to Top

MDCT technology, however, has its limitations; it does not have the ability to correctly identify and differentiate between functionally significant and nonsignificant stenosis, or allow for intervention during the examination if needed. Positive findings frequently require confirmation with selective cardiac catheterization angiography, or stress myocardial perfusion to evaluate the functional significance. One of the difficulties in imaging the coronary vessels is the constant motion of the heart, which leads to artifacts and influences the image quality even with the significant improvements in the technology. Reducing the heart rate to 50-60 bpm with beta-blockers, now routinely used by most investigators, increases the cardiac rest period and reduces, but does not eliminate motion artifacts. To date, it is not possible to perform CT angiography in patients with atrial fibrillation unless it is highly regular.

One other significant problem, even with the most recent generations, is the inability of the MDCT to assess the degree of luminal obstruction within a calcified zone when there is dense calcification of the coronary arteries. This may lead to relatively high rate of false positive results and overestimate the severity of the disease. The use of MDCT is also limited for in-stent visualization, for evaluation of distal anastomosis among patients with previous bypass graft surgery, and for patients with higher body mass index. Moreover, MDCT requires the administration of contrast material and exposure to ionizing radiation. The radiation dose used is equivalent to 2-3 times the dose typically used during an invasive angiogram. This may be considered a low radiation exposure but might be of concern among women in childbearing age, or younger individuals who may use the test repeatedly. History of severe allergic reactions to an iodinated contrast material or of impaired renal function (creatinine level >1.5 mg/dL) are contraindications to CT coronary angiography (Garcia 2005, De Roos 2006, Leber 2006, Berman 2006, Hoffmann 2006, Rixe 2009, Min 2009).

Medical Technology Assessment Committee (MTAC)

Virtual Coronary Angioscopy

04/03/2006: MTAC REVIEW

Evidence Conclusion: All published studies on MSCT scanners investigated the accuracy of MCST in patients with known or suspected CAD, who was referred for evaluation with catheter angiography. None of the studies evaluated the technology for screening healthy, asymptomatic, or low risk individuals. Schuijf and colleagues' meta-analysis (2006) included 24 studies with 1,300 participants that compared MSCT scans head to head with invasive catheter angiography in patients with known or suspected CAD. The studies used one of the 4, 8, or 16 slice CT scanners. Those evaluating the 64-slice CT scans were not published to the date of analysis. The results of the meta-analysis show that the 4,8, and 16 MSCT scan generations had an overall high specificity (95%) and negative predictive value (97%) but lower sensitivity (85%) and positive predictive value (76%) compared to invasive angiography as the gold standard. Published studies evaluating 64-slice CT scanners had some differences in the methodology and patient characteristics, but all used invasive catheter angiography as the gold standard, included only patients with known or suspected CAD, excluded those with cardiac arrhythmias and unstable conditions, defined significant coronary stenosis as >50% lumen narrowing, and the majority used beta-blockers to reduce the heart rate. The trials ranged in size from 35 to 84 patients, used the same Sensation 64 CT Siemens Medical Solutions scanners, and almost all reported analysis of sensitivity, specificity, positive and negative predictive values. Analysis of MSCT performance was limited to coronary segments > 1.5 or 2 mm in diameter, and most studies used individual coronary vessels or vessel segments as the unit of analysis. Not all studies reported on the performance characteristics of MSCT using the patient as a unit of analysis. The results of the studies critically appraised show that 4-13% of the coronary segments were non-evaluable due to motion artifacts, severe calcified plaques, and/or other technical imaging problems. The sensitivity and specificity of MSCT for detecting >50% diameter reduction in the evaluated coronary segments ranged from 73% to 95% and from 80% to 97% respectively. Only two studies reported on the performance characteristics of MSCT using the patient as a unit of analysis showing a sensitivity of 95-96% and specificity of 90-91%. The negative predictive values ranged from 92-100% when segments were used as the unit of analysis and 93% to 98% when analyses were per patients. The positive predictive value on the other hand was much lower (as low as 56 % per segment and 83% per patient). Leber et al (2005) went a step beyond assessment of stenosis and evaluated the 64-MSCT scan for detecting and quantifying coronary atherosclerotic plaque compared to intravascular ultrasound (IVUS), and reported a 84% sensitivity and 91% specificity. This, however, was studied on a very small subgroup of only 18 patients with stable angina. The overall results of the published studies may indicate that MSCT scanning may have a high sensitivity of diagnosing CAD, and a high NPV that would accurately rule out CAD among the selected symptomatic patients with a negative MSCT scan result. However, all studies were small, conducted in single, highly specialized centers, conducted among selected intermediate to high risk patients, with stable conditions, regular heart rhythm, and a high prevalence of CAD. These factors in addition to analyzing the diagnostic performance of the technology based on the evaluable segments of the vessels only, would overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be

Back to Top

generalizable to a broader population. In conclusion: There is insufficient evidence to support the use of MSCT as a method of screening for CAD among healthy, low risk populations, or asymptomatic patients with known risk factors. There is insufficient evidence that the technology is as beneficial as catheter angiography in the diagnosis of CAD. There is insufficient evidence to support the use of MSCT scanning in monitoring progress of the disease and its outcome after an intervention, in patients with confirmed disease. There is insufficient evidence that the technology improves health outcomes. A multicenter study (CorE 64), and study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway.
Articles: The search yielded around 170 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. The search revealed several studies using 4, 8, and 16-slice CT scanners for the detection of coronary artery lesions. A recent meta-analysis of 24 of these studies was also identified, as well as seven studies that used the 64-slice CT angiography for detecting CAD stenosis and comparing the technology with invasive coronary angiography. The meta-analysis and four of the studies on the 64-slice scanners were critically appraised. Fine JJ, Hopkins CB, Ruff N, et al. Comparison of accuracy of 64-slice cardiovascular computed tomography with coronary angiography in patients with suspected coronary artery disease. Am J Cardiol. 2006; 97:173-174. See Evidence Table. Leber Aw, Knez A, von Ziegler F, et al. Quantification of obstructive and nonobstructive coronary lesions by 64-slice computed tomography. A comparative study with quantitative coronary angiography and intravascular ultrasound. J Am Coll Cardiol. 2005; 46:147-154. See Evidence Table. Raff G L, Gallagher MJ, O'Neill WW, et al. Diagnostic accuracy of noninvasive coronary angiography using 64-slice spiral computed tomography. J Am Coll Cardiol. 2005; 46:552-557. See Evidence Table. Ropers D, Rixe J, Anders K, et al. Usefulness of multidetector row spiral computed tomography with 6.4x0.6 mm collimator and 330 –ms rotation for the noninvasive detection of significant coronary artery stenoses. Am J Cardiol. 2006; 97:343-348. See Evidence Table. Schuijf JD, Bax JJ, Shaw LJ, et al. Meta-analysis of comparative diagnostic performance of magnetic resonance imaging and multislice computed tomography for noninvasive coronary angiography. Am Heart J. 2006; 151:404-411. See Evidence Table.

The use virtual coronary angioscopy of in the evaluation of coronary artery disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/05/2007: MTAC REVIEW
MDCT in the Treatment of Coronary Heart Disease
Evidence Conclusion: *Use of MDCT for the diagnosis of coronary artery stenosis* - The published studies evaluating the use of MDCT scanners in the diagnosis of coronary artery stenosis are all relatively small trials mainly conducted in single specialized centers, and among selected patients with stable conditions who were referred for invasive coronary angiography for a known or suspected CAD. The technology was not assessed for screening healthy, asymptomatic, or low risk individuals. The studies evaluated MDCT angiography in respect to its accuracy in identifying coronary stenosis (per segment, per-vessel and per- patient), but not its effect on the treatment decisions, patient management, and health outcomes. Certain segments or whole patients were excluded from the analysis due to nonassessable images, which would overestimate the accuracy of the test. Three recently published meta-analyses (Hamon 2006, Sun 2006, and Stein 2006) pooled the results of published individual small studies. There were some variations between the three meta-analyses in the inclusion/exclusion criteria, but many of the same studies were included in all three analyses. Hamon and colleagues' analysis included more up-to date studies, and only those using 16 or more slice MDCT scans. The other two meta-analyses included older studies with 4, 8, 12 as well as the newer 16 and 64-slice scans. The authors of all three meta-analyses performed per-segment, per-vessel, and per-patient analyses. The per-patient analysis would be the most relevant if the MDCT is intended for use as a substitute for invasive angiography. Overall, the results of the three meta-analyses show that MDCT angiography had a sensitivity ranging from 81-94%, and specificity ranging from 93-94% for the per-segment analysis. Analyses based on patients showed a sensitivity of 91 –95%, and specificity of 74-84%. The per-patient pooled positive likelihood ratios were 5.4 and 6 and negative likelihood ratios were 0.05 and 0.07 in the two analyses that reported them. Hamon and colleagues also pooled the results of the positive and negative predictive values which were 83% and 94% respectively for the per-patient analysis. Nikolaou and colleagues, 2006 evaluated the clinical value of the 64-slice computed tomographic (MDCT) in the diagnosis of coronary artery disease among 72 patients with and without a history of a known coronary artery disease (CAD) in a cardiology center in Germany. 40% of the participants had already been diagnosed with CAD and angiographically verified. Invasive coronary angiography was the gold standard and was evaluated by an independent observer blinded to the MDCT results. Scan results were analyzed by two independent experienced observers blinded to the invasive angiography results, and patients' history. 6% of patient-based and 10% of the segment-based CT angiograms were nonassessable. 64% of the assessable CT angiograms had a high image quality, 30% had moderate quality and 6% were poor. The results of this study showed a sensitivity of 86% and specificity of 94% for the per-segment analysis. These were 97% and 79% respectively for the per-patient analysis. The negative predictive value was 100% for patients with known CAD, and 93% for those with a
 Back to Top

suspicious disease. These rates were computed from very small number of patients with a high prevalence of CAD and would not necessarily apply to populations at a lower risk. *Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain:* The few studies that evaluated the use of the technology in the emergency room did not compare it to the gold standard of catheter angiography but used a combination of noninvasive tests and observations as a surrogate gold standard. Gallagher and colleagues, 2006 evaluated the diagnostic accuracy of the 64-slice multidetector computed tomographic (MDCT) coronary angiography compared to stress nuclear imaging for the detection of an acute coronary syndrome (ACS) or 30-day major cardiac adverse events. The study included 92 low-risk chest pain patients seen in the emergency department of a teaching hospital in Michigan USA. The participants had negative serial ECG and cardiac marker results at presentation to the ER. They were admitted to the emergency department observation unit for the chest pain diagnostic protocol (cardiac monitoring, serial ECG. and cardiac marker tests) 4 hours after arrival. Those with abnormal markers had repeat tests and ECG at 8 hours. If these latter tests were negative the patients received a stress nuclear imaging test followed by MDCT coronary angiography using 64-slice multidetector CT scanners. Patients were treated based on the findings of both tests, and then followed up for evidence of ACS or major adverse events within 30 days of their initial visit. Those with positive tests suggesting unstable angina underwent cardiac catheterization to confirm the diagnosis. The authors used clinical markers and outcomes as a surrogate gold standard, and 7 (7.6%) of the study participants were not included in the analysis due to uninterpretable MDCT images. The numbers were too small and show a MDCT sensitivity of 86% specificity of 92%, NPV of 99% and a PPV of 50%. Hoffmann et al, 2006 also assessed MDCT angiography among 103 patients presenting to the ER with acute chest pain in a university hospital in Massachusetts. The participants had no ischemic ECG changes and negative initial biomarkers. They all underwent contrast enhanced 64-slice MDCT coronary angiography before admission. The results were not compared to the gold standard of catheter angiography. The diagnosis of acute coronary syndrome was made by an expert panel blinded to the results of MDCT, based on the results of serial ECGs, cardiac biomarkers, and subsequent cardiac testing including exercise testing, stress perfusion imaging, or cardiac cauterization during the index hospitalization and 5-months follow-up. The results of the study showed that MDCT had a sensitivity of 100%, specificity of 82%, negative predictive value of 100%, and a positive predictive value of 47% in detecting a significant stenosis. These, however, were not verified with catheter angiography for all patients. Two other studies (White et al 2005, and Sato et al 2005) also evaluated MDCT use in small numbers of patients (N=69 and 31 respectively) admitted to ER with chest pain. They used the older 4 and 16 row CT detectors. Patients included also had non-diagnostic ECGs and normal cardiac enzymes. Invasive angiography was not used as a gold standard. The reference standards used were similar to those discussed earlier. The sensitivities and specificities were 83% and 96% respectively in White's study, and 95.5% and 88.9% respectively in Sato's study. This relatively moderate accuracy indicates that some cases might be missed, and others may undergo unnecessary invasive angiograms based on the results of the MDCT.
In conclusion: The patient-based analysis of the results of the studies, as presented individually or pooled in meta-analyses show high sensitivity and negative predictive values, but lower specificity and positive predictive value of the MDCT angiograms in the diagnosis of CAD in selected patients. This indicates that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients, but at the expense of up to 25% false positive tests among population groups with a high prevalence of CAD. The latter would overestimate the calculated accuracy and predictive values of the test, and in turn the results may not be generalizable to a broader lower-risk population. There is insufficient evidence to determine whether using the technology to diagnose coronary artery stenosis improves the net health outcomes. The published literature on the use of MDCT angiography in an ER does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. There are no published data to date on the effect of the using the technology on patient treatment or management decisions. A multicenter study (CorE 64) and a study with long-term healthcare outcomes conducted by the Medical College of Wisconsin are underway.
Articles: The search yielded around 55 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Three meta-analyses published after the last review were identified, as well as several small studies on MDCT with patient sizes ranging from 51 to 129. Four studies (Nikolaou 2006l, Plass 2006, Schuijf 2006, and Muhlenbruch 2006) compared the technology with invasive coronary angiography, Dewey et al, compared the 16-slice scanner with exercise electrocardiography, in one study and MRI in another study using the invasive angiography as the gold standard. Four published studies evaluating the use of MDCT for patients presenting to the ER with acute chest pain were identified. None of the latter studies compared the technology to the gold standard of invasive angiography, and only two used the 64-slice CT scans. All meta-analyses and recent studies were reviewed. The meta-analysis that included the most recent studies that used the newest generations of MSCT (> 16 slices), compared MDCT to invasive coronary angiography, and had a valid methodology was critically appraised. A recent study comparing the 64-slice MDCT with invasive angiography, and another evaluating its use in patients presenting to the emergency room with acute chest pain were also selected for critical appraisal. Hamon M, Biondi-Zoccai GG, Malagutti P, et al. Diagnostic performance multislice spiral computed tomography of coronary arteries as compared with conventional invasive coronary angiography.
 Back to Top

J Am Coll Cardiol. 2006; 48:1896-1910. See Evidence Table. Nikolaou K, Knez A, Rist C, et al. Accuracy of 64-MDCT in the diagnosis of ischemic heart disease. AJR 2006; 187:111-117. See Evidence Table. Gallagher MJ, Ross MA, Raff GL, et al. The diagnostic accuracy of 64-slice computed tomography coronary angiography compared with stress nuclear imaging in emergency department low-risk chest pain patients. Ann Emerg Med. 2006; See Evidence Table.

The use of MDCT in the treatment of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/01/2009: MTAC REVIEW
MDCT in the Treatment of Coronary Heart Disease
Evidence Conclusion: Use of 64-multidetector computed tomography (MDCT) for the diagnosis of coronary artery stenosis in nonemergent settings: The published studies that evaluated the use of MDCT scanners in the diagnosis of coronary artery stenosis had generally valid methodology but were relatively small and mainly conducted among selected patients with stable conditions who were referred for invasive coronary angiography for a known or suspected CAD. The technology was not assessed for screening healthy, asymptomatic, or low-risk individuals. The meta-analyses that pooled the results of the published studies had some variations in their inclusion/exclusion criteria, but a large number of same studies were included in all. The participants in ACCURACY (Budoff 2008) and CORE-64 (Miller 2008) studies, not included in the meta-analyses, were also patients with suspected symptomatic CAD referred for conventional coronary angiography. ACCURACY excluded patients with a known history of CHD, but no exclusions were made based on coronary artery calcium scoring or BMI. On the other hand, CORE 64 included patients with or without a history of CAD and excluded those with coronary artery calcium score >600 or BMI >40. Only coronary artery segments >1.5 mm was included in the analysis. These two studies as well as the other included in the meta-analyses performed patient-based and vessel-based analyses. Per-segment analyses were also performed in several studies. Accuracy of 64-slice MDCT. The patient-based analysis of the results of the studies, as presented individually or pooled in meta-analyses show high sensitivity (85-99%) and negative predictive values (95-100%), but lower specificity (83-91%) and positive predictive value (64-91%) of the MDCT angiograms in the diagnosis of significant (>50%) stenosis of CAD in selected patients. The technology was less sensitive (75-85%) but more specific (90-96%) in detecting stenosis per vessel. The accuracy of the test varied widely by artery and was highest for the left main artery followed by the left circumflex artery. These results indicate that the test may be useful in excluding CAD and avoiding a conventional angiography among some patients with a suspected disease. This however could be at the expense of more than 20% false positive tests among population groups with a high prevalence of CAD. Impact on management and health outcomes: There was insufficient evidence to determine the effect of 64-slice on patient management or net health outcomes. The published studies to date evaluated MDCT angiography in respect to its accuracy in identifying coronary stenosis, but not its effect on the treatment decisions, patient management, and health outcomes. Use of MDCT to evaluate patients presenting to emergency rooms with acute chest pain. The published literature on the use of MDCT angiography in emergency departments (ED) does not provide sufficient evidence to determine the benefits and harms of the test in diagnosing patients presenting with acute chest pain. Hoffmann 2009 (ROMICAT study), as well as earlier smaller studies that evaluated the use of the technology in the ED, did not compare it to the gold standard of catheter angiography, but used a combination of noninvasive tests and observations as a surrogate gold standard. The ROMICAT study aim was to determine the usefulness of MDCT angiography in patients with acute chest pain who presented to an emergency department and were admitted with low to intermediate risk for acute coronary syndrome. However, the results of the CT angiography findings were not provided to the physicians managing the patients, and thus it is not possible to determine whether the management or outcomes would have been altered based on the CT angiography findings. It is uncertain whether the clinicians would have performed less stress tests, more invasive angiograms, treated the patients more or less aggressively, or discharged the patients earlier had they known the results of the CT angiograms.
Articles: The search yielded around 325 articles on CT angiography. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Six meta-analyses published after the last review were identified. Four evaluated the diagnostic performance of the 64-slice CT scanners, one compared the performance of the 16 vs. the 64-slice scanners and another evaluated all 4, 16-slice, and 64 slice CT scanners. Two of the four meta-analyses on 64-slice scanners were performed by the same group of investigators (Mowatt and colleagues) and included the same studies. The literature search also identified two more recent multicenter studies (ACCURACY, and CORE 64) on the accuracy of the 64-slice CT scans in non-emergent settings, and one study on patients presenting to an emergency department (ROMICAT study). None was included in the meta-analyses. There were no published studies that prospectively compared MDCT to other noninvasive stress testing. The most recent valid meta-analysis that compared the performance of 64-slice scanners to invasive coronary angiography was selected for critical appraisal, as well as the newer studies ACCURACY, CORE 64, and ROMICAT. The
 Back to Top

references for the studies reviewed are: Mowatt G, Cook JA, Hillis GS, et al. 64-slice computed tomography angiography in the diagnosis and assessment of coronary artery disease: systematic review and meta-analysis. Heart. 2008; 94:1386-1393. See Evidence Table. Budoff MJ, Dowe D, Jollis JG, et al. Diagnostic performance of 64-multdetector row coronary computed tomographic angiography for evaluation of coronary artery stenosis in individuals without known coronary artery disease. Results from the prospective multicenter ACCURACY (Assessment by Coronary Computed Tomographic Angiography of Individuals Undergoing Invasive Coronary Angiography) trial. J Am Coll Cardiol 2008; 52:1724-1732. See Evidence Table. Miller JM, Rochite CE, Dewey M, et al. Diagnostic performance of coronary angiography by 64-Row CT. N Engl J Med 2008;359:2324-2336. See Evidence Table. Hoffmann U, Bamberg F, Chae CU, et al. Coronary computed tomography angiography for early triage of patients with acute chest pain. The ROMICAT (Rule Out Myocardial Infarction using Computer Assisted Tomography) trial. J Am Coll Cardiol 2009; 53:1642-1650. See Evidence Table.

The use of MDCT in the treatment of coronary heart disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Fractional Flow Reserve Computed Tomography (FFRCT) for CAD
MTAT Review: September 2021
Evidence Conclusion:
The Medical Technology Assessment Team (MTAT) reviewed the evidence on Fractional Flow Reserve Computed Tomography (FFRCT) Software (HeartFlow, Inc.) for Coronary Artery Disease (CAD) on September 7, 2021.

- Overall, there is a large body of literature examining the clinical validity and clinical utility of FFRCT in patients with known or suspected coronary artery disease.
- We identified one systematic review/meta-analysis (Luo, 2021) and two health technology assessments (ECRI; Hayes, Inc.) that addressed the clinical question. •
- A Hayes, Inc. (2020)1 assessment, which was used as the primary evidence source for this review, included 3 systematic reviews/meta-analyses and 28 additional studies (20 on clinical validity of FFRCT, 8 on clinical utility of FFRCT). Regarding evidence quality, the report noted:
    - The body of evidence concerning FFRCT for detection of HSS in patients with known or suspected CAD is large in size and moderate in quality for clinical validity, but low in quality for clinical utility. Overall quality was determined based on the balance of benefits and harms and was assessed taking into consideration the quality of individual studies; the precision, directness, and consistency of data; and the applicability of data to general practice.
    - It was further noted: The available studies of FFRCT have not provided sufficient evidence that this technique provides information that improves patient management, primarily due to a lack of randomized controlled trials (RCTs).
- Our bridge search identified 7 additional individual studies:
    - One small prospective comparative study2 (N=42) evaluated the clinical validity (i.e., diagnostic performance) of FFRCT in patients with suspected or known CAD. Consistent with the findings of the Hayes, Inc. review, diagnostic accuracy was better than CCTA alone for evaluation of CAD.
    - Two comparative studies (one prospective cohort study2 and one RCT3) and 5 observational studies4-8 examined clinical utility (total N=4,372).
        - Overall, there were statistically significant correlations between reduced FFRCT values and 1 or more types of ACE.
        - There is recent data available from a large RCT3 showing that FFRCT led to 22% reduction in ICA use (p=0.01) and no difference in symptoms, quality of life, major adverse cardiac and cerebrovascular events, or use of coronary revascularization vs. no FFRCT in patients with stable chest pain (Curzen, 20213 ; N=1,400); however, the study had a follow-up period of only 9 months. There remains a need for longer term clinical utility data.
    - The studies identified in our search were limited by small sample sizes, lack of randomized studies with adequate follow-up data, and retrospective, non-comparative designs.
- Thus, the results of the studies identified in our bridge search (for both clinical validity and clinical utility) are in line with the findings of the Hayes, Inc. review.

Overall Conclusion(s)

- The quality of the evidence on the clinical validity of FFRCT in patients with known or suspected CAD is moderate. The quality of the evidence on the clinical utility of FFRCT in patients with known or suspected CAD is low.
- Therefore, the overall quality of the body of evidence on FFRCT in patients with known or suspected CAD is low.

 Back to Top

- Additional trials with randomized controlled designs or high-quality comparative studies with longterm follow-up periods are needed to determine whether use of FFRCT in patients with known or suspected CAD leads to clinically meaningful changes in treatment decision-making and health outcomes.

Hayes Technology Assessment

Noninvasive Computed Fractional Flow Reserve from Computed Tomography (FFRCT) for Diagnosis of Coronary Artery Diesase

Dec 11, 2020 ; annual review 1/30/2023

Technology Description

FFRCT is a noninvasive alternative to FFR testing that involves computer-assisted processing of CCTA images to estimate changes in blood pressure inside coronary arteries that have partial or intermediate stenosis. By using information from CCTA to model fluid dynamics of the coronary arteries, FFRCT seeks to determine whether the stenotic lesion causes an appreciable reduction in blood flow to the heart, which may lead to myocardial ischemia or infarction, and whether the lesion can be treated medically or requires a percutaneous coronary intervention (PCI), such as balloon angioplasty and stenting. FFRCT is an alternative to invasive assessment of FFR that uses a pressure-sensing wire inserted into the coronary arteries. A stenosis with an FFRCT value ≥ 0.80 creates a small drop in blood pressure, has a low probability of causing inducible ischemia, and is not considered to need PCI. FFRCT is performed using already obtained CCTA images at a center equipped with the specialized software.

Conclusion

The available studies have provided consistent evidence that FFRCT is more accurate than CCTA alone for detection of HSS but insufficient evidence to evaluate FFRCT relative to other noninvasive methods such as CCTP, SPECT, PET, and CMR. There is also insufficient evidence to evaluate the clinical utility of FFRCT relative to invasive FFR. The only available study with prospective controls found that FFRCT-guided management reduced the use of unnecessary ICA in a significant proportion of patients with no increased occurrence of adverse clinical outcomes. However, this study did not randomize patients to FFRCT versus invasive testing and it involved only 1 year of follow-up. Studies of FFRCT for prediction of CAD events found correlations between reduced FFRCT and adverse clinical outcomes but had significant shortcomings, such as limited or incomplete use of multivariate analysis to identify independent predictors. FFRCT does not pose any notable safety concerns. Although most studies in the evidence base included patients with stable chest pain and suspected or known CAD, most did not limit the patient population to those with intermediate coronary artery blockages and reported results for all lesions, making it difficult to determine which patients would benefit from testing. Additional studies, particularly of clinical utility, are needed to determine the long-term efficacy and safety of FFRCT for guidance of CAD management in this patient population.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Noninvasive Computed Fractional Flow Reserve from Computed Tomography (FFRCT) for Diagnosis of Coronary Artery Disease. Dallas, TX: Hayes; January 30, 2023. Retrieved February 21, 2023, from https://evidence.hayesinc.com/report/dir.noninvasiveffrct3647

Applicable Codes

Medicare & Non-Medicare- Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)

Back to Top

75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/27/2006	04/03/2006, 02/05/07, 07/13/2009[MDCRPC], 06/01/2010[MDCRPC], 04/05/2011[MDCRPC], 02/07/2012[MDCRPC], 12/04/2012[MDCRPC], 06/04/2013[MDCRPC], 10/01/2013[MPC], 4/1/2014[MPC], 01/06/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC],06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	08/08/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
07/28/2016	Added retired LCD language
07/25/2017	Chest CT angiography no longer requires review
06/02/2020	Removed CPT code 71275 and reference for Chest CT Angiography since it does not require medical necessity review
03/06/2023	Addition of Medicare LCD, LCA links for Non-Invasive Fractional Flow Reserve (FFR) for stable Ischemic Heart Disease and applicable codes for Medicare added 0501-0504T.
08/08/2023	MPC approved clinical indications for Fractional Flow Reserve (FFR). Requires 60-day notice, effective date 01/01/2024.
1/31/2024	Updated CPT codes added new code 75580 effective 1/1/2024 and removed CPT 0501T, 0502T, 0503T, 0504T which were deleted 1/1/2024 and replaced with 75580.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiovascular Risk Panel

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Biomarkers in Cardiovascular Risk Assessment (L36362)
Local Coverage Article	Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that Cardiovascular Risk Panels provide better long-term outcomes than current standard services/therapies.

Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels*) are considered **not medically necessary**. Some examples of commercially available cardiovascular risk panels include but are not limited to the following:

- Applied Genetics Cardiac Panel
- Atherotech® Diagnostics Lab CVD Risk Panel and VAP Lipid Panel
- Berkeley Heart Lab (a Quest Diagnostics service) Cardio IQ® Lipid Panel
- Health Diagnostics Cardiac Risk Panel
- Boston Heart Diagnostics
- Genova Diagnostics CV Health Plus Genomics Panel
- Genova Diagnostics CV Health Plus Panel
- Metametrix Cardiovascular Health Profile
- Cleveland HeartLab CVD Inflammatory Profile
- Applied Genetics Cardiac Panel
- Genetiks Genetic Diagnosis and Research Center Cardiovascular Risk Panel
- Quest Diagnostics 4myheart
- Singulex Cardiac Related Test Panels
  - Cardiac Dysfunction panel
  - Vascular Information and Dysfunction panel
  - Dyslipidemia panel
  - Cardiometabolic

* A simple lipid panel is generally composed of the following lipid measures:
- Total cholesterol
- LDL cholesterol
- HDL cholesterol

Back to Top

- Triglycerides

Certain calculated ratios, such as the total/HDL cholesterol may also be reported as part of a simple lipid panel. Other types of lipid testing, i.e., apolipoproteins, lipid particle number or particle size, lipoprotein (a), etc., are not considered to be components of a simple lipid profile.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Cardiovascular risk panels refer to different combinations of cardiac markers that are intended to evaluate risk of cardiovascular disease. There are numerous commercially available risk panels that include different combinations of lipids, noncardiac biomarkers, measures of inflammation, metabolic parameters, and/or genetic markers. Risk panels report the results of multiple individual tests, as distinguished from quantitative risk scores that combine results of multiple markers into one score. While the individual risk factors have in most cases been associated with increased risk of CV disease, it is not clear how the results of individual risk factors impact management changes, so it is also not certain how the panels will impact management decisions. Given the lack of evidence for clinical utility of any individual risk factor beyond simple lipid measures, it is unlikely that the use of CV risk panels improve outcome.

2010 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults: Recommendation for Assessment of Lipoprotein Concentrations, Other Lipoprotein Parameters, and Modified Lipids: “Measurement of lipid parameters, including lipoproteins, apolipoproteins, particle size, and density, beyond standard fasting lipid profile is not recommended for cardiovascular disease risk assessment in asymptomatic adults.”
http://circ.ahajournals.org/content/122/25/e584.full.pdf

Applicable Codes

Considered Not Medically Necessary when billed as part of a Cardiovascular Risk Panel:

This is not an all-inclusive list.

CPT® Codes	Description
81225	CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81229	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81240	F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	F5 (coagulation factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant
81291	MTHFR (5,10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
81400	Molecular pathology procedure, Level 1(eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis)
81401	Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)
81479	Unlisted molecular pathology procedure (when utilized with a description of KIF6, 9p21, 4q25-AF, LPA Aspirin, LPA-Intron 25)

Back to Top

82163	Angiotensin II
82172	Apolipoprotein, each
82306	Vitamin D; 25 hydroxy, includes fraction(s), if performed
82652	Vitamin D; 1, 25 dihydroxy, includes fraction(s), if performed
82397	Chemiluminescent assay (Leptin)
82542	Column chromatography, includes mass spectrometry, if performed (eg, HPLC, LC, LC/MS, LC/MS-MS, GC, GC/MS-MS, GC/MS, HPLC/MS), non-drug analyte(s) not elsewhere specified, qualitative or quantitative, each specimen [not covered for cardiovascular disease risk]
82610	Cystatin C
82664	Electrophoretic technique, not otherwise classified
82725	Fatty acids, nonesterified [not covered for cardiovascular disease risk]
82777	Galectin-3 [not covered for cardiovascular disease risk]
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
83090	Homocysteine
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified [adiponectin] [leptin] [interleukin-6 (IL-6)] [tumor necrosis factor alpha (TNF-a)] [Oxidized phospholipids] [interleukin 17] [toll-like receptor 4 (TLR4)]
83525	Insulin, total [not covered for cardiovascular disease risk]
83695	Lipoprotein (a)
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)
83700	Lipoprotein, blood; electrophoretic separation and quantitation
83701	Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed
83719	Lipoprotein, direct measurement; VLDL cholesterol
83876	Myeloperoxidase (MPO)
83880	Natriuretic peptide
85384	Fibrinogen; activity
85385	Fibrinogen; antigen

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/25/2017	02/07/2017[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC] , 06/06/2023[MPC]	12/09/2022

[MPC] Medical Policy Committee

Revision History	Description
02/07/2017	MPC approved to adopt criteria to manage cardiovascular risk panels that are commercially available; 60 day notice effective May 1, 2017
06/07/2018	Added LCD – L36362
06/02/2020	Added LCA Billing and Coding: MolDX: Biomarkers in Cardiovascular Risk Assessment (A57055)
06/01/2021	Updated applicable coding – removed deleted codes 0111T and 0126T
12/09/2022	Updated applicable coding – removed deleted codes 0423T

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Microinvasive Glaucoma Surgery (MIGS)

- Cypass (no longer available)
- iStent Device and Hydrus
- XEN Gel Implant (XEN® Gel stent) for Glaucoma

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Micro-Invasive Glaucoma Surgery (MIGS) (L38301)
Local Coverage Article	Billing and Coding: Micro-Invasive Glaucoma Surgery (MIGS) (A57864)

For Non-Medicare Members

iStent Device and Hydrus – 66989, 66991	iStent Device and Hydrus will be considered medically necessary when **ALL of the following** are met: 1. Only used in conjunction with Cataract Surgery when the individual is currently being treated with an ocular hypotensive medication **AND/OR** had prior laser trabeculoplasty 2. Used to reduce intraocular pressure (IOP) of greater than 21, except when clinical circumstances would support a lower IOP (this rationale should be documented in the note) 3. 18 years old or over **AND** 4. Mild to Moderate primary open-angle glaucoma defined as how much vision loss via visual field testing 5. Eyes do **NOT** have the following* a. Prior significant trauma b. In eyes with abnormal anterior segment c. In eyes with chronic inflammation d. In glaucoma associated with vascular disorders e. In pseudophakic patients with glaucoma f. In uveitic glaucoma g. In eyes with prior incisional glaucoma surgery or cilioablative procedures h. In eyes with prior laser trabeculoplasty (LT) with selective LT within 90 days prior to screening or prior argon laser trabeculoplasty (ALT) at any time i. In patients with unmedicated IOP greater than 36 mmHg after "washout" of medications j. Plan for implantation of more than two stents

Back to Top

Date Sent: 4/29/24

	k. After complications during cataract surgery, including but not limited to, severe corneal burn, vitreous removal/vitrectomy required, corneal injuries, or complications requiring the placement of an anterior chamber IOL l. When implantation has been without concomitant cataract surgery with IOL implantation for visually significant cataract Contraindicated in the following patients: • In eyes with angle-closure glaucoma. • In eyes with traumatic, malignant, uveitic, or neovascular glaucoma or discernible congenital anomalies of the anterior chamber (AC) angle. • In patients with retrobulbar tumor, thyroid eye disease, Sturge-Weber Syndrome or any other type of condition that may cause elevated episcleral venous pressure *Exclusions include clinical circumstances that were not tested in the initial FDA approval.

Xen Gel Implant – 0449T, 66183	The use of Xen Gel Implant will be considered medically necessary when **ONE of the following** are met: 1. Refractory glaucoma, defined as prior failure of filtering/cilioablative procedure and/or uncontrolled IOP (progressive damage and mean diurnal medicated IOP ≥20 mm Hg) on maximally tolerated medical therapy (i.e., ≥4 classes of topical IOP-lowering medications, or fewer in the case of tolerability or efficacy issues) **OR** 2. Previous surgical treatment has failed (angle-based procedures, laser trabeculoplasty) **OR** 3. Primary open-angle glaucoma **OR** 4. Pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy Should **NOT** be used if any of the following are met: a. Angle-closure glaucoma where the drainage angle of the eye has not been surgically open b. Glaucoma drainage device previously implanted c. Presence of conjunctival scarring, prior conjunctival surgery or other conjunctival pathologies (e.g., pterygium) in the target quadrant d. Pathologies of the conjunctiva (clear membrane covering the white outer layer of the eye) in the area needed for this implant Active iris neovascularization or neovascularization of the iris within six months of the surgical date (abnormal formation of new blood vessels on the iris) e. Eye inflammation (e.g., conjunctivitis, keratitis, uveitis) f. Artificial lens implanted in the anterior chamber (intraocular lens) g. Presence of intraocular silicone oil h. Vitreous present in the anterior chamber

Criteria adopted based on FDA premarket approval and input from KP Ophthalmology leadership.

Cypass device – 0474T
The Cypass device was taken off the market on 8/29/2018 by the manufacturer due to safety concerns. This device will no longer be covered for Kaiser Permanente members.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist

Back to Top

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The term micro-invasive or minimally invasive glaucoma surgery (MIGS) refers to a group of newer surgical procedures that are performed by using an ab interno (from inside the eye) approach via gonioscopic guidance and involve minimal trauma to ocular tissues. In contrast to external filtration surgeries such as trabeculectomy and aqueous tube shunt, these procedures are categorized as internal filtration surgeries. Compared with traditional filtration surgery, MIGS holds the promise of faster recovery time and less severe complications.

It is this potentially improved safety profile that opened up the indications for MIGS to include patients with early-stage glaucoma to reduce the burden of medications and problems with compliance (due to eye drop application difficulty, cost, cosmetic effects, and frequency). Another area of investigation is patients with glaucoma who require cataract surgery. An advantage of ab interno shunts is that they may be inserted into the same incision and at the same time as cataract surgery. In addition, most devices do not preclude subsequent trabeculectomy if needed. Therefore, health outcomes of interest are the IOP achieved, reduction in medication use, ability to convert to trabeculectomy, complications, and device durability.

There are three FDA approved/cleared micro-invasive surgical stents, the iStent Trabecular Micro-Bypass Stent (2011), the CyPass Micro-Stent System (July 2016), and the XEN Glaucoma Treatment System (Nov 2016). The iStent is a small (1 mm x 0.5 mm) L-shaped titanium device that is inserted into Schlemm's canal to augment the natural outflow system. CyPass is a 6.35 mm long fenestrated microstent made of biocompatible polyimide inserted into the supraciliary space, thus using an alternative outflow system. The XEN45 is a 6 mm long porcine-derived gelatin stent inserted into the subconjunctival space, bypassing the natural outflow system.

Both iStent and CyPass were FDA approved for use in combination with cataract surgery to reduce IOP in adults with mild or moderate OAG and a cataract that are currently being treated with medication to reduce IOP. XEN45 was granted FDA clearance for the management of refractory glaucoma, including cases where previous surgical treatment has failed, cases of primary open angle glaucoma, and pseudoexfoliative or pigmentary glaucoma with open angles that are unresponsive to maximum tolerated medical therapy.

07/08/2019: MTAC REVIEW

XEN Gel Implant (XEN® Gel stent) for Glaucoma

BACKGROUND

Glaucoma is one of the leading causes of blindness affecting almost 65 million people worldwide. It is a progressive eye disease that causes an irreversible, but potentially preventable damage to the optic nerve leading to visual field and acuity loss. Glaucoma is a heterogeneous group of optic neuropathies, the most common etiology of which is primary open angle glaucoma (POAG) caused by either elevated intraocular pressure IOP-related) or an alternative mechanism (non-IOP-related) (Lavia 2017, Agrawal 2018, Buffault 2019).

Currently, the only proven treatment for IOP-related glaucoma is lowering the intraocular pressure with the aim of preventing additional damage to the ganglionic cells and the optic nerve. Treatment is typically initiated with topical ocular hypotensive medications. Surgery is performed for the treatment of patients with moderate to advanced glaucoma inadequately controlled by the maximally tolerated medical therapy. Currently trabeculectomy is considered the gold standard and most common surgical procedure used for uncontrolled glaucoma. It is an incisional (ab-externo) filtering surgery that lowers the IOP by creating a pathway for release of aqueous humor from the anterior chamber (AC) of the eye into a subconjunctival space known as the filtration bleb (FB). Trabeculectomy is highly effective at lowering the IOP but, is an invasive procedure that requires intense postoperative care and may be associated with complications including hemorrhage, hypotony, scarring, aqueous leak, inflammation of the bleb, and endophthalmitis (Kerr 2017, Hengerer 2017, Agrawal 2018, Yook 2018, Buffault 2019, Heidinger 2019).

Over the last several years, several new devices and less invasive procedures have been developed with the intention of achieving lower IOP with shorter surgical time, less risk, and faster recovery. These are collectively termed "minimally invasive glaucoma surgery (MIGS)" and include trabecular drainage devices (e.g. iStent, iStent inject, and Hydrus microstent), suprachondral drainage devices (such as Cypass and iStent supra), and

Back to Top

subconjunctival drainage devices including Express shunt, InnFocus micro shunt, and XEN Gel implant. However, some investigators debate whether XEN Gel should be considered as a MIGS (Kerr 2017, Widder 2018).

The XEN®45 Gel implant or stent (Allergan plc, Dublin), the focus of the current review, is intended to decrease IOP by creating a permanent outflow pathway from the anterior chamber to the subconjunctival space through a scleral channel. It is a 6mm long, 45µm wide, soft hydrophilic tube made of a porcine gelatin cross-linked with glutaraldehyde. The implant is stiff when dehydrated but becomes soft and flexible within 1-2 minutes of contact with the aqueous humor, allowing it to conform to the ocular tissue, thus theoretically minimizing migration, erosion, and endothelial damage (Pillunat 2017, Gregorio 2018, Karimi 2018).

The XEN® Gel implant procedure can be performed under local or topical anesthesia. The device is inserted from the anterior chamber (ab-interno) using a pre-loaded disposable injector and implanted into the subconjunctival space opposite the incision with minimal conjunctival tissue disruption. The tube creates a conduit that is intended to maintain outflow of the aqueous humor at 2-2.5µL/min as calculated by Hagen-Poiseuille equation (where the diameter and length of the tube defines the amount of outflow). The channel created leads to the formation of a bleb that assists in the drainage of the aqueous fluid. The bleb is a significant risk factor for scar formation and thus an antimetabolite such as mitomycin C (MMC) at a concentration of 0.1-0.2 mg/ml is generally injected in the subconjunctiva approximately 20 minutes before the procedure to reduce the risk of scar formation. XEN Gel uses the same pathway as trabeculectomy, but with the difference of leaving a foreign body in the tissue. The implant is frequently used in combination with phacoemulsification and lens implantation. In that case, the implantation of the stent is performed after placement of the posterior chamber intraocular lens (IOL) (Pillunat 2017, Ker 2017, Gregorio 2017, Karimi 2018, Bufault 2019).

There are three generations of XEN Gel implants (diameter sizes 45, 63, and 140 µm), but XEN®45 Gel is the one currently recommended and available.

XEN® Gel Stent and XEN Injector received US Food and Drug Administration (FDA) approval in November 2016 for use in patients with refractory glaucoma who failed previous surgical treatment or in patients with primary open angle glaucoma, pseudo exfoliative or pigmentary glaucoma with open angle that are unresponsive to maximum tolerated medical therapy.

The use of XEN Gel stent is contraindicated in certain conditions including angle closure glaucoma; previous glaucoma shunt/valve in the target quadrant; presence of conjunctival scarring; prior conjunctival surgery; other eye pathologies e.g. pterygium in the target quadrant; active eye inflammation; active iris neovascularization; AC IOL; presence of intraocular silicone oil; vitreous present in the AC; impaired episcleral venous drainage; suspected or known allergy to any of the device components or the drugs used with the procedure; and /or a history of dermatological keloid formation (Gregorio 2018).

Reported adverse events associated with XEN Gel implant include hypotony, hyphema, choroidal effusion, choroidal detachment, leaking bleb, bleb inflammation, subconjunctival hemorrhage, conjunctival erosion, conjunctival perforation, stent obstruction, implant migration, extrusion, brakeage, and implant exposure, and the need for secondary interventions and/or intraocular surgeries. Serious complications such as endophthalmitis, and visual acuity loss due to retinal detachment have also been reported (Kerr 2018, Lapira 2018, Lim 2018, Arnold 2019).

Conclusion:

- There is no published high-quality evidence from randomized controlled trials (to date) to determine the comparative effectiveness and safety of XEN Gel implantation versus trabeculectomy or other minimally invasive procedure used to lower IOP in patients with open angle glaucoma uncontrolled with optimal local medications.

- Low quality evidence from several prospective and retrospective observational studies suggest that XEN Gel implant lowers the IOP and reduces the number of IOP- lowering medication used in selected patients with open angle glaucoma uncontrolled with optimal local medications. The results, however, must be interpreted with caution due to the non-randomized design, potential confounding, and other inherent limitations of observational studies.

- The success rates varied between studies from 37-68% depending on definition of success based on the level of IOP reached, duration of follow up, use of topical medications, and need for revision surgeries.

Back to Top

- XEN Gel implant is associated with intra-and post- operative adverse events (AEs). Many were reported to resolve spontaneously without the need for intervention. However, few were serious and /or required immediate and inevitable interventions.

- More than one third of the eyes require additional surgeries after XEN Gel implant.

Articles: The literature search did not identify any randomized controlled trials that compared the safety and efficacy of XEN45 Gel implant versus trabeculectomy or any other surgical procedure. The search revealed 3 systematic reviews with meta-analyses that pooled the results of the different of MIGS procedures, two studies (published in 3 articles on the earlier generations of the implant (XEN140 and XEN 63), around 10 observational studies with pre-post comparisons after XEN45 Gel implant with or without cataract surgery, and one retrospective observational study that compared the results the microstent implant to those of a trabeculectomy procedure.

The meta-analyses of studies on MIGS as well as the studies using the earlier generations of XEN Gel (60 and 140) were excluded. The observational study with a comparison group (Schlenker, 2017) was critically appraised (Evidence table 1) and the larger prospective and retrospective observational studies were summarized in a following table. See Evidence Table.

The use of Xen Gel Implant as a surgical treatment for glaucoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Xen Gel - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach

iStent and Hydrus - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (eg, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (eg, irrigation and aspiration or phacoemulsification); with insertion of intraocular (eg, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

Considered not medically necessary:

CPT® Codes	Description
0253T	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more

Back to Top

Cypass (no longer available) - Considered not medically necessary:

CPT® Codes	Description
0474T	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/06/2018	02/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC] , 02/07/2023[MPC]	01/27/2022

[MPC] Medical Policy Committee

Revision History	Description
06/05/2018	MPC approved criteria for commercial members
10/08/2018	Non-coverage language for the Cypass device
11/14/2018	Language regarding iStent added
08/06/2019	MTAC review for Xen Gel was added
11/15/2019	Added all requests for Xen Gel must go to Medical Director for review
04/07/2020	MPC approved to adopt new coverage criteria for Xen Gel & iStent/Hydrus as surgical treatments for glaucoma, effective 08/01/2020.
08/12/2020	Removed Non-Medicare criteria prior to 08/01/2020
01/27/2022	Updated applicable coding (removed deleted codes 0191T, 0376T, added 66989, 66991, 0671T)

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Deep Brain Stimulation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Deep Brain Stimulation for Essential Tremor and Parkinson's Disease (160.24)
Local Coverage Determinations (LCD)	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Deep Brain Stimulation (KP-0403) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

> ***MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Neurology, Neurosurgery)

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for the following:

- Refractory Obsessive - Compulsive Disorder
- Primary Headache
- Neuropathic Pain (see Background information in KP-0403)

(See also Occipital Nerve Stimulation for Primary Headache)

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Deep-brain stimulation (DBS) was first developed in the late 1980's. DBS involves ongoing electrical stimulation of a particular target in the brain and is designed to block the abnormal firing of neurons. The exact mechanism of action of DBS is not known. DBS has been used since the early 1990s to treat movement disorders such as Parkinson's disease, and, in 1999, the first report was published applying DBS to the treatment of refractory obsessive-compulsive disorder.

DBS consists of an insulated wire lead with four electrodes at its end that are surgically implanted into the affected area of the brain. A wire runs under the skin to a battery-operated pulse generator implanted near the

Back to Top

collarbone or in abdomen. The generator is programmed to send continuous low voltage electrical pulses to the brain. It can be turned on or off when the patient swipes a special magnet over the generator. (Movement disorders patients typically turn off the device at night, because tremors usually stop during sleep.) The voltage can be adjusted in relation to the symptoms being treated.

To implant the electrodes, a neurosurgeon uses a stereotactic head frame and magnetic resonance or computed tomography imaging to map the brain and pinpoint the problem area. The patient's scalp is anesthetized before the procedure, but the patient is awake to report side effects while the electrodes are placed. This allows the lead to be placed for maximum effectiveness and minimum side effects.

Evidence and Source Documents

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor
Globus Pallidus and Subthalamic Nucleus Stimulator Implant- Parkinson's
Refractory Obsessive-Compulsive Disorder
Primary Headache

Medical Technology Assessment Committee (MTAC)

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor

BACKGROUND

Essential tremor is the most common form of tremor that affects more than 1 million patients in the US. It is defined as tremor which is postural, usually involving the upper limbs, absent at rest, not exacerbated by movement and not of cerebellar or extrapyramidal origin. One of the symptoms of Parkinson's Disease is tremor. Treatment for mild cases of tremor involves pharmacologic therapy with propranolol or L-dopa for Parkinsonian tremor. Severe debilitating tremor is usually treated with stereotactic surgical thalamic ablation (thalamotomy). However, thalamotomy can result in clinically significant neurologic side effects and once lesioned, no further tremor control is possible. The beneficial effects of thalamic stimulation on tremor were first identified when stimulation was used to localize the electrode prior to making a lesion in the thalamus for tremor control.

Electrical tremor control systems consist of an electrode implanted in the thalamus connected to an implanted radio-frequency pulse generator. The stimulator is programmed for optimal tremor control by a Neurologist and can be turned on or off by the patient using a magnet.

04/19/1999: MTAC REVIEW

Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor

Evidence Conclusion: Several case series have been published examining the role of thalamic stimulation in essential tremor and in Parkinson's disease. It is clear that stimulation reduces contralateral upper limb tremor to a clinically significant extent. In essential tremor improvement was noted when performing activities such as writing, drinking and eating. Although quality of life was not formally assessed the degree of change is likely to be clinically important. In Parkinson's disease the utility of reducing tremor is less clear, with no change in ability to write, dress, cut food, or speak. Perioperative complications occur in approximately 10%, and at 12 months neurologic complications related to stimulus intensity are common, each of the following occurring in 2-4%: dystonia, dysarthria, paresthesia, and disequilibrium.

Articles: Koller, W, et al, High Frequency Unilateral Thalamic Stimulation in the Treatment of Essential and Parkinsonian Tremor, *Ann Neurol.* 1997, 42:292-299 See Evidence Table**.** Limousin, JD et al, Multicentre European Study of Thalamic Stimulation in Parkinsonian and Essential Tremor. *J Neurol. Neurosurg Psychiatry.* 1999:66:289-296 See Evidence Table**.** Ondo, W et al. Unilateral Thalamic Deep Brain Stimulation for Refractory Essential Tremor and Parkinson's Disease Tremor. *Neurology*, 1998;51:1063-1069 See Evidence Table.

Members noted that patients who had debilitating non-tremor symptoms of Parkinson's disease such as rigidity and cogwheel movements would probably not show clinically significant improvements in their ability to eat, write or drink and therefore the benefits of thalamic stimulation would probably not outweigh the harms of this invasive surgical procedure in this population.

Electrical stimulation of the thalamus for the treatment of essential tremor meets GHC Medical Technology Assessment Criteria 1-5 for effectiveness and 6 for appropriateness and is therefore considered to be medically appropriate for patients who have failed maximal medical therapy for controlling their tremor.

Thalamic stimulation for treatment of Parkinsonian tremor also meets GHC Medical Technology Assessment Criteria 1-6 only for patients whose primary functional disability is tremor despite maximal medical therapy.

Back to Top

10/03/2006: MTAC REVIEW
Electrical Stimulation of the Thalamus for Essential and Parkinsonian Tremor
Evidence Conclusion: The evidence on deep brain stimulation for treating Parkinson's disease consists of two randomized controlled trials. Both studies had results favoring deep brain stimulation. The stronger study methodologically found a statistically significant reduction in motor symptom scores in the group assigned to deep brain stimulation in a double-blind comparison to no stimulation (Deep Brain Stimulation Study Group, 2001). However, Medtronic, the device manufacturer funded the study and was responsible for data collection and analysis. The other randomized controlled trial found more improvement in quality of life and symptom severity scores in patients assigned to neurostimulation compared to medical management (Deutschl et al., 2006). Limitations of the latter study are the study was not blinded and study participants had already failed medical management. The Deutschl study was not funded by Medtronic, but several authors had financial links with the company.
Articles: Deutschl G, Schade-Brittinger C, Krack P et al. A randomized trial of deep-brain stimulation for Parkinson's Disease. *N Engl J Med* 2006; 355: 896-908. See Evidence Table.

Evidence updated but not brought to MTAC as no change from previous review outcome.

Globus Pallidus and Subthalamic Nucleus Stimulator Implant
BACKGROUND
Deep brain stimulation (DBS) is a technique that is being used to treat symptoms of Parkinson's disease (PD). The main pharmacotherapy for PD is levodopa. Although levodopa is generally initially effective at reducing symptoms of PD, it eventually leads to side effects such as dyskinesias in many patients. Surgeries such as thalamotomy, pallidotomy are other possible treatments. An advantage of DBS is that, unlike other surgeries, it does not create lesions or destroy brain tissue.

Deep brain stimulation involves implanting an electrode into a specific region of the brain using stereotactic neurosurgical techniques. The electrode is connected to a programmable pulse generator that generates high frequency stimulation (>100 Hz) in a target nucleus. The pulse generator is implanted below the clavicle.

Thalamic stimulation, used to treat tremor, is the most well-established application of DBS with Parkinson's patients (thalamic stimulation for tremor met MTAC evaluation criteria in April 1999). Other targets are the internal globus pallidus and subthalamic nucleus which are believed to be effective for treating a wider range of PD symptoms, including bradykinesia, rigidity dystonia and gait disorder, as well as tremor.

Medtronic, Inc. manufactures the device that provides deep brain stimulation (the Activa System). The FDA approved a version of this device in 1997 for stimulation of the thalamus to control Parkinson's tremor and essential tremor. In March 2000, an FDA panel gave a premarket approval with conditions for bilateral DBS for the treatment of other Parkinson's symptoms.

10/10/2001: MTAC REVIEW
Globus Pallidus and Subthalamic Nucleus Stimulator Implant
Evidence Conclusion: The highest quality evidence consisted of one study that had a double-blind randomized component. In the double-blind randomized assessment, the study found a statistically significant reduction in motor symptom scores during deep-brain stimulation of the subthalamic nucleus or pars interna of the globus pallidus compared to no stimulation. The case series portion of the study found that symptoms improved significantly with stimulation 3- and 6-months post-implantation compared to pre-implantation. There were a substantial number of adverse effects but no comparison with adverse effects with other treatments or no treatment. A limitation of the study was that Medtronic, the device manufacturer, not only funded the study but also was responsible for data collection and analysis.
Articles: The search yielded 146 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were a number of small studies (n=25 or less), mainly case series; one was an RCT with n=10. The strongest study was published after the formal search was conducted. This study included a randomized double-blind assessment of outcomes and the sample size was over 100. This partially randomized study was critically appraised: Deep-brain stimulation for Parkinson's disease study group. Deep-brain stimulation of the subthalamic nucleus or the pars interna of the globus pallidus in Parkinson's disease. N Engl J Med 2001;345: 956-63. See Evidence Table.

The use of Globus Pallidus and Subthalamic Nucleus Stimulator Implant in treatment of Parkinson's Symptoms does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Back to Top

Refractory Obsessive-Compulsive Disorder

BACKGROUND

Obsessive-compulsive disorder is a common psychiatric diagnosis, affecting approximately 3% of people worldwide (Burdick et al., 2009). For initial treatment of OCD, the American Psychiatric Association (APA) recommends cognitive behavioral therapy (CBT), pharmacotherapy with SSRIs, or a combination of the two. For patients who do not respond to monotherapy, the next step is either switching medications, augmenting with another medication, or adding CBT if not already initiated (Harvard Medical Letter, 2009).

Approximately 20-40% of patients have worsening symptoms despite conventional treatment. Surgery is an option for patients who experience severe and incapacitating symptoms in spite of multiple medication trials and/or medication and CBT. Primary surgical approaches are subcaudate tractotomy (creating a lesion beneath the head of the caudate nucleus in the substantial innominata), cingulotomy (radiofrequency ablation of the anterior cingulum), limbic leucotomy (combination of previous two procedures), and anterior capsulotomy (interrupting fibers between the thalamus and the anterior frontal lobe) (Burdwick et al., 2009).

Another potential alternative therapy for treatment-resistant patients is deep brain stimulation (DBS). DBS involves chronic electrical stimulation of a particular target in the brain and is designed to modulate transmission of the neural circuit. The exact mechanism of action of DBS is not known and this is an area of active research. DBS has been used since the early 1990s to treat movement disorders such as Parkinson's disease, and, in 1999, the first report was published applying DBS to the treatment of refractory OCD. The optimal target for DBS in OCD patients is still being determined (Burdwick et al., 2009).

In February 2009, the FDA approved a humanitarian device exemption for a deep brain stimulator for severe OCD by Medtronic (Reclaim device). The humanitarian device exemption is an FDA classification signifying that the technology is used to treat conditions that affect fewer than 4,000 new patients per year. The FDA reviews the safety of the device but does not require that efficacy is established before approval. The FDA decision stipulates that deep brain stimulation is indicated for treatment of OCT in adult patients who have failed at least three SSRIs, and it can be used as an adjunct to medication. DBS is contraindicated in patients exposed to diathermy or MRIs, or who are unable to properly operate the brain stimulator. Medtronic plans to release the product commercially in the United States in mid-2009 (Medtronic website; FDA documents).

The Reclaim device by Medtronic includes a neurostimulator that is implanted subcutaneously in the upper abdominal region. The neurostimulator produces electrical stimulation pulses that are carried to an implanted set of leads via a lead extension. The leads are stereotactically introduced into the target area of the brain and are fixed at the skull with a burr hole cap and ring. The neurostimulator is battery-powered. There are sparse clinical data on battery life. According to Medtronic, the battery is expected to last 6-16 months, or longer depending on the neurostimulator setting used. When the battery is depleted, it can be replaced surgically. The primary clinical data submitted by Medtronic for FDA approval was a case series of 26 patients treated at 3 centers in the US and one in Europe (FDA and Medtronic documents).

06/01/2009: MTAC REVIEW

Deep brain stimulation for the treatment of refractory obsessive-compulsive disorder

Evidence Conclusion: There is insufficient evidence to draw conclusions about the safety and effectiveness of deep brain stimulation for patients with refractory obsessive-compulsive disorder. The empirical literature consists of case series with 10 or fewer patients.

Articles: The Medline search limited to a range of clinical trials yielded 10 articles. No additional articles were identified on the manufacturer's Web site. There were no randomized controlled trials or non-randomized comparative studies. The empirical literature consisted of small case series, with sample sizes ranging from 4 to 10. The studies do not meet MTAC criteria for reviewable evidence which requires that studies are published and, for case series, has a minimum sample size of 25.

The use of Deep brain stimulation for the treatment of refractory obsessive-compulsive disorder does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Primary Headache

BACKGROUND

Headache is a major worldwide health problem disabling millions of people and resulting in considerable economic burden. Up to 40% of patients seen in major headache clinics suffer from chronic daily headache. Chronic headache disorders include migraine, cluster headache, cervicogenic headache, occipital neuralgia, and other types of primary headache (Maizels 1998, Jasper 2008).

Back to Top

Cluster headache (CH), an excruciating headache syndrome, is the most common type of trigeminal autonomic cephalalgias, and is thought to be the most severe primary headache disorder. 10-20% of CH patients develop a chronic form in which the attacks persist for more than one year without remissions, or with remissions lasting less than a month. Acute treatment for the attacks includes injectable or intranasal triptans or oxygen inhalation. About one percent will become refractory to medical treatment and fulfill the criteria of intractable headaches. These patients may get some relief with attack treatments, but the disorder could be disabling and may be associated with depression and suicidality (Magis 2007, Leroux 2008).

Migraine headache is a chronic headache that affects about 15% of the population and is one of the most common problems seen in emergency departments and doctors' offices. Migraine is believed to result from changes in the brain and surrounding blood vessels. The attacks typically last from 4-72 hours and vary in frequency from daily to less than one per year. Transformed migraines are chronic daily or almost daily headaches (>15/month) that lasts more than 4 hours. There is no cure for migraine, and medications can only help reduce the frequency and severity of disorder (Bigal 2008).
Cervicogenic headache is a chronic hemicranial pain that usually occurs daily. It usually begins at the suboccipital region and spreads anteriorly to the ipsilateral orbital, frontal, and temporal areas. It is typically unilateral bur occasionally affects the two sides. It is believed to be due to convergence of upper cervical and trigeminal sensory pathways allowing pain signals to refer from the neck to the trigeminal sensory fields of the head and face. Treatments with pain medication, physical therapy, manipulative treatment, and surgical interventions may provide only some inconsistent temporary relief of pain (Naja 2006).

Various ablative surgical procedures targeting the trigeminal nerve, or the cranial parasympathetic outflow have been tried to treat these patients with intractable headaches. These include gamma knife surgery or root section of the trigeminal nerve, trigeminal tractotomy, microvascular decompression of the trigeminal nerve, glycerol injection of the Gasserian ganglion, and others. However, none of these procedures has a consistent effect, and many are associated with serious complications (Magis 2007).

Electrical stimulation of the brain was first attempted late in the 19th century, but its application for pain control began in the 1960s with spinal cord stimulation. The neurostimulation technique for ablating pain is based on the theory that peripheral nerve stimulation can produce specific focal analgesia and anesthesia. In addition, the technique may alter perception of pain by blocking cell membrane depolarization and axonal conduction with directly applied current (Shealy 1967, Lim 2007, Trentman 2008).

In the early 2000s, neurostimulation therapy emerged as a potential treatment option for a variety of different intractable primary headache disorders. This is an invasive device- based approach that has two broad types:
1. Peripheral therapy that involves branches of the occipital nerve: occipital nerve stimulation (ONS), and supraorbital nerve stimulation.
2. Central which refers to deep-brain stimulation (DBS) approaches e.g. hypothalamic deep brain stimulation used for chronic cluster headache (Schwedt 2009).

The occipital nerve stimulators (ONS) are implanted surgically in a 3-phase procedure: Phase 1. An incision is made over the occipital region at the level of the first cervical vertebra for the subcutaneous implantation of bilateral electrodes. These are tunneled in a cephalad direction so that they come to lie across the path of the greater occipital nerve on each side of the head. Phase 2. Confirmation of the electrode position by testing each separately by an external stimulator. The operator gradually increases the amplitude delivered to the electrodes from 0 to 4 v, and the patient is asked to locate and describe any sensation he /she feels. Correct placement is confirmed by the patient describing a vibrating sensation that radiates at least 4 cm cephalad from the base of the skull, on the side of the tested electrode, and Phase 3. Implantation of the stimulator battery in the pectoral, abdominal, or gluteal region, and connecting it to the electrodes via subcutaneously tunneled leads. The procedure is performed under sedation or general anesthesia, however during the second phase the patients are required to be awake and to be able to identify the position of the occipital electrodes when the electric stimulus is applied. Potential complications of the procedure include lead migration, infection, localized pain, muscle spasm, and lack or loss of effect (Lim 2007, Trentman 2008).

The deep brain stimulation (DBS) of the posterior hypothalamus has been investigated in patients with chronic cluster headaches or SUNCT (short-lasting, unilateral, neuralgiform headache attacks with conjunctival injection and tearing). DBS involves MRI guided stereotactic placement of an electrode into the brain (e.g. thalamus, globus pallidus, or subthalamic nucleus). It is typically implanted unilaterally on the side corresponding to the most severe symptoms. The use of bilateral stimulation using two electrodes has been investigated in patients with bilateral, severe symptoms. Initially, the electrode(s) is/are attached to a temporary transcutaneous cable to validate treatment effectiveness and, if effective, the patient returns to surgery several days later for permanent

Back to Top

subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator. After implantation, noninvasive programming of the neurostimulator can be adjusted to control the patient's symptoms. The procedures can be performed only by a highly experienced neurosurgeon and may be associated with a small risk of mortality due to intra-cerebral hemorrhage. Before implantation, all patients must undergo complete preoperative neuroimaging to exclude disorders associated with increased hemorrhagic risk (Leon 2006, Bartsch 2008).

Neither the occipital nerve stimulation nor the deep brain stimulators are approved to date by the U.S. Food and Drug Administration for the treatment or prevention of primary headaches.

08/03/2009: MTAC REVIEW
Deep Brain Stimulation for the Treatment of Primary Headache
Evidence Conclusion: The literature on brain stimulation for the treatment of chronic primary headache is limited and does not provide sufficient evidence to determine the efficacy or safety of either occipital or deep brain stimulation therapy for the prevention or treatment of chronic headache. There are no published randomized or nonrandomized controlled trials on the intervention to date. The empirical studies consist of a few very small case series with no comparison groups and a number of case reports. The outcome measures varied between studies as some reported change in pain and others reported on headache frequency intensity, disability and/or medication use. To date all published studies on hypothalamic deep brain stimulation are small case series and case reports with a combined total of 55 participants with refractory chronic cluster headache. Leone et al's series had the largest size (N=16) and follow-up duration (mean 23 months). The results of this study and other case series indicate that this invasive procedure has potential serious complications and is not always effective. Deep brain stimulation was not compared to another treatment or intervention to determine that the benefit observed was no a placebo effect.
Articles: The search yielded almost four hundred articles. The majority was review articles, opinion pieces, or dealt with technical aspects the procedure. DBS: The search identified 12 small case series and reports with a total number of 57 patients on deep-brain stimulation for chronic cluster headache. Leone M, Franzini A, Broggi G, et al. Hypothalamic stimulation for intractable cluster headache; long-term experience. Neurology 2006:67:150-152. See Evidence Table.

The use of Deep brain stimulation for the treatment of primary headache does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays

Back to Top

61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure)
HCPC Codes	**Description**
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
L8679	Implantable neurostimulator, pulse generator, any type
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/03/2010	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 05/07/2013[MDCRPC], 12/03/2013[MPC], 04/01/2014[MPC], 02/03/2015[MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/02/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/02/2019	MPC approved to adopt indications for Mini-Mental State Examination with score of at least 24 and no evidence of severe depression

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Defecography for Diagnosing Defecation Disorders

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Magnetic Resonance Imaging (220.2)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Defecation is a highly complex physiologic process that requires normal colonic transit, ano-rectal sensation, expulsion force, and coordinated function of the pelvic floor for successful evacuation. A disturbance at any level of this process can lead to a defecation disorder (DD) (Maccioni 2013). DDs encompass a variety of clinical conditions including obstructed defecation syndrome, rectocele, rectal intussusception, rectal prolapse and enterocele. Patients typically report symptoms such as excessive straining, sensation of blockage, and a feeling of incomplete evacuation. Some patients even report a need to use digital maneuvers to defecate, and frequent use of enemas or suppositories. While the true prevalence of DD is unknown, the symptom of constipation is extremely common in the United States with a reported 5.7 million constipation-related physician visits in 2006 alone. While not life threatening, DDs can cause a considerable amount of morbidity and, in some cases, have devastating impacts on quality of life.

In most cases, diagnosis of DDs can be established accurately based on physical examination and detailed history. However, symptoms can be nonspecific and overlapping. While there is no gold standard for pinpointing the cause of DD, current practice guidelines from national bodies recommend physiological testing such as anorectal manometry (ARM) and rectal balloon expulsion tests (BET). In the event of equivocal results, however, direct visualization of the pelvic floor and lower bowel may be necessary (AGA 2013; Wald, Bharucha et al. 2014). Defecography, first described in 1952 by Wallden, was initially developed for the evaluation of outlet obstruction (Wallden 1952). Since then, however, defecography has evolved to not only detect structural abnormalities, but also to assess functional parameters. Although it has been recognized as a useful diagnostic technique, methods and interpretation of defecography have not yet been standardized. Conventionally, the technique involves placement of a contrast medium into the rectum, similar to the consistency of stool, and laterally imaging activity throughout defecation using fluoroscopy. Alternatively, defecography can also be performed in the supine or upright position with magnetic resonance imaging (MRI). In any case, interpretation of the imaging focuses on the anal rectal angle (ARA) at rest and during straining providing an indirect measurement of the function of the puborectalis muscle. Additionally, imaging can provide information about perineal descent, anal diameter, indentation of the puborectalis, and the amount of rectal and rectocele emptying.

Back to Top

Medical Technology Assessment Committee (MTAC)

Defecography for Diagnosing Defecation Disorders

10/20/2014: MTAC REVIEW

Evidence Conclusion: A 2011 study conducted in France by Vitton and colleagues compared the accuracy of both MRI defecography and dynamic anal endosonography (DAE) using conventional defecography as the gold standard. The study involved 56 female patients with a history of dyschezia. Patients received each procedure randomly over a one-month period. Using conventional defecography as the criterion standard, the investigators calculated a range of sensitivities and specificities for detecting rectoceles, perineal descent, and enterocele. For both DAE and MRI, the sensitivities were highest in detecting rectoceles at 73.5% and 81.6%, respectively. For detecting perineal descent and enterocele the sensitivities were 61% and 58.3% for DAE and 46.3% and 66.7% for MRI. Specificities were 100% in both DAE and MRI for identifying enteroceles. The specificities were lower for perineal descent 73.3% (DAE) and 86.7% (MRI) and rectoceles 85.7% (DAE) and 85.7% (MRI). Although MRI defecography performed better than DAE no significant differences were observed between the diagnostic techniques and both correlated well with conventional defecography under the Youden index and the Yule correlation coefficient. Regardless, conventional defecography is an imperfect gold standard limiting the value of these results (Vitton, Vignally et al. 2011). Foti and colleagues also prospectively compared conventional and MRI defecography. In this study, 19 consecutive patients with outlet obstruction syndrome (OOS) underwent both conventional and MRI defecography. With the overall aim to develop a protocol for MRI defecography the comparisons between the two techniques showed no significant differences in sphincter hypotonia, dyssynergia, rectocele and rectal prolapse. Significant differences were, however, seen in descending perineum. Ultimately, the authors concluded that while MR imaging provides morphological and functional study of pelvic floor structures it cannot replace CD and may offer benefit if offered as a complementary tool to CD in evaluating OOSs (Foti, Farina et al. 2013). In a meta-analysis that sought to estimate the prevalence of abnormal findings associated with dyssynergic defecation across testing modalities, 79 studies including 7,581 patients were pooled and analyzed. The overall prevalence of any single abnormal dynamic pelvic floor test ranged from 14.9% to 52.9% with a median of 37.2%. The investigators note that the prevalence of abnormal tests tended to be lower in defecographic studies accounting for the lower end of this range. In addition to identifying a high prevalence of dyssynergic defecation in patients with chronic constipation, the investigators suggest that the lower prevalence of abnormalities found with defecography supports the use of ARM and BET for initial evaluation (Videlock, Lembo et al. 2013). None of the selected studies overtly assessed the safety and harms of defecography however, theoretically, the harms of conventional defecography include all those that we know to be associated with radiation exposure. In the study by Vitton and colleagues, patient tolerance and preference for assessment procedures was examined using a visual analogue scale. Tolerance was rated “high” or “very high” more frequently in the MRI defecography group (44.9%) than in the conventional defecography group (36.7%), although this difference was not significantly significant (P=0.9). This partiality was mirrored in a 2012 study, by Pilkington and colleagues, assessing patient acceptance of conventional and MRI defecography. In this study, the investigators administered questionnaires to 42 patients undergoing defecography (of these patients 25 patients completed for both conventional and MRI defecography). Over half of patients (62%) who underwent both procedures identified MRI proctography as the preferred technique. When asked why, all of these patients cited ‘less embarrassing’ as the reason for preference (Pilkington, Nugent et al. 2012). The clinical utility of diagnostic tests for constipation in adults was examined in a 2005 systematic review by Rao and colleagues. The investigators were able to identify ten case series related to the use of defecography. Although the results of the included studies did not allow for meta-analysis, the investigators found the results of the included studies to be conflicting citing significant overlap of findings between patients and healthy controls and poor correlation of symptoms with defecographic findings. Ultimately, defecography was recognized as a useful source of information regarding the anatomical and functional changes of the anorectum but concluded that the technique should only be regarded as an adjunct to clinical assessment and not relied upon as a sole diagnostic test. This study was not critically appraised due to lack of meta-analysis (Rao, Ozturk et al. 2005). Overall, the literature should be interpreted with caution. Beyond the heterogeneous nature of the populations across the literature, an inherent difficulty of evaluating the accuracy of defecography is that there is the lack of a true gold standard. To add to this, diagnostic criteria are continually changing inhibiting the ability to establish a standard technique or interpretation. Without adequately defined ranges for quantified measures and parameters interpretation relies on opinion rather than objective findings. Beyond that, no studies have been able to demonstrate that defecography contributes to improved diagnosis and more appropriate patient management.

Conclusions: There is insufficient evidence to conclude that defecography is accurate in the evaluation of DD. There is insufficient evidence to conclude that defecography is not harmful to patients. There is insufficient evidence to conclude that defecography contributes to improved diagnosis of DD. There is insufficient evidence to conclude that defecography leads to more appropriate management of patients with DD.

Back to Top

Articles: The literature search revealed just over 200 publications addressing defecography, the majority of which were continuing medical educational materials, manuscripts or editorials. The remainder was comprised of small studies either describing various techniques or attempting to establish standards for interpretation. No studies were identified that aimed to assess the accuracy of conventional defecography by comparing the technique to other available techniques. The best available evidence came from two prospective studies comparing conventional defecography with MRI defecography and one meta-analysis comparing different testing modalities in the assessment of chronic constipation. The following articles were selected for critical appraisal: Vitton V, Vignally P, Barthet MB, et al. Dynamic anal endosonography and MRI defecography in diagnosis of pelvic floor disorders: comparison with conventional defecography. Diseases of the colon & Rectum 2011;(54) 11:1398-1404. See Evidence Table 1. Foti PV, Farine R, Riva G, et al. Pelvic floor imaging: comparison between magnetic resonance imaging and conventional defecography in studying outlet obstruction syndrome. Abdominal Radiology 2013;(118) 1:23-39. See Evidence Table 2. Videlock EJ, Lembo A, Cremonini. Diagnostic testing for dyssynergic defecation in chronic constipation: meta-analysis. Neurogastroenterology & Motility 2013;(25) 6:509-519. See Evidence Table 3.

The use of Defecography for Diagnosing Defecation Disorders does not meet the *Kaiser Permanente Medical Diagnostic Test Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary -

CPT® or HCPC Codes	Description
72195	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)
72196	Magnetic resonance (eg, proton) imaging, pelvis; with contrast material(s)
72197	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences
	With diagnosis codes
K59.00	Constipation, unspecified
K59.01	Slow transit constipation
K59.02	Outlet dysfunction constipation
K59.03	Drug induced constipation
K59.04	Chronic idiopathic constipation
K59.09	Other constipation
K59.4	Anal spasm
K62.89	Other specified diseases of anus and rectum

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/28/2014	11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC, 02/07/2023MPC	11/04/2014

MPC Medical Policy Committee

Revision History	Description

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Dermatology Services

Cosmetic vs Medical for the following:

- Alopecia, Keloids, Laser Treatments, Benign Lesions
- Broad Band UVB Therapy
- Excimer Laser for Vitiligo
- Home Narrow Band UVB Therapy for Psoriasis
- Narrow Band UVB Therapy
- PUVA Therapy
- UV Lights

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Laser Procedures (140.5) Treatment of Psoriasis (250.1) Treatment of Actinic Keratosis (AKs) (250.4) Durable Medical Equipment Reference List (280.1)--*(for home phototherapy requests outside of **psoriasis diagnosis** please defer to Kaiser Permanente Medical Policy below)*
Local Coverage Determinations (LCD)	Benign Skin Lesion Removal (Excludes Actinic Keratosis, and Mohs) (L33979) Plastic Surgery (L37020) Mohs Micrographic Surgery (L35704)
Local Coverage Article	Local Coverage Article: Additional Information Required for coverage and pricing for Category III CPT® Codes A55681- RETIRED 06/30/2020 Noridian retired **Local Coverage Article (LCA A55681).** These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on Kaiser Permanente commercial criteria or literature search. ***includes CPT 0479T, 0480T***

Back to Top

Kaiser Permanente Medical Policy	For phototherapy requests other than Psoriasis (see above) such as Eczema 96900, 96910, as well as other dermatological conditions: Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **for in office or home UVB Phototherapy use Phototherapy, Skin (KP-0255 v2) MCG** for medical necessity determinations.

For Non-Medicare Members

1) The following treatments are considered cosmetic and are therefore not covered:
   a) Botulinum injections for treatment of wrinkles and facial imperfections (for covered indications for botulinum injections see the pharmacy prior authorization criteria)
   b) Tattoo removal (CPT 15783)
   c) Laser treatment of pigmented lesions, rosacea, superficial leg and face veins, cherry angiomas, telangiectasias, spider angiomas, or spider veins/venous ectasias
   d) Chemical peel (CPT 15788, 15789, 15792, 15793, 17360)
   e) Micro-dermabrasion (No codes specific for this service)
   f) Dermabrasion (CPT 15780, 15781, 15782, 15783, 15786)
   g) Acne scar repair (CPT 15780)
   h) Tattooing, depigmentation, and melanocyte transplant for vitiligo

2) The following treatments are covered and are not considered cosmetic when conditions are met:
   a) ***Alopecia treatment*** when the alopecia results from **ONE of the following**:
      - Infection (treatment is for the infection)
      - Autoimmune disorder
      - Discoid lupus
      - Low iron stores
      - Folliculitis decalvans

      Laser treatment services described in 2b no longer require medical necessity review (CPT: 17000, 17003, 17004, 17106, 17107, 17108, 17110, 17111, and 17250)
   b) **Laser treatment** for **ONE of the following**:
      - Port wine stain on head or neck
      - Telangiectasias scarring when caused by removal of skin cancer or radiation therapy
      - Facial angiofibroma secondary to tuberous sclerosis
      - Vascular lesions with history of spontaneous bleeding as documented in the patient's medical record
      - Actinic Keratoses (AK) for chemo sensitive agents

   c) **Excimer Laser** (CPT code 96920, 96921, 96922) is covered when **ALL of the following** are meet:
      1. Member must have **ONE of the following** conditions:
         a. Vitiligo: vitiligo on the face, neck or hands.
         b. Psoriasis: scalp, face, neck or hands
      2. There must be documentation of the failure of medical management with topical therapy

   d) **Scar/keloid revision**: Kaiser Permanente has elected to use the Scar Revisions (KP-0495) MCG* for medical necessity determinations.

   e) **Fractional Laser for burns and traumatic scars:** *Currently not covered due to lack of efficacy per the published medical literature (0479T, 0480T).*

   f) Removal of **benign skin lesions** (seborrheic keratoses, skin tags, milia, molluscum contagiosum, sebaceous (epidermoid) cysts, moles (nevi), acquired hyperkeratosis (keratoderma) and viral warts) are medically necessary and not cosmetic and are covered when **ONE or more of the following** criteria are met:
      1. The clinical diagnosis is uncertain, particularly where malignancy is a realistic consideration based on lesion appearance (non-responsive to conventional treatment or change in appearance).
      2. The lesion has **ONE or more of the following** characteristics:

Back to Top

- Bleeding
- Intense itching
- Pain
- Has physical evidence of inflammation (purulence, oozing, edema, erythema, etc.)
- Clinically restricts an orifice or vision
- Is in an anatomical region subject to recurrent physical trauma and there is documentation of resulting pain, itching, or bleeding

g) **Laser/intense pulse light treatment** is covered for hair removal when the excess hair is a result of a documented endocrine abnormality confirmed by blood test. (commonly submitted with CPT 17999)

h) **PUVA:** Kaiser Permanente has elected to use the Skin Phototherapy (PUVA) (KP-0253) MCG* for medical necessity determinations. CPT code 96912, 96913

i) **UVB:** Kaiser Permanente has elected to use the Phototherapy, Skin (KP-0255 v2) MCG* for medical necessity determinations. CPT code 96900, 96910

j) **Home narrowband UVB phototherapy** is covered for qualifying conditions per Phototherapy, Skin (KP-0255 v2) MCG* when:
- The member has durable medical equipment coverage
- The light is ordered by a dermatology provider
- Home phototherapy requires initial support/teaching for frequency, dose of treatment to avoid over or undertreatment as well as follow up on a regular basis to ensure correct treatment, as arranged by the ordering provider

Related criteria:
Electronic Brachytherapy for non-melanoma skin cancer
Dermal Fillers for Facial Lipoatrophy

*** MCG Manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist (dermatology, surgery notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Dermatology services include a wide array of therapies. Some therapies are purely cosmetic, others are considered from a benefits standpoint to be "medically necessary" and relate to function and/or have an impact on an individual's physical, social and/or mental well-being.

The purpose of expanding the criteria set is to distinguish between dermatology services that are considered purely cosmetic versus those which are seen as medically necessary and are covered in part or whole. The creation of the criteria set incorporated what was previously found in coverage policy and other reference documents.

Medical Technology Assessment Committee (MTAC)

Home Narrowband UVB Phototherapy

BACKGROUND

Psoriasis is a chronic skin disease that affects 1-3% of the population. With psoriasis, the life cycle of skin cells is

Back to Top

shortened from about a month to a few days. Consequently, cells build up rapidly on the outer layer of skin, forming thick erythematous plaques that are often pruritic. (Mayoclinic.com; BMJ clinical evidence). Treatments for psoriasis include: 1) self-care: baths, avoidance of alcohol, moisturizer; 2) topical medications: corticosteroids, vitamin D analogues, anthralin, retinoids; 3) oral medications: retinoids, methotrexate, azathioprine, cyclosporin, immunomodulator drugs (biologics); 4) phototherapy; 5) combination therapy e.g. phototherapy and oral medications. The biologic Etanercept is current covered by GHC for patients with extensive, severe psoriasis who meet the following criteria: failed topical treatments, failed at least one systemic agent (e.g. methotrexate), and failed a 12-week course of phototherapy. Phototherapy is one of the more commonly used treatments for psoriasis. The rationale behind phototherapy is that it causes photochemical reactions of endogenous absorbing molecules results in reduction of DNA synthesis that leads to a treatment effect. The therapy was first proposed in the 1920s by Dr. Goeckerman at the Mayo clinic who found a beneficial effect of natural sunlight in combination with coal tar. In the 1970s, it was shown that broadband ultraviolet B (UVB) radiation alone could treat milder clinical forms of psoriasis. After experimentation with different wavelengths, it was found that wavelengths between 311-313 nm were best at balancing the clearing of psoriasis while at the same time minimizing the adverse effect of erythema. The first well-designed lamp that emitted narrow-band radiation at 311-313 nm, the Phillips TL-01 fluorescent lamp, was introduced in 1984 (Kist, 2005; Honigsmann, 2001). The main treatment-limiting side effect of narrowband UVB is erythema, reported by 10-94% of patients depending on treatment regimen and definition of erythema. Other short-term side effects include dry skin with pruritis, blistering, and increased frequency of recurrent herpes simplex outbreaks. Long-term side effects, as with other types of phototherapy, include photo ageing and skin cancer. However, the incidence of skin cancer in patients with psoriasis treated with narrowband UVB is not well known (Kist et al., 2005, Naldi et al., 2005). The recommended initial treatment dose of narrowband UVB is 50-80% of a patient's minimal erythema dose (MED), established through phototesting. This is followed by increases of 10-40%, depending on the aggressiveness of the treatment and the patient's response (Kist, 2005; Honigsmann, 2001). The American Academy of Dermatology guidelines recommend giving up to 20-25 treatments of narrowband UVG, 2-3 times a week (Menter et al., 2008).

10/06/2008: MTAC REVIEW
Home Narrowband UVB Phototherapy
Evidence Conclusion: There is insufficient evidence to draw conclusions about the safety and effectiveness of home narrowband UV-B phototherapy for patients with psoriasis. There are no published randomized or non- randomized trials that use modern home phototherapy equipment. Findings from an RCT are expected to be published within the next 3-6 months.
Articles: A 2006 review article (Koek et al., 2006) on home ultraviolet B phototherapy for psoriasis identified 7 empirical clinical studies, 5 of which were published in English. 3 of the 5 studies in English were published between 1979-1983, before the introduction of the Phillips TL-01 fluorescent lamp. Thus, they did not use currently available phototherapy technology. Both of the more recent studies (Cameron et al., 2002; Feldman et al., 1996) were case series with fewer than 25 patients. One of the 3 older studies (Paul et al., 1983) had a comparison group, the others were case series. The Paul et al. study, which included 40 patients, compared the efficacy of a Metec-Helarium unit emitting low-intensity selective UV phototherapy (LISUP) at home to 3 times/week in-office UVB therapy. In-office UVB therapy was found to be more effective than home LISUP treatment; 90% (18/20) of patients in the UV-B group experienced clearing of psoriasis compared to 40% (8/20) of patients in the home LISUP group. No additional completed studies were identified that compared home UVB phototherapy to in-office UVB phototherapy or to a different type of treatment. A published protocol for an RCT was identified (Koek et al., 2006). This trial, called the PLUTO study, is a multi-center trial comparing home UVB treatment to in-center UV-B phototherapy in 196 patients with psoriasis. The home phototherapy treatments is Waldmann UV-100 unites with TL-01 lamps. According to the lead author (personal communication), a manuscript on the study outcomes is currently under review by the BMJ.

The use of Home narrowband UVB phototherapy in the treatment of psoriasis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/05/2009: MTAC REVIEW
Home Narrowband UVB Phototherapy
Evidence Conclusion: PLUTO study (Koek 2009) on home versus outpatient ultraviolet B phototherapy for psoriasis randomized 196 patients (in the Netherlands) with mild to severe psoriasis and clinically eligible for narrowband ultraviolet B phototherapy, to receive the treatment at home or in an outpatient setting. The trial had valid methodology and design as a noninferiority study. The patients and providers were not blinded, however assessment of the severity of and extent of the disease were evaluated by an independent research nurse blinded to the treatment arms. The results of the trial indicate that home phototherapy was not inferior to that provided in outpatient department, mainly for the self-administered psoriasis area and severity index (SAPASI) 50, 75, and 90 (i.e. proportion of patients achieving at least 50%, 75%, or 90% decline of baseline SAPASI at the end of therapy) as well as the psoriasis area and severity index (PASI) 90. However, the possible inferiority of home ultraviolet phototherapy to that provided in an outpatient setting,

Back to Top

could not be entirely excluded for the primary outcome of PASI 50, or PASI 75, as the lower limits of the 95% confidence intervals were slightly lower than -15% preset noninferiority margin. The differences observed in SAPASI and PASI results may indicate a bias in the patient's self-assessment. The results of the trial also showed that patients in the home therapy group had a significantly higher mean number of irradiations, but an insignificantly higher cumulative dose at the end of therapy. 87% of the all participants had at least one occurrence of mild erythema, 58% a burning sensation, and 39% severe erythema with no significant differences between the two study groups. No significant differences were observed in the disease specific or generic quality of life among patients treated on outpatient setting or at home. The home therapy however, was associated with a lower burden of treatment and greater patient satisfaction.

Articles: A study on home versus outpatient ultraviolet B phototherapy for psoriasis was recently published in BMJ in 2009. Koek MB, Buskens E, vanWeelden H, et al. Home versus outpatient ultraviolet B phototherapy for mild to severe psoriasis: pragmatic multicenter randomized controlled non-inferiority trial (PLUTO study). *BMJ* 2009; 338: b1542 doi 10.1136/bmj. b1542

The use of Home narrowband UVB phototherapy in the treatment of psoriasis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

Fractional carbon dioxide (CO_2) and erbium-doped yttrium aluminum garnet (Er:YAG) lasers are commonly used for treatment of excessive scarring. Laser therapy may be used to improve erythema, texture, pliability, and pain associated with burn and traumatic scars. Fractional laser ablation refers to the process in which a laser beam is split into hundreds of microbeams, which create small thermal injuries to the skin. It is believed that the injury caused by laser induces collagen formation and tissue remodeling. As opposed to ablative lasers, nonablative lasers induce coagulation only and do not cause epidermal injury and tissue vaporization.

Conclusion

An overall very-low-quality body of evidence is insufficient to draw regarding the efficacy and safety of CO2 fractional laser ablation or Er:YAG fractional treatment of burn or traumatic scars for functional improvement. Although most of the reviewed studies reported improved scar pliability following fractional laser treatment, this represents a surrogate outcome that does not directly address the primary Key Question. There is a large body of evidence on fractional laser ablation of hypertrophic scars and keloids; however, it primarily addresses cosmetic outcomes. The literature evaluating the impact of fractional laser treatment on functional outcomes is wholly comprised of case reports, which only supply anecdotal information. Large, well-designed trials of fractional laser treatment that directly address improvement of functional outcomes associated with scarring as a result of burns or trauma are needed.

Hayes Rating: D² --Insufficient Evidence: For carbon dioxide (CO^2) fractional laser ablation for functional improvement related to burn or traumatic scars. D² --Insufficient Evidence: For Erbium-doped yttrium platinum garnet (Er:YAG) fractional laser treatment for functional improvement related to burn or traumatic scars.

Hayes. Hayes Technology Assessment. *Fractional Laser Treatment of Burn and Traumatic Scars for Functional Improvement.* Dallas, TX: Hayes; May 11, 2021. Retrieved February 03, 2023, from https://evidence.hayesinc.com/report/htb.fractionallaser4442

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met (unless otherwise noted):

Alopecia Treatment

CPT® or HCPC Codes	Description
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
96902	Microscopic examination of hairs plucked or clipped by the examiner (excluding hair collected by the patient) to determine telogen and anagen counts, or structural hair shaft abnormality
With Diagnosis Codes	
L63.0	Alopecia (capitis) totalis
L63.1	Alopecia universalis

Back to Top

L63.2	Ophiasis
L63.8	Other alopecia areata
L63.9	Alopecia areata, unspecified
L64.0	Drug-induced androgenic alopecia
L64.8	Drug-induced androgenic alopecia
L64.9	Androgenic alopecia, unspecified
L66.2	Folliculitis decalvans
L66.8	Other cicatricial alopecia
L66.9	Cicatricial alopecia, unspecified

Benign Skin Lesions

CPT® or HCPC Codes	Description
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
11420	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.5 cm or less
11421	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 0.6 to 1.0 cm
11422	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 1.1 to 2.0 cm
11423	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 2.1 to 3.0 cm
11424	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter 3.1 to 4.0 cm
11426	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia; excised diameter over 4.0 cm
11440	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.5 cm or less
11441	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 0.6 to 1.0 cm
11442	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 1.1 to 2.0 cm
11443	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 2.1 to 3.0 cm
11444	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter 3.1 to 4.0 cm
14446	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; excised diameter over 4.0 cm
11450	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with simple or intermediate repair
11451	Excision of skin and subcutaneous tissue for hidradenitis, axillary; with complex repair
11462	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with simple or intermediate repair
11463	Excision of skin and subcutaneous tissue for hidradenitis, inguinal; with complex repair
11470	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with simple or intermediate repair

Back to Top

11471	Excision of skin and subcutaneous tissue for hidradenitis, perianal, perineal, or umbilical; with complex repair

Excimer Laser (Vitiligo & Psoriasis)

CPT® or HCPC Codes	Description
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
96921	Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm
96922	Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm

Home Narrowband UVB Phototherapy

***Note: Code E0691 can be ordered more than once (e.g., scalp and hand/foot device) or billed with codes E0692-E0694.**

CPT® or HCPC Codes	Description
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection
A4633	Replacement bulb/lamp for ultraviolet light therapy system, each

Fractional Laser for burns and traumatic scars

Medicare – Considered not medically necessary

Non-Medicare – Considered not medically necessary

CPT® or HCPC Codes	Description
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)

Laser/Intense Pulse Light Treatment for hair removal

CPT® or HCPC Codes	Description
No specific codes – ***c**ommonly submitted with CPT code 17999 Unlisted procedure, skin, mucous membrane and subcutaneous tissue*	

PUVA

CPT® or HCPC Codes	Description
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

Scar/Keloid Revision

Back to Top

CPT® or HCPC Codes	Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children
15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
23921	Disarticulation of shoulder; secondary closure or scar revision
24149	Radical resection of capsule, soft tissue, and heterotopic bone, elbow, with contracture release (separate procedure)
24925	Amputation, arm through humerus; secondary closure or scar revision
25907	Amputation, forearm, through radius and ulna; secondary closure or scar revision
25922	Disarticulation through wrist; secondary closure or scar revision
25929	Transmetacarpal amputation; secondary closure or scar revision
26121	Fasciectomy, palm only, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft)
26123	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft);
26125	Fasciectomy, partial palmar with release of single digit including proximal interphalangeal joint, with or without Z-plasty, other local tissue rearrangement, or skin grafting (includes obtaining graft); each additional digit (List separately in addition to code for primary procedure)
27594	Amputation, thigh, through femur, any level; secondary closure or scar revision
27884	Amputation, leg, through tibia and fibula; secondary closure or scar revision
31830	Revision of tracheostomy scar
67343	Release of extensive scar tissue without detaching extraocular muscle (separate procedure)
With Diagnosis Codes	
L73.0	Acne keloid
L91.0	Hypertrophic scar
L90.5	Scar conditions and fibrosis of skin

UVA

CPT® or HCPC Codes	Description
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B

Considered not medically necessary:

Botulinum Injections

CPT® or HCPC Codes	Description
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
64612	Chemodenervation of parotid and submandibular salivary glands, bilateral
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and

Back to Top

Date Sent: 4/29/24

	accessory nerves, bilateral (eg, for chronic migraine)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
64646	Chemodenervation of trunk muscle(s); 1-5 muscle(s)
64647	Chemodenervation of trunk muscle(s); 6 or more muscles

Tattoo Removal

CPT® or HCPC Codes	Description
15783	Dermabrasion; superficial, any site (eg, tattoo removal)

Chemical Peel

CPT® or HCPC Codes	Description
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
17360	Chemical exfoliation for acne (eg, acne paste, acid)

Micro-dermabrasion

CPT® or HCPC Codes	Description
No Specific Codes	

Dermabrasion

CPT® or HCPC Codes	Description
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)

Tattooing, Depigmentation, and Melanocyte Transplant for Vitiligo

CPT® or HCPC Codes	Description
No specific codes	

Acne Scar Repair

CPT® or HCPC Codes	Description
11400	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or

Back to Top

	legs; excised diameter 0.5 cm or less
11401	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 0.6 to 1.0 cm
11402	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 1.1 to 2.0 cm
11403	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 2.1 to 3.0 cm
11404	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter 3.1 to 4.0 cm
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
With Diagnosis Code	
L70.0	Acne vulgaris
L70.1	Acne conglobata
L70.2	Acne varioliformis
L70.3	Acne tropica
L70.4	Infantile acne
L70.5	Acne excoriee
L70.8	Other acne
L70.9	Acne, unspecified

Medical Necessity Review not required:
Laser treatment (described in 2b):

CPT® or HCPC Codes	Description
17000	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion
17003	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)
17004	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), premalignant lesions (eg, actinic keratoses), 15 or more lesions
17106	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq cm
17110	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions
17250	Chemical cauterization of granulation tissue (ie, proud flesh)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Dates Reviewed	Date Revised

Back to Top

Date Sent: 4/29/24

07/25/2002	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC] ,07/02/2013[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023 [MPC]	04/18/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Review History	Description
05/21/2015	Added CPT codes
09/01/2015	Excimer Laser: added scalp psoriasis as indication
02/02/2016	Home UVB Phototherapy: Add psoriasis as a covered indication
08/02/2016	Home UVB Phototherapy: Add diagnosis of eczema will be reviewed on a case-by-case basis
12/19/2017	Added Plastic Surgery LCD (L37020)
06/17/2019	Added Eczema as an indication to Home Narrowband UVB phototherapy
08/06/2019	Minor changes were made to benign skin lesions criteria to allow removal of warts
12/01/2020	MPC approved to adopt updates to the existing hybrid Phototherapy, Skin criteria, KP-0255, to expand coverage for additional indications including Granuloma annulare and Pityriasis lichenoides chronica for in-office and home phototherapy. Members must have durable equipment coverage and requires initial support/teaching by the ordering provider for home phototherapy. Requires 60-day notice, effective date 05/01/2021.
04/28/2021	Added diagnosis codes covered by Medicare for home phototherapy; removed retired LCD L35008
05/04/2021	Laser treatment services described in 2b in criteria above, and represented by CPT codes: 17000, 17003, 17004, 17106, 17107, 17108, 17110, 17111, and 17250, will no longer require medical necessity review. Requires 60-day notice, effective date October 1, 2021.
03/01/2022	Updated applicable codes.
10/28/2022	Updated Medicare Policy to defer to KP Non-Medicare criteria for phototherapy for skin conditions other than psoriasis.
11/01/2022	Updated Medicare Policy to defer to KP non-Medicare criteria for phototherapy for all skin conditions including home UVB.
02/07/2023	Clarified criteria for Fractional Laser Treatment of Burn and Traumatic Scars for Functional Improvement. Added Hayes Technology Assessment dated May 11, 2021, to references.
04/18/2023	Added retired Medicare Retired Local Coverage Article A55681 for supporting documentation

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Diabetes Tests and Supplies

- Home A1c Test
- iPort Injection Port

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Diabetes Tests and Supplies"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

Service	Criteria
• Home A1c Test • i-Port/i-Port Advance Injection Port	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Diabetes Sentry Monitor (no longer available)
GlucoWatch Biographer™ (no longer available)
Home A1c Test
iPort Injection Port

Medical Technology Assessment Committee (MTAC)

Diabetes Sentry Monitor

BACKGROUND

There is evidence that tight glycemic control is associated with a lower incidence of diabetic complications including reduced rates of retinal, neurologic, and renal damage. Strict control of blood glucose, however, is associated with an increased risk of hypoglycemia (DCCT Research Group, 1993).

Back to Top

Hypoglycemic episodes commonly occur at night. Mild episodes of nocturnal hypoglycemia are generally asymptomatic but may affect mood and well-being the following day. Recurrent exposure to nocturnal hypoglycemia may impair cognitive function. Severe episodes can cause convulsions and coma and may lead to cardiac arrhythmias resulting in sudden death. Strategies to reduce nocturnal diabetes include regular blood glucose monitoring, eating appropriate bedtime snacks, and use of short- and long-acting insulin analogues (Allen & Frier, 2003).

The Diabetes Sentry monitor is designed to monitor hypoglycemia and alert patients when they are experiencing physiological symptoms. The device was originally developed as the Sleep Sentry monitor in approximately 1980s. The device was later taken off the market and a re-designed version received FDA approval in 2003. In 2005, the FDA approved the name change to Diabetes Sentry. The device is manufactured by Diabetes Sentry Products in Bellingham, WA.

According to manufacturer's materials, the Diabetes Sentry monitors two symptoms of hypoglycemia: perspiration and drop in skin temperature (decrease of 2o F). Either of these symptoms will trigger an audible alarm loud enough to awaken most people. Patients are instructed that, when the alarm sounds, they need to verify whether they are in fact experiencing hypoglycemia with a blood glucose monitor. The company acknowledges that there are false-positive alarms since there are other reasons for nocturnal perspiration and temperature drop, for example, change in room temperature or a shift in blankets. The manufacturer estimates that there will be an approximately one false alarm per night. The device is designed for people with insulin-dependent diabetes who have a severe enough problem with nocturnal hypoglycemia that they are willing to accept false-positives.

Other potential limitations of the Diabetes Sentry monitor are that patients may forget to turn on the device and some individuals may not awaken when the alarm sounds. In addition, the device is not useful for patients with hypoglycemia unawareness since they may not perspire or experience a drop-in temperature during mild hypoglycemic episodes.

Unlike the Glucowatch, which is intended to measure blood glucose levels, the Diabetes Sentry measures symptoms of hypoglycemia (perspiration and temperature).

This is the first time that MTAC has reviewed the Diabetes Sentry.

Assessment objective: To evaluate the accuracy of the Diabetes Sentry for detecting hypoglycemic events. To evaluate the impact of device use on health outcomes (e.g. reduction in morbidity from hypoglycemia).

08/07/2006: MTAC REVIEW
Diabetes Sentry Monitor

Evidence Conclusion: There is no published evidence on the Diabetes Sentry approved by the FDA in 2003.

Articles: The search yielded 3 articles; all of these were small case series (n<25 each) and were published in the 1980s on the original Sleep Sentry device. There were no published articles evaluating the re-designed Diabetes Sentry device approved by the FDA in 2003.

The use of Sleep Sentry Monitor in the treatment of Diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

GlucoWatch

BACKGROUND

Intensive glucose control to maintain a lower level of blood glucose has been associated with fewer long-term complications of diabetes (e.g. UKPDS, 1998). Self-monitoring of blood glucose is an important part of a program to maintain tight glucose control. The standard procedure for self-monitoring of blood glucose involves frequent finger-stick measurements which can be painful and/or inconvenient for patients.

The GlucoWatch Biographer (Cygnus Inc., Redwood City, CA) is proposed as a non-invasive blood glucose self-monitoring device. The GlucoWatch Biographer was approved by the FDA to supplement (not replace) the information provided by standard finger-stick, glucose monitoring devices. The theoretical advantages of the GlucoWatch over standard self-monitoring procedures are increased convenience and less pain since patients could take fewer finger-stick measurements, increased accuracy of blood glucose levels through continuous monitoring and increased safety since the GlucoWatch has the capacity to sound an alarm when blood glucose reaches a dangerous level.

The GlucoWatch is worn on the forearm and has the appearance of a wristwatch. It extracts extracellular fluid by applying a low-level electrical current to the skin, a process known as reverse iontophoresis. The fluid is collected in gel discs on a single use component of the device, called the Autosensor. The fluid undergoes a chemical reaction after being catalyzed by glucose oxidate and. The GlucoWatch calculates a blood glucose level using the electrical signal produced by this chemical reaction, the strength of which is proportional to the glucose level.

 Back to Top

After a 3-hour warm-up period and calibration with a blood glucose level, the Autosensor provides up to 12 hours of glucose readings produced every 20 minutes. The Glucowatch displays the most recent glucose level and stores the remaining readings. It can be set to produce an audible alarm if the glucose level is above or below pre-specified limits. The alarm will also sound if the glucose level falls more than 35% compared to the last measurement, or if the device senses perspiration, which can interfere with functioning of the device and is also associated with hypoglycemia.
The FDA approved the GlucoWatch Biographer in March 2001 for individuals, age 18 and older. In August 2002, the GlucoWatch was approved for use by children between the ages of 7 and 17 years.

02/13/2003: MTAC REVIEW
GlucoWatch
Evidence Conclusion: *Children:* There is no published evidence on the efficacy of the GlucoWatch Biographer for monitoring blood glucose levels among children with diabetes.
Adults: There is no published evidence on whether use of the GlucoWatch Biographer improves health outcomes or glucose control among people with diabetes compared to standard self-monitoring techniques. The evidence on the accuracy of the GlucoWatch suggests that measurements are reasonably accurate compared to fingerstick measurements (approximately 70% of measurements would lead to clinically correct decisions and about 95% would lead to clinically acceptable decisions). However, the data may be biased because all studies were conducted by investigators affiliated with the device manufacturer, and most data were collected in a controlled clinical environment and accuracy may differ in a “real-life” setting.
Articles: The search yielded nine articles. One was an article reviewing several glucose monitoring devices, one was a report announcing the new technology, and the remaining seven were authored by the Cygnus Research Team. There were no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on health outcomes e.g. macrovascular or microvascular complications of diabetes. There were also no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on the ability to maintain tight glucose control. The empirical data all addressed the accuracy of the GlucoWatch to detect current blood glucose levels. All of the studies were conducted among adults. The two studies on accuracy with the strongest methodology were critically appraised. Features examined for study selection were sample size, thoroughness of methods description, setting (controlled environment vs. home setting) and comparison with finger-stick measurements. The following articles were reviewed: Tierney MJ, Tamada JA, Potts et al. Clinical evaluation of the GlucoWatch biographer: a continual, non-invasive glucose monitor for patients with diabetes. *Biosensors & Bioelectronics* 2001; 16: 621-629. See Evidence Table

The use of GlucoWatch in the evaluation of diabetic control does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Home A1c Tests
BACKGROUND
A1c (also known as hemoglobin HbA1c or HbA1c) gives information about the average blood glucose level over the previous 2-3 months and is the best measure of overall blood glucose control for patients with diabetes (Kaiser Permanente diabetes guideline). The A1c test measures the concentration of glycosylated hemoglobin in the blood. A1c forms when some of the glucose circulating in the blood binds irreversibly to hemoglobin A, forming a stable glycated hemoglobin complex. The A1c level is proportional to the amount of glucose in the blood over the life span of red blood cells. It does not fluctuate with daily blood glucose levels.
An HbA1c target of <7% is recommended for most patients with type 1 or type 2 diabetes. Research has found that, if a patient's HbA1c level is higher than 8%, reducing it by one-tenth (e.g., from 10% to 9%) will slow down damage to their body by about 50% from the current rate (DCCT Research Group 1997). The Kaiser Permanente diabetes glycemic control guideline recommends that people with diabetes routinely monitor their HbA1c every 6 months. For patients who have elevated blood glucose and are attempting to reduce their blood glucose levels, Kaiser Permanente recommends checking HbA1c every 3 months until the target level is reached.
HbA1c tests have traditionally been conducted in a health-care setting. Several in-home HbA1c tests have been cleared by the FDA. The FlexSite A1c At-Home test was FDA-approved in 1997 and is available over-the-counter. It includes a blood sample collection kit that uses treated filter paper for spotting blood. The patient provides one or two drops of blood to each of two target areas on the filter paper and lets the sample dry overnight. The dried blood sample is then mailed to the FlexSite lab where it is evaluated. Results are available by phone or mail. The manufacturer claims that its sample collection technique allows a dried blood sample to be transported for up to 12 days without significant artifactual in vitro glycation (manufacturer’s website; Parkes et al., 1999).
Another home A1c test was approved by the FDA in 2002 under the name Metrica A1cNow. It was cleared both for prescription and over-the-counter use. Beginning in 2004, the test has been distributed exclusively by Bristol-

 Back to Top

Meyers Squibb and it is now called the ChoiceDM A1c Home test. Unlike the FlexSite test, the Metrika A1cNow/Choice DM A1c Home test provides results at home. The test comes as a disposable, one-use device about the size of a pager. It incorporates microelectronics, optics and dry-reagent chemistry strips. Individuals collect a sample of whole blood via fingerstick or venipuncture, place the sample in a cartridge and mix it with the dilution solution provided by the manufacturer. The diluted sample is added to the monitor which activates the device (there are no buttons or switches, the device is self-activated). Activating the device causes blue microparticles conjugated to an anti-HbA1c antibody to migrate along the reagent strips. The amount of blue microparticles captured on the strips is proportionate to the amount of HbA1c in the sample. After about eight minutes, the results are displayed in numeric form on the digital display. Total hemoglobin in the sample is also measured (manufacturer's website; Kordella, 2002).

02/05/2007: MTAC REVIEW
Home A1c Test
Evidence Conclusion: No published evidence was identified on the Metrika A1cNow/Choice DM A1c Home test, the test that provides results to patients within minutes at home. In addition, there was no published evidence the ability of home A1c testing to improve clinical outcomes. One published study was identified on the FlexSite at-home A1c sampling kit, which requires mailing samples to a centralized laboratory. This study found that A1c levels using the usual method for analyzing in-home samples was highly correlated with two standard methods of establishing A1c levels. However, the accuracy e.g. sensitivity and specificity of any of the tests was not reported. In addition, the study involved having patients and staff collect blood samples, but the test results for the two types of samples were not reported in the analysis. The authors of the study had links to the test manufacturer which may have introduced bias.
Articles: No published studies were identified on the Metrika A1cNow/Choice DM A1c Home test. An FDA talk paper from 2002 states that the Metrica device was cleared for non-prescription use based on a study by the manufacturer comparing test results obtained by lay users to those obtained by medical professionals. The Medline search did not identify a published version of this study and the company did not respond to a request for the manuscript. One published study was identified on the Flexsite at-home test. This study was critically appraised: Parkes J, Ray R, Kerestan S et al. Prospective evaluation of accuracy, precision, and reproducibility of an at-home hemoglobin A1c sampling kit. Diab Tech Ther 1999; 1: 411-419. See Evidence Table.

The use of Home A1c tests in the treatment of diabetes does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

I-Port™ Injection Port
BACKGROUND
The I-Port is a device that is placed on the skin, and through which patients can self-administer subcutaneous injections of prescription medications using a standard syringe and needle. A removable insertion needle allows placement of the body of the I-Port device on the skin. The device is held in place by an adhesive pad and a soft cannula. The I-Port body is 1.5" (38mm) in diameter and 1/3" (9mm) tall. The disposable I-Port can be worn for up to 72 hours and, during this time, up 75 needle sticks can be made through the soft cannula. During an injection of medication, the needle of the syringe remains above the surface of the skin. Medication is delivered through the cannula into the subcutaneous tissue. The I-Port is manufactured by Patton Medical Devices, a company founded by K.K. Patton, the inventor of the device. The I-Port was approved by the FDA in September 2005 as a class II device judged to be substantially equivalent to predicate devices. It is approved for marketing to adults and children who require multiple daily injections of prescription medication, including insulin.
The manufacturer materials warns consumers to use as specified by a health care provider and not to re-use the I-Port, not to use the same I-Port for longer than 72 hours and not to use a needle longer than 8mm or thicker than 28 gauge when injecting into the I-Port. In addition, the I-Port website Q&A section states that irritation, inflammation and infection are rare, but the potential for these exist, especially when the skin surface is not adequately cleaned before application or when the device is improperly applied to the body.
There was one adverse event report on the FDA Manufacturer and User Facility Device Experience Database (MAUDE) database. This was a device malfunction that occurred on July 24, 2007 with a life-threatening patient outcome. Details of the event were not included in the report.

10/01/2007: MTAC REVIEW
I-Port™ Injection Port
Evidence Conclusion: There is no published evidence to support the use of the I-Port and no published information on the safety of the device.

 Back to Top

Articles: No published articles were identified.

The use of iPort in the delivering of prescription medications does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Home A1c- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use

iPort- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
A4211	Supplies for self-administered injections

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/13/2003	02/13/2003[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC], 11/07/2023[MPC]	11/03/2020

[MPC] Medical Policy Committee

Revision History	Description
11/03/2020	Removed Diabetes Sentry Monitor and GlucoWatch Biographer from list of services as the specific products are no longer available.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Frequent Hemodialysis - Greater Than 3 Days a Week

- Facility
- In Home
- Nocturnal
- Short Daily

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Frequency of Hemodialysis (L37504)
Local Coverage Article	Billing and Coding: Frequency of Hemodialysis (A55676)

For Non-Medicare Members

Standard hemodialysis 3 days a week is covered for members with end stage renal disease. For home dialysis the following additional criteria must be met:

1. The member is stable on dialysis.
2. The member is free of complications and significant concomitant disease that would render home dialysis unsuitable or unsafe.
3. The member or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen.
4. Adequate caregiver is available during dialysis
5. Back-up arrangements have been made with the facility-based dialysis center.

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

End-stage renal disease (ESRD) is defined as an irreversible decline in kidney function that is severe enough to be fatal without treatment. In 2008, the prevalence of ESRD in the United States was 547,982 (Collins 2011). Treatment options for patients with ESRD include kidney transplantation and dialysis. Kidney transplantation is

Back to Top

the preferred treatment for ESRD; however, the demand for kidney transplant exceeds the supply of transplantable organs (Pauly 2009). Of the 547,982 patients with ESRD, approximately 382,343 patients received dialysis (Collins 2011).

Dialysis filters blood to rid the body of harmful wastes, extra salt, and water. There are two types of dialysis peritoneal dialysis and hemodialysis. The majority of patients are treated using hemodialysis; however, there is no consensus on the optimal dose and frequency of hemodialysis. Difference hemodialysis regimens include: conventional hemodialysis, nocturnal hemodialysis, and short-daily hemodialysis (Toussaint 2010).

There are two types of dialysis: 1) Peritoneal dialysis: Removes waste products via the peritoneum, the membrane that lines the inside of the abdomen. The membrane is bathed in a special fluid called dialysate that is placed into the abdomen through a small tube, and after a designated period of time, the fluid is drained and replaced by new fluid. 2) Hemodialysis: Access is through surgical placement of an arteriovenous fistula, generally in the forearm, and less commonly by a venous catheter. After access is established, the fistula is connected to a hemodialysis machine that drains the blood, bathes it in dialysate solution and returns it to the bloodstream.

Conventional hemodialysis consists of three treatment sessions per week, with each session lasting 3 to 5 hours. Treatments can be performed in a dialysis center, hospital, or at home. Although this is a life-saving treatment, mortality in patients with ESRD is still remarkably high. Compared to the general population, mortality is four times higher in patients under 30 receiving dialysis and six times higher in patients over 65. Additionally, patients receiving dialysis often experience hypertension, fluid overload and the attendant cardiac sequelae, anemia, mineral and bone disorders, inflammation, poor nutritional status, poor functional status, and psychological disorders (Bayliss 2009, Ng 2010). Moreover, this approach to dialysis is inconvenient for patients receiving treatment in a dialysis center or hospital, who must travel to a dialysis unit several times a week.

Both nocturnal hemodialysis (typically 6-8 hours, 3-7 nights per week) and short-daily hemodialysis (typically 1.5-3 hours, 4-6 days per week) can take place at home or at a dialysis center. It is thought that increasing the frequency and duration of hemodialysis will lead to less fluid gain leading to improved blood pressure control, increased hemodynamic stability, and increased efficiency of solute clearance. A potential harm is an increased risk of vascular access complications due to more frequent use (Ng 2010, Toussaint 2010).

There are several hemodialysis devices approved by the FDA for home use. Some are large, non-portable devices that require modifications to the home electrical and plumbing systems. These include the Fresenius 2008K and the B. Braun Dialog Plus. Others are smaller and portable. The NxStage System One is specifically designed for home use; it does not require infrastructure changes.

Medical Technology Assessment Committee (MTAC)

Frequent Home Dialysis

08/04/2008: MTAC REVIEW

Evidence Conclusion: on home nocturnal or short daily dialysis versus in-center dialysis 3 times a week:
One RCT and two cohort studies were identified that compared nocturnal home dialysis to in-center dialysis 3 times a week. The RCT (Culleton et al., 2007) found statistically significant improvement in the primary outcome, LV mass, a surrogate marker for cardiovascular disease. Among other secondary outcomes, phosphate level was significantly lower in the nocturnal home dialysis group, and there was no significant between group differences in calcium level and anemia. Two cohort studies matched patients who received nocturnal dialysis to similar patients receiving conventional in-center dialysis 3 times a week. Bergman et al. (2008) found significantly lower dialysis-related or cardiovascular-related hospital admissions (the primary outcome) in the group converted to nocturnal dialysis, but no significant difference in all-cause hospitalization. Schwartz et al., (2005) also had significant findings for the primary study outcomes, increase in hemoglobin concentration and increase in the proportion of patients who were EPO-free after 12 months. None of the studies had mortality as an outcome. There are fewer published studies on short-daily dialysis. A statistical analysis (Blagg et al., 2006) found a lower mortality rate in 117 patients who received short-daily dialysis either in-center or at home compared to national rates on patients receiving conventional hemodialysis (standardized mortality ratio=0.39). Patients who received short-daily dialysis may have differed from those in the national database, and there were financial links between the authors of this study and the home dialysis device used in the study.
Evidence on home nocturnal or short daily dialysis versus home dialysis 3 times a week:
No randomized controlled trials were identified, and there were no comparative studies with mortality as an outcome. The highest grade of evidence comparing different frequencies of home nocturnal dialysis is a retrospective cohort study by Mahadevan and colleagues (2006). The investigators evaluated biological

Back to Top

parameters in 13 patients receiving nocturnal dialysis 6 nights a week and 21 patients receiving nocturnal dialysis every other night (3-4 times a week). After 3-6 months of follow-up, levels of urea, creatinine and PTH were all significantly lower in the group treated 6 nights/week, and there were no significant differences between groups in phosphate, calcium, albumin and homocysteine levels, or in use erythropoietin or phosphate binders. There were no significant differences at follow-up in the proportion of patients taking phosphate binders, calcitriol, blood pressure medications or erythropoietin. The evidence is limited due to lack of randomization (there may have been pre-existing differences between groups) and the small sample size (may be underpowered).
There is no high-grade evidence on health outcomes associated with short daily dialysis at home versus home hemodialysis 3 times a week.
Conclusions:
Objective 1:

- There is insufficient evidence that home nocturnal dialysis improves important health outcomes compared to in-center dialysis. An RCT found improvement in LV mass and phosphate level, intermediate outcomes, and mixed findings in QOL. There is weak evidence from a single cohort study that nocturnal dialysis lowers the rate of dialysis-related or cardiovascular-related hospitalizations. In this cohort study, all-cause hospitalizations did not decrease significantly.
- There is insufficient evidence that home short-daily dialysis improves health outcomes compared to in-center dialysis. One statistical analysis found a lower mortality rate with short daily dialysis compared to national rates, but patients may have differed in ways that affect outcomes, and there was potential financial bias.

Objective 2:

- There is insufficient evidence that home nocturnal dialysis 6 nights a week improves important health outcomes compared to home hemodialysis 3 times a week.
- There is insufficient evidence that home short-daily dialysis 5 or more times a week improves important health outcomes compared to home hemodialysis 3 times a week

Articles: Assessment objectives:

1) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional in-center dialysis 3 times a week.
2) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to home dialysis 3 times a week.

Important health outcomes are survival, hospitalizations and quality of life.
Objective 1: Comparison with in-center hemodialysis One randomized controlled trial (Culleton et al., 2007) and two cohort studies (Bergman et al., 2008; Schwartz et al., 2005) comparing frequent nocturnal home hemodialysis to in-center hemodialysis were identified and critically appraised. Case series were not reviewed due to the availability of higher-grade evidence. The studies on short-daily hemodialysis were all case series. Most were small (<15 patients) and or included patients who primarily received dialysis in-center and thus were not suitable for critical appraisal. The strongest study identified compared outcomes in 117 patients on short-daily dialysis (84% at home) to outcomes of patients from a national database receiving conventional dialysis (Blagg et al., 2006). The Blagg study was critically appraised. *Objective 2: Comparison with home hemodialysis 3 times a week*
One comparative study was identified, and critically appraised (Mahadevan et al., 2006). This was a small retrospective cohort study comparing outcomes in patients who received home nocturnal dialysis either six nights per week or on alternate nights (3-4 times a week). An RCT by the Frequent Hemodialysis Network (FHN) is underway comparing nocturnal home hemodialysis 3 versus 6 times a week. The study is currently recruiting patients; the estimated completion date is January 2010 (Clinicaltrials.gov). *Studies reviewed include:*
Blagg CR, Kjellstrand CM, Ting GO, Young BA. Comparison of survival between short-daily hemodialysis and conventional hemodialysis using the standardized mortality ratio. Hemodialysis International 2006; 10: 371-374. See Evidence Table Culleton BF, Walsh M, Klarenbach SW et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life. JAMA 2007; 298: 1291-1299. See Evidence Table Bergman A, Fenton SSA, Richardson RMA, Chan CT. Reduction in cardiovascular related hospitalization with nocturnal home hemodialysis. Clin Nephrol 2008; 69: 33-39. See Evidence Table Schwartz DI, Pierratos A, Richardson RMA et al. Impact of nocturnal home hemodialysis on anemia management in patients with end-stage renal disease. Clin Nephrol 2005; 63: 202-208. See Evidence Table Mahadevan K, Pellicano R, Reid A et al. Comparison of biochemical, hematological and volume parameters in two treatment schedules of nocturnal home hemodialysis. Nephrology 2006; 11: 413-418. See Evidence Table.

The use of home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nocturnal Dialysis
04/18/2011: MTAC REVIEW

Back to Top

Evidence Conclusion: *Short-daily dialysis compared to conventional dialysis*: A recent RCT that included 245 patients and evaluated whether short-daily dialysis (1.5 to 2.75 hours, six times per week) would improve patient outcomes compared to conventional dialysis (2.5 to 4 hours, three times per week). There were two composite primary outcome variables: death or 12-month change in left ventricle mass as assessed by cardiac MRI, and death or 12-month change in physical-health composite score from the RAND 36-item health survey. Compared to conventional dialysis, frequent dialysis was associated with favorable changes in both of the primary composite outcomes. As the mortality rate in both groups was low, the bulk of the treatment effect was seen in intermediate outcomes. The sample size was insufficient to determine the effects of frequent versus conventional dialysis on overall mortality, cause-specific mortality, or hospitalizations (FHN Trial Group 2010). *Nocturnal dialysis compared to conventional dialysis*: There is no high-quality evidence on health outcomes associated with nocturnal dialysis versus conventional dialysis. The majority of studies identified assessed intermediate outcomes such as mineral metabolism. Very few studies had mortality as an outcome. Results from these studies are inconsistent due to the low-quality of the studies. Conclusion: There is insufficient evidence to determine whether nocturnal dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional dialysis 3 times a week. There is fair evidence that short-daily dialysis leads to improvements in intermediate outcomes such as left ventricle mass and physical-health composite score compared to conventional dialysis 3 times a week. **Articles:** Studies were selected for review if they included at least 25 subjects and assessed the effect of nocturnal or short-daily dialysis on health outcomes. The majority of studies identified were non-randomized, observational studies. As these studies are more prone to bias, they were not selected for review. An RCT that compared the quality of life of patients receiving nocturnal dialysis to conventional dialysis was not selected for review as it did not have adequate power. A recent RCT comparing short-daily dialysis to conventional dialysis was selected for review.
The following study was critically appraised: FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010;* 363:2287-2300. See Evidence Table

The use of nocturnal dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Frequent Home Dialysis

08/20/2012: MTAC REVIEW

Evidence Conclusion:

Survival – There is lower quality evidence upon which to draw conclusions about survival with home versus in-center hemodialysis. Three observational studies specifically reported on death or measures of mortality and survival with home hemodialysis compared to in-center hemodialysis. One study had no deaths and therefore found no difference. The two other studies favored home hemodialysis but were either small or had a higher likelihood of residual confounding (Kaiser 2011).
Since the Kaiser review, a recent matched-cohort study was identified that included 11,508 subjects assessed the relative mortality between daily home hemodialysis and thrice-weekly in-center hemodialysis. Results from this study suggest that home hemodialysis may be associated with a reduction in all-cause mortality compared to thrice-weekly in-center hemodialysis (HR 0.87, 95% CI 0.78-0.97, P=0.01). Limitations of the study include: residual confounding, approximately 1 in 4 home hemodialysis patients switched to in-center hemodialysis, more patients in the in-center treatment group were dually eligible for Medicare and Medicaid, and the cause of death was unknown in 10-20% of cases (Weinhandl 2012).
Hospitalizations – There is lower quality evidence upon which to draw conclusions about hospitalizations with home versus in-center hemodialysis. One nested-case control study favored home hemodialysis in terms of hospitalizations per patients and two additional studies appeared to possibly favor home hemodialysis but were underpowered (Kaiser 2011).
Quality of life – The evidence is of insufficient quantity and quality to draw conclusions on quality of life with home versus in-center hemodialysis. Two small observational studies did not find differences in quality of life with home versus in-center hemodialysis. One study reported that both groups had about the same number of subjects working (Kaiser 2011).
Change in left ventricular mass – No studies were identified that evaluated this outcome (Kaiser 2011).
Blood pressure control – There is lower quality evidence upon which to draw conclusions. Two studies reported significant decreases in blood pressure measures with home hemodialysis compared to in-center hemodialysis. One study also appeared to favor home hemodialysis in terms of need for antihypertensive medications (Kaiser 2011).
Nutritional status and serum albumin – There are lower quality evidence upon which to draw conclusions. Three observational studies reported mixes results on measures of serum albumin, with one study significantly favoring home as compared to in-center hemodialysis. One study found no difference in intradialytic weight gain with home versus in-center hemodialysis (Kaiser 2011).

Back to Top

Vascular access complications/ Safety – The studies evaluating vascular access complications have been very small and the results were somewhat mixed. One study evaluated the operations (per patient) due to vascular access and found no significant difference, but the data tended toward favoring home hemodialysis. Another small study appeared to favor in-center, but the study was not adequately powered to evaluate this outcome. In terms of other safety reports, one small study appeared to have more machine malfunctions with home hemodialysis, another study reported that a composite measure of intradialytic adverse events appeared to favor home hemodialysis, but this was not significant (Kaiser 2011).

Articles: In March 2011, Kaiser reviewed alternative approaches to hemodialysis. Since the Kaiser review three observational studies were identified. Two studies were excluded as they did not compare in-center hemodialysis to home hemodialysis. The remaining observational study was selected for review.

Several studies were identified that reanalyzed results from the FHN trial; however, they were not selected for review since the FHN trial evaluated whether short-daily in-center hemodialysis improved patient outcomes compared to conventional in-center hemodialysis, and whether nocturnal home hemodialysis improved patient outcomes compared to conventional home hemodialysis. The following article and medical technology assessment were selected for review: Kaiser Permanente. Alternative approaches to hemodialysis: short "daily" and nocturnal. March 2011. The committee voted to accept the Kaiser technology assessment. The studies were insufficient to draw conclusions on clinical benefit as compared to standard forms of dialysis.

Frequent Home Dialysis

10/12/2020: MTAC REVIEW

Evidence Conclusion:

- There is a lack of high-quality randomized controlled trials assessing the effectiveness of frequent home hemodialysis versus conventional in-center hemodialysis in patients with ESRD.

- The available evidence is of low quality, mainly from uncontrolled studies, and suggests:
  - Home hemodialysis may decrease mortality compared to in-center hemodialysis
  - No difference between groups in terms of all-cause mortality, hospitalization, cardiovascular mortality, access survival, and transplantation rate
  - Mixed findings regarding quality of life and adverse events.
  - Home hemodialysis may be comparable to in-center dialysis in patients with ESRD

The use of frequent home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Standard Hemodialysis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
99512	Home visit for hemodialysis
90999	Unlisted dialysis procedure, inpatient or outpatient
E1629	Tablo hemodialysis system for the billable dialysis service

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Creation Date	Review Dates	Date Last Revised

Back to Top

08/04/2008	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/30/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC	10/26/2022

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
12/09/2015	Added Medicare and Noridian links
10/29/2018	Updated the Medicare links
08/04/2020	Added Medicare LCA A55676; Added CPT codes 90999 and 99512
08/03/2021	Added the October 12, 2020 MTAC review
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dialysis Services

- Facility
- In Home
- Nocturnal
- Short Daily
- Ultrafiltration for the Treatment of Congestive Heart Failure

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
National Coverage Determinations (NCD)	Ultrafiltration, Hemoperfusion and Hemofiltration (110.15)
Local Coverage Determinations (LCD)	Frequency of Hemodialysis (L37504)
Local Coverage Article	Billing and Coding: Frequency of Hemodialysis (A55676)

For Non-Medicare Members

Service	Criteria
Hemodialysis	**Standard hemodialysis 3 days a week** is covered for members with end stage renal disease. For home dialysis the following additional criteria must be met: 1. The member is stable on dialysis. 2. The member is free of complications and significant concomitant disease that would render home dialysis unsuitable or unsafe. 3. The member or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen. 4. Adequate caregiver is available during dialysis 5. Back-up arrangements have been made with the facility-based dialysis center.
Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Ultrafiltration for the Treatment of Congestive Heart Failure	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as

Back to Top

Date Sent: 4/29/24

	standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

End-stage renal disease (ESRD) is defined as an irreversible decline in kidney function that is severe enough to be fatal without treatment. In 2008, the prevalence of ESRD in the United States was 547,982 (Collins 2011). Treatment options for patients with ESRD include kidney transplantation and dialysis. Kidney transplantation is the preferred treatment for ESRD; however, the demand for kidney transplant exceeds the supply of transplantable organs (Pauly 2009). Of the 547,982 patients with ESRD, approximately 382,343 patients received dialysis (Collins 2011).

Dialysis filters blood to rid the body of harmful wastes, extra salt, and water. There are two types of dialysis peritoneal dialysis and hemodialysis. The majority of patients are treated using hemodialysis; however, there is no consensus on the optimal dose and frequency of hemodialysis. Difference hemodialysis regimens include: conventional hemodialysis, nocturnal hemodialysis, and short-daily hemodialysis (Toussaint 2010).

There are two types of dialysis: 1) Peritoneal dialysis: Removes waste products via the peritoneum, the membrane that lines the inside of the abdomen. The membrane is bathed in a special fluid called dialysate that is placed into the abdomen through a small tube, and after a designated period of time, the fluid is drained and replaced by new fluid. 2) Hemodialysis: Access is through surgical placement of an arteriovenous fistula, generally in the forearm, and less commonly by a venous catheter. After access is established, the fistula is connected to a hemodialysis machine that drains the blood, bathes it in dialysate solution and returns it to the bloodstream.

Conventional hemodialysis consists of three treatment sessions per week, with each session lasting 3 to 5 hours. Treatments can be performed in a dialysis center, hospital, or at home. Although this is a life-saving treatment, mortality in patients with ESRD is still remarkably high. Compared to the general population, mortality is four times higher in patients under 30 receiving dialysis and six times higher in patients over 65. Additionally, patients receiving dialysis often experience hypertension, fluid overload and the attendant cardiac sequelae, anemia, mineral and bone disorders, inflammation, poor nutritional status, poor functional status, and psychological disorders (Bayliss 2009, Ng 2010). Moreover, this approach to dialysis is inconvenient for patients receiving treatment in a dialysis center or hospital, who must travel to a dialysis unit several times a week.

Both nocturnal hemodialysis (typically 6-8 hours, 3-7 nights per week) and short-daily hemodialysis (typically 1.5-3 hours, 4-6 days per week) can take place at home or at a dialysis center. It is thought that increasing the frequency and duration of hemodialysis will lead to less fluid gain leading to improved blood pressure control, increased hemodynamic stability, and increased efficiency of solute clearance. A potential harm is an increased risk of vascular access complications due to more frequent use (Ng 2010, Toussaint 2010).

There are several hemodialysis devices approved by the FDA for home use. Some are large, non-portable devices that require modifications to the home electrical and plumbing systems. These include the Fresenius 2008K and the B. Braun Dialog Plus. Others are smaller and portable. The NxStage System One is specifically designed for home use; it does not require infrastructure changes.

Medical Technology Assessment Committee (MTAC)

Frequent Home Dialysis

08/04/2008: MTAC REVIEW

Evidence Conclusion: on home nocturnal or short daily dialysis versus in-center dialysis 3 times a week:

Back to Top

One RCT and two cohort studies were identified that compared nocturnal home dialysis to in-center dialysis 3 times a week. The RCT (Culleton et al., 2007) found statistically significant improvement in the primary outcome, LV mass, a surrogate marker for cardiovascular disease. Among other secondary outcomes, phosphate level was significantly lower in the nocturnal home dialysis group, and there was no significant between group differences in calcium level and anemia. Two cohort studies matched patients who received nocturnal dialysis to similar patients receiving conventional in-center dialysis 3 times a week. Bergman et al. (2008) found significantly lower dialysis-related or cardiovascular-related hospital admissions (the primary outcome) in the group converted to nocturnal dialysis, but no significant difference in all-cause hospitalization. Schwartz et al., (2005) also had significant findings for the primary study outcomes, increase in hemoglobin concentration and increase in the proportion of patients who were EPO-free after 12 months. None of the studies had mortality as an outcome.
There are fewer published studies on short-daily dialysis. A statistical analysis (Blagg et al., 2006) found a lower mortality rate in 117 patients who received short-daily dialysis either in-center or at home compared to national rates on patients receiving conventional hemodialysis (standardized mortality ratio=0.39). Patients who received short-daily dialysis may have differed from those in the national database, and there were financial links between the authors of this study and the home dialysis device used in the study.
Evidence on home nocturnal or short daily dialysis versus home dialysis 3 times a week:
No randomized controlled trials were identified, and there were no comparative studies with mortality as an outcome. The highest grade of evidence comparing different frequencies of home nocturnal dialysis is a retrospective cohort study by Mahadevan and colleagues (2006). The investigators evaluated biological parameters in 13 patients receiving nocturnal dialysis 6 nights a week and 21 patients receiving nocturnal dialysis every other night (3-4 times a week). After 3-6 months of follow-up, levels of urea, creatinine and PTH were all significantly lower in the group treated 6 nights/week, and there were no significant differences between groups in phosphate, calcium, albumin and homocysteine levels, or in use erythropoietin or phosphate binders. There were no significant differences at follow-up in the proportion of patients taking phosphate binders, calcitriol, blood pressure medications or erythropoietin. The evidence is limited due to lack of randomization (there may have been pre-existing differences between groups) and the small sample size (may be underpowered).
There is no high-grade evidence on health outcomes associated with short daily dialysis at home versus home hemodialysis 3 times a week.
Conclusions:
Objective 1:
- There is insufficient evidence that home nocturnal dialysis improves important health outcomes compared to in-center dialysis. An RCT found improvement in LV mass and phosphate level, intermediate outcomes, and mixed findings in QOL. There is weak evidence from a single cohort study that nocturnal dialysis lowers the rate of dialysis-related or cardiovascular-related hospitalizations. In this cohort study, all-cause hospitalizations did not decrease significantly.
- There is insufficient evidence that home short-daily dialysis improves health outcomes compared to in-center dialysis. One statistical analysis found a lower mortality rate with short daily dialysis compared to national rates, but patients may have differed in ways that affect outcomes, and there was potential financial bias.

Objective 2:
- There is insufficient evidence that home nocturnal dialysis 6 nights a week improves important health outcomes compared to home hemodialysis 3 times a week.
- There is insufficient evidence that home short-daily dialysis 5 or more times a week improves important health outcomes compared to home hemodialysis 3 times a week

Articles: Assessment objectives:
1) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional in-center dialysis 3 times a week.
2) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to home dialysis 3 times a week.

Important health outcomes are survival, hospitalizations and quality of life.
Objective 1: Comparison with in-center hemodialysis One randomized controlled trial (Culleton et al., 2007) and two cohort studies (Bergman et al., 2008; Schwartz et al., 2005) comparing frequent nocturnal home hemodialysis to in-center hemodialysis were identified and critically appraised. Case series were not reviewed due to the availability of higher-grade evidence. The studies on short-daily hemodialysis were all case series. Most were small (<15 patients) and or included patients who primarily received dialysis in-center and thus were not suitable for critical appraisal. The strongest study identified compared outcomes in 117 patients on short-daily dialysis (84% at home) to outcomes of patients from a national database receiving conventional dialysis (Blagg et al., 2006). The Blagg study was critically appraised. *Objective 2: Comparison with home hemodialysis 3 times a week*
One comparative study was identified, and critically appraised (Mahadevan et al., 2006). This was a small retrospective cohort study comparing outcomes in patients who received home nocturnal dialysis either six nights per week or on alternate nights (3-4 times a week). An RCT by the Frequent Hemodialysis Network (FHN) is

Back to Top

underway comparing nocturnal home hemodialysis 3 versus 6 times a week. The study is currently recruiting patients; the estimated completion date is January 2010 (Clinicaltrials.gov). *Studies reviewed include:*
Blagg CR, Kjellstrand CM, Ting GO, Young BA. Comparison of survival between short-daily hemodialysis and conventional hemodialysis using the standardized mortality ratio. Hemodialysis International 2006; 10: 371-374. See Evidence Table Culleton BF, Walsh M, Klarenbach SW et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life. JAMA 2007; 298: 1291-1299. See Evidence Table Bergman A, Fenton SSA, Richardson RMA, Chan CT. Reduction in cardiovascular related hospitalization with nocturnal home hemodialysis. Clin Nephrol 2008; 69: 33-39. See Evidence Table Schwartz DI, Pierratos A, Richardson RMA et al. Impact of nocturnal home hemodialysis on anemia management in patients with end-stage renal disease. Clin Nephrol 2005; 63: 202-208. See Evidence Table Mahadevan K, Pellicano R, Reid A et al. Comparison of biochemical, hematological and volume parameters in two treatment schedules of nocturnal home hemodialysis. Nephrology 2006; 11: 413-418. See Evidence Table.

The use of home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nocturnal Dialysis

04/18/2011: MTAC REVIEW

Evidence Conclusion: *Short-daily dialysis compared to conventional dialysis*: A recent RCT that included 245 patients and evaluated whether short-daily dialysis (1.5 to 2.75 hours, six times per week) would improve patient outcomes compared to conventional dialysis (2.5 to 4 hours, three times per week). There were two composite primary outcome variables: death or 12-month change in left ventricle mass as assessed by cardiac MRI, and death or 12-month change in physical-health composite score from the RAND 36-item health survey. Compared to conventional dialysis, frequent dialysis was associated with favorable changes in both of the primary composite outcomes. As the mortality rate in both groups was low, the bulk of the treatment effect was seen in intermediate outcomes. The sample size was insufficient to determine the effects of frequent versus conventional dialysis on overall mortality, cause-specific mortality, or hospitalizations (FHN Trial Group 2010). *Nocturnal dialysis compared to conventional dialysis*: There is no high-quality evidence on health outcomes associated with nocturnal dialysis versus conventional dialysis. The majority of studies identified assessed intermediate outcomes such as mineral metabolism. Very few studies had mortality as an outcome. Results from these studies are inconsistent due to the low-quality of the studies. Conclusion: There is insufficient evidence to determine whether nocturnal dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional dialysis 3 times a week. There is fair evidence that short-daily dialysis leads to improvements in intermediate outcomes such as left ventricle mass and physical-health composite score compared to conventional dialysis 3 times a week. **Articles:** Studies were selected for review if they included at least 25 subjects and assessed the effect of nocturnal or short-daily dialysis on health outcomes. The majority of studies identified were non-randomized, observational studies. As these studies are more prone to bias, they were not selected for review. An RCT that compared the quality of life of patients receiving nocturnal dialysis to conventional dialysis was not selected for review as it did not have adequate power. A recent RCT comparing short-daily dialysis to conventional dialysis was selected for review.
The following study was critically appraised: FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010;* 363:2287-2300. See Evidence Table

The use of nocturnal dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Frequent Home Dialysis

08/20/2012: MTAC REVIEW

Evidence Conclusion:

Survival – There is lower quality evidence upon which to draw conclusions about survival with home versus in-center hemodialysis. Three observational studies specifically reported on death or measures of mortality and survival with home hemodialysis compared to in-center hemodialysis. One study had no deaths and therefore found no difference. The two other studies favored home hemodialysis but were either small or had a higher likelihood of residual confounding (Kaiser 2011).
Since the Kaiser review, a recent matched-cohort study was identified that included 11,508 subjects assessed the relative mortality between daily home hemodialysis and thrice-weekly in-center hemodialysis. Results from this study suggest that home hemodialysis may be associated with a reduction in all-cause mortality compared to thrice-weekly in-center hemodialysis (HR 0.87, 95% CI 0.78-0.97, P=0.01). Limitations of the study include: residual confounding, approximately 1 in 4 home hemodialysis patients switched to in-center hemodialysis, more patients in the in-center treatment group were dually eligible for Medicare and Medicaid, and the cause of death was unknown in 10-20% of cases (Weinhandl 2012).

Back to Top

Hospitalizations – There is lower quality evidence upon which to draw conclusions about hospitalizations with home versus in-center hemodialysis. One nested-case control study favored home hemodialysis in terms of hospitalizations per patients and two additional studies appeared to possibly favor home hemodialysis but were underpowered (Kaiser 2011).
Quality of life – The evidence is of insufficient quantity and quality to draw conclusions on quality of life with home versus in-center hemodialysis. Two small observational studies did not find differences in quality of life with home versus in-center hemodialysis. One study reported that both groups had about the same number of subjects working (Kaiser 2011).
Change in left ventricular mass – No studies were identified that evaluated this outcome (Kaiser 2011).
Blood pressure control – There is lower quality evidence upon which to draw conclusions. Two studies reported significant decreases in blood pressure measures with home hemodialysis compared to in-center hemodialysis. One study also appeared to favor home hemodialysis in terms of need for antihypertensive medications (Kaiser 2011).
Nutritional status and serum albumin – There are lower quality evidence upon which to draw conclusions. Three observational studies reported mixes results on measures of serum albumin, with one study significantly favoring home as compared to in-center hemodialysis. One study found no difference in intradialytic weight gain with home versus in-center hemodialysis (Kaiser 2011).
Vascular access complications/ Safety – The studies evaluating vascular access complications have been very small and the results were somewhat mixed. One study evaluated the operations (per patient) due to vascular access and found no significant difference, but the data tended toward favoring home hemodialysis. Another small study appeared to favor in-center, but the study was not adequately powered to evaluate this outcome. In terms of other safety reports, one small study appeared to have more machine malfunctions with home hemodialysis, another study reported that a composite measure of intradialytic adverse events appeared to favor home hemodialysis, but this was not significant (Kaiser 2011).
Articles: In March 2011, Kaiser reviewed alternative approaches to hemodialysis. Since the Kaiser review three observational studies were identified. Two studies were excluded as they did not compare in-center hemodialysis to home hemodialysis. The remaining observational study was selected for review.
Several studies were identified that reanalyzed results from the FHN trial; however, they were not selected for review since the FHN trial evaluated whether short-daily in-center hemodialysis improved patient outcomes compared to conventional in-center hemodialysis, and whether nocturnal home hemodialysis improved patient outcomes compared to conventional home hemodialysis. The following article and medical technology assessment were selected for review: Kaiser Permanente. Alternative approaches to hemodialysis: short “daily” and nocturnal. March 2011. The committee voted to accept the Kaiser technology assessment. The studies were insufficient to draw conclusions on clinical benefit as compared to standard forms of dialysis.

Frequent Home Dialysis
10/12/2020: MTAC REVIEW
Evidence Conclusion:

- There is a lack of high-quality randomized controlled trials assessing the effectiveness of frequent home hemodialysis versus conventional in-center hemodialysis in patients with ESRD.

- The available evidence is of low quality, mainly from uncontrolled studies, and suggests:
    - Home hemodialysis may decrease mortality compared to in-center hemodialysis
    - No difference between groups in terms of all-cause mortality, hospitalization, cardiovascular mortality, access survival, and transplantation rate
    - Mixed findings regarding quality of life and adverse events.
    - Home hemodialysis may be comparable to in-center dialysis in patients with ESRD

The use of frequent home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Ultrafiltration in the Treatment of Congestive Heart Failure
08/07/2006: MTAC REVIEW
Evidence Conclusion: The RAPID-CHF trial (Bart 2005) was a randomized, controlled, non-blinded trial that compared usual care vs. usual care plus ultrafiltration (UF) in 40 patients admitted to hospital with acute decompensated heart failure and fluid overload. Patients randomized to the usual care group received the conventional heart failure therapy. Those in the UF group received an 8 hour UF treatment with a maximum fluid removal rate of 500 cc/hour. Diuretics were administered after the 8 hours of UF, and additional courses of UF were allowed after 24 hours. The results of the trial show that the weight loss (primary endpoint of the trial) was not significantly different between the two study groups. The average volume removal of fluid was significantly

higher in the UF group at 24 and 48 hours. Patients in the two treatment groups experienced improvement in their symptoms during the treatment period. The improvement observed was significantly greater in the UF group compared to the usual care group at 48 hours but not at 24 hours. The significant difference may be due to the greater fluid removal or due to chance as the trial was small, un-blinded, and the outcome measure was subjective. Costanzo et al (2005) reported their experience with early initiation of UF in 20 selected HF patients admitted to hospital with manifest signs and symptoms of fluid overload. The patients underwent UF which was continued until the acute decompensation heart failure symptoms were resolved. The removal of fluid was aggressive (8,654 + 4,205 ml) and resulted in a mean decrease of 6 kg of weight at discharge, and improvement in the clinical signs of symptoms of fluid overload that seem to have lasted for the 90 days of follow-up. This was only an observational case series with no comparison or control group and subject to selection and observation bias. The results of the UNLOAD (or UltrafiltrationN versus IV diuretics for patients hospitalized for Acute Decompensated congestive heart failure) trial was presented at the 2006 ACC conference in Atlanta, but have not been published in a peer reviewed journal to date. The trial randomized 200 patients from 28 centers to receive the standard intravenous diuretic drug therapy or IV diuretics plus ultrafiltration to treat fluid overload. The study was not blinded, the primary outcomes were weight loss and dyspnea score at 48 hours, and the patients were followed up for 90 days. The unpublished results of the trial indicate that both treatments were associated with significant improvement in the dyspnea score at 48 hours, but with no significant difference between the two treatment groups. Patients in the UF group had significantly greater net fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. The results also show that the hospital readmission rate, during the 3 months of follow-up, was significantly lower in the UF group, vs. the IV diuretic group. All three studies were funded or supported by the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota, which may introduce bias. In conclusion, there is insufficient evidence to date to determine the efficacy and long-term safety of ultrafiltration versus standard care in acute decompensated heart failure, or to determine who would benefit most from the intervention.

Articles: The search yielded around 280 articles most of which were review articles, opinion pieces, or dealt with the technical aspects of the procedures. There was one RCT, and several small case series, many of which dated back in the 1980s and 1990s. The RCT and the relevant case series using the new UF device (System 100, CHF Solutions, Minneapolis, Minnesota) were selected for critical appraisal: Bart BA, Boyle A, Bank AJ, et al. Ultrafiltration versus usual care for hospitalized patients with heart failure. The Relief for Acutely fluid-overloaded Patients with Decompensated Congestive Heart Failure (RAPID-CHF) trial. J Am Coll Cardiol 2005; 46:2043-2046. **See** Evidence Table. MR, Saltzberg M, O'sollivan J, et al. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol 2005;46:2047-2051. **See** Evidence Table.

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/17/2013: MTAC REVIEW

Ultrafiltration in the Treatment of Congestive Heart Failure

Evidence Conclusion: All published trials on the use of ultrafiltration in patients with acute decompensated heart failure with or without renal dysfunction compared UF with IV diuretic-based therapy. No published RCT, to date, examined the efficacy and safety of ultrafiltration in patients with ADHF who refractory to diuretics were. This latter indication of ultrafiltration was only evaluated in a one retrospective study with no control group.

Ultrafiltration as a first line therapy The UNLOAD (ultrafiltration versus Intravenous Diuretics for Patients Hospitalized for Acute Decompensated Congestive Heart Failure) trial compared ultrafiltration to diuretic therapy in patients hospitalized for acute decompensated heart failure. The trial examined UF as a first-line early therapy not as a rescue therapy (i.e. patients did not have to fail an initial diuretic therapy to be included in the trial). 200 patients were randomized to receive early UF (within 24 hours of hospitalization) or intravenous diuretic drug therapy. The co-primary outcomes were weight loss and patient self-assessed dyspnea score at 48 hours. The results show that both the UF and IV diuretic therapies were associated with significant improvement in the dyspnea score at 48 hours, with no statistically significant difference between the two treatment groups. Patients in the UF group had significantly greater fluid and weight loss at 48 hours, and a lower incidence of hypokalemia. This however, did not have an impact on the length of the index hospital stay. The rates of rehospitalization and unscheduled visits during the 90 days of follow-up were significantly lower in the UF group, vs. the IV diuretic group. The results also show a higher rise in serum creatinine levels in the UF group vs. the IV diuretic group (twice as many patients in the UF arm experienced an increase in sCr level >0.3 ml/dL during the first 24 hours of therapy) but the difference did not reach a statistically significant level. The authors considered the lack of significant difference between the two groups for this as well as other outcomes, as similar effects when the trial was not designed as equivalent study, and the lack of significant differences could results from insufficient statistical power. The study was a multicenter RCT but had several limitations many of which were acknowledged by the authors. The trial had a relatively small size and short follow-up duration, excluded patients with hypotension or hemodynamic instability, and used suboptimal dose and mode of administration of loop diuretics.

Back to Top

The dose of the diuretic, duration, and rate of UF were all based on the discretion of the attending physician who was not blinded to the randomization groups and could be a source of bias. In addition, the authors did not present any data on low-salt diet compliance, or criteria for hospitalization. The study was supported by CHF Solution Inc., and the primary author as well as a number of other authors had financial ties to the manufacturer of the device CHF Solutions, Brooklyn Park, Minnesota. The Cardiorenal Rescue Study in Acute Decompensated Heart Failure (CARRESS-HF, sponsored by the NHLBI) investigated the role of UF as a treatment for patients with persistent congestion and worsening of kidney function (increase in serum creatinine ≥0.3 mg/dL within 12 weeks before or 10 days after index admission). 188 patients were randomized to undergo ultrafiltration (fluid removal at a rate of 200 ml/hour using Aquadex System 100; CHF Solutions), or to receive stepped pharmacological therapy involving increasing the doses of loop diuretics (with or without metolazone), vasodilators and inotropes (based on an algorithm that aimed at achieving urine output of 3-5 liters/ day). The assigned treatment was continued in the two groups until signs and symptoms of congestion were improved as possible. The primary endpoint was bivariate (simultaneous) change in serum creatinine level and body weight in 96 hours after randomization. The trial was not blinded, and the patients were followed-up for 60 days. Recruitment for the trial was stopped early before reaching the planned size of 200 subjects based on the advice of the data and safety monitoring board due to lack of benefit and excess adverse events with ultrafiltration. The results of CARRESS-HF show that stepped pharmacological therapy was superior to UF when the primary end point was assessed at 96 hours after randomization. There was a statistically significant reduction the serum creatinine (sCr) in the pharmacologic therapy group compared to the UF group. There was no significant difference between the groups in weight loss at 96 hours. At the 60 days of follow-up, there were no statistically significant differences in weight loss, or rate of hospitalization due to heart failure. There was a nonsignificant increase in the all-cause readmission rate in the UF group. UF, was also associated with a significantly higher rate of serious adverse events including kidney failure, bleeding complications, and catheter– related complications. The sixty-day mortality was17% for the UF group and 13% for the pharmacological therapy group with no significant difference between the groups, however, as indicated earlier, a lack of significant difference does not indicate equivalence due to the study design. These results should be interpreted with caution and cannot be generalized to patients with ADHF with better renal function than those included in the trial.
Other published trials Two other very small published RCTs (ULTRADISCO (Giglioli et al 2011), and Hanna and colleagues' trial (2012) also compared ultrafiltration versus intravenous diuretics inpatients hospitalized for ADHF. The trials had intermediate outcomes (hemodynamic variables in the ULTRADISCO trials, and time for pulmonary wedge pressure to be maintained at >18 mmHg for ≥4 consecutive hours in Hanna and colleagues' study). Their overall results showed greater fluid loss with UF vs. diuretic therapy with no significant difference between the groups in the serum creatinine levels. Ultrafiltration as a rescue therapy for patients with ADHF who are refractory to IV diuretic therapy The literature search did not identify any published RCT to date, that examined the efficacy and safety of ultrafiltration in patients with ADHF who were refractory to diuretics. In a retrospective observational study with no comparison group, Patarroyo and colleagues (2012) analyzed data from hospital records for adult patients with ADHF admitted to one heart failure intensive care unit in Cleveland Ohio ((2004-2009) and who required slow continuous ultrafiltration therapy (SCUF). The study population was a highly selected group of 63 adult patients with advanced HF, worsening renal function, and congestion refractory to hemodynamically guided intensive medical therapy. Their median age was 58 years, mean LV ejection fraction 26 ±15%, baseline serum creatinine (sCr) 1.9 ± 0.8 mg/dL and hemodynamics consistent with cardiogenic shock. SCUF was initiated after a mean of 8 days from admission, was performed at a rate of 200ml/hr. and for a mean duration of 8 days. At the initiation of SCUF therapy the sCr level was 2.2 ± 0.9 mg/dL. The mean duration of the UF therapy was 3+2 days, and the primary endpoint of the study was all-cause mortality and the secondary endpoint included number of readmissions for ADHF and dialysis-dependent status at time of discharge. The results of the analysis showed that after 48 hours of SCUF the overall cohort lost weight significantly compared to baseline (mean 4.4 kg). This was associated with significant improvement in hemodynamic variables but with no improvements in sCr levels or blood urea. 37 patients (59%) required conversion to continuous hemodialysis during their hospital stay and 9 (14%) were dependent on hemodialysis at hospital discharge. 34/37 (93%) of these patients were readmitted to the hospital within 60 days form discharge.19/63 patients (30%) died during the index hospitalization, and 4 were discharged to terminal care in hospice. The overall 1-year all-cause mortality was 70% and 2 of the surviving patients underwent heart transplantation. The results of the study should be interpreted with caution due to the study design and its inclusion of severely ill patients. Conclusion: There is insufficient evidence to support the use of ultrafiltration as a first-line treatment in hospitalized ADHF with volume overload. There is insufficient evidence to determine the safety and efficacy of ultrafiltration in patients with ADHF who are refractory to diuretic therapy. Results from UNLOAD trial, suggest, but do not provide good evidence, that ultrafiltration may provide better correction of volume overload than IV diuretics (given at the dose used in the trial) in patients hospitalized ADHF who are not resistant to diuretic therapy. The trial had its limitations and does not provide any evidence on the safest and most effective rates of fluid removal, duration of treatment, or the conditions for termination of ultrafiltration. There is evidence from the CARRESS-HF that IV loop diuretic-based therapy adding distal-acting diuretics, IV vasodilator and inotropic agents as needed is superior to ultrafiltration in patients with acute

Back to Top

decompensated heart failure and worsening renal function. CARESS-HF results show increased incidence of worsening kidney function in the ultrafiltration group versus the stepped pharmacologic therapy group.
A large ongoing trial (AVOID-HF) (NCT01474200) involving 810 patients in 40 US centers is examining the effect of UF vs. intravenous diuretics in reducing hospitalization in patients with ADHF before worsening renal function.
Articles: UNLOAD trial (Costanzo et al 2007, evidence table 1) See Evidence Table. CARRESS-HF (Bart yet al 2012, evidence table 2) See Evidence Table

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Standard Hemodialysis - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
99512	Home visit for hemodialysis
90999	Unlisted dialysis procedure, inpatient or outpatient
E1629	Tablo hemodialysis system for the billable dialysis service

Ultrafiltration for the Treatment of Congestive Heart Failure
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0692T	Therapeutic ultrafiltration

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
08/04/2008	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/30/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC	04/17/2024

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/09/2015	Added Medicare and Noridian links
10/29/2018	Updated the Medicare links
08/04/2020	Added Medicare LCA A55676; Added CPT codes 90999 and 99512
08/03/2021	Added the October 12, 2020 MTAC review
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
04/17/2024	Merged “Ultrafiltration for the Treatment of Congestive Heart Failure” criteria and retitled to Dialysis

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

	Services

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Digital Breast Tomosynthesis

Criteria

For Medicare Members and Non-Medicare Members

Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Mammography is the gold-standard for population-based breast cancer screening. The sensitivity of mammography in randomized trials is in the range of 68-88% (Elmore 2005). However, mammography is less sensitive in women with dense breasts (Brem 2008; Killela 2009). Because of these new technologies are being developed to improve detection and characterization of breast lesions. One of these technologies is digital breast tomosynthesis (Helvie 2010).

Digital breast tomosynthesis is a modified form of digital mammography. With digital breast tomosynthesis, multiple views of a stationary compressed breast are taken at different angles. These images are then reconstructed using an algorithm to create 3D radiographic images of the breast. It has been hypothesized that this technology may be able to decrease the number of false positive and false negative results and decrease recall rates. One limitation of digital breast tomosynthesis is that the specifications of many parameters including the number of projections, dose, angle, and post-processing algorithm differ across manufactures making clinical comparisons between manufactures difficult (Helvie 2010, Holloway 2010).

The Selenia Dimensions 3D System (Holistics, Inc.) has received approval from the FDA.

Medical Technology Assessment Committee (MTAC)

Digital Breast Tomosynthesis

12/19/2011: MTAC REVIEW

Evidence Conclusion: Based on evidence from observational studies, the Kaiser MTAT concluded that the evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer in average-risk or high risk women, in evaluating those with equivocal/indeterminate mammography and/or ultrasound, or evaluating women considering breast conserving therapy. The current evidence base consists primarily of studies reporting diagnostic results of women with abnormal screening mammograms and is not representative of key populations under consideration. In addition, the sample sizes were too small and not powered to compare accuracy measures (Kaiser 2011). Conclusion: The evidence is of insufficient quantity and quality to conclude that digital breast tomosynthesis is more effective than any other technologies to screen for breast cancer.

Articles: The Kaiser Permanente Medical Technology Assessment Team (MTAT) reviewed digital breast tomosynthesis in 2009, 2010, and 2011. No additional studies were identified since the 2011 review. The

Back to Top

following technology assessments were selected for review: Kaiser Permanente Interregional New Technologies Committee. Tomosynthesis. 2011; http://pkc.kp.org/national/cpg/intc/topics/04_04_116.html Kaiser Permanente Medical Technology Assessment Team. Breast Imaging: Digital Breast Tomosynthesis. 2010; See Evidence Table.

The use of digital breast tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/20/2015: MTAC REVIEW
Digital Breast Tomosynthesis
Evidence Conclusion: The external technology assessments by HTA, INTC, and TEC all concluded that there is insufficient evidence to determine that benefits of using breast tomosynthesis for screening asymptomatic women for breast cancer.
Health Technology Assessment (HTA), January 2015

Studies comparing DBT to DM for screening asymptomatic women
(Table reproduced from HTA Executive Summary)

Study	Sensitivity		Specificity	
	M %	DBT %	M %	DBT %
Ciatto, 2013 * (Italian STORM)	66.1	100	95.5	96.6
Skaane, 2013* (Oslo trial)	62.6	82.1	93.8	94.6
Haas2013 **‡	100	100	NR	NR
Friedwald, 2014 ‡	NR	NR	NR	NR
Rose, 2013 ‡	100	100	91.7	95.1
Destounis, 2014 ‡‡**	100	75	97.9	99.4
Lorenco, 2014 ‡‡	NR	NR	91.1	94.0
Greenberg, 2014‡	NR	NR	84.3	87.0
McCarthy,2014‡‡	NR	NR	NR	NR

M=mammography, DBT=digital breast tomosynthesis.
* Prospective studies
‡ Retrospective multicenter study
‡‡ Retrospective single center study
** US study
The majority of the studies compared DBT+DM vs DM alone.
There was population overlap between Greenberg, McCarthy, and Friedwald studies
All the trials had their limitations

Estimated yield of DBT in combination with digital mammography
Vs. digital mammography alone in women presenting for population screening
(Table reproduced from HTA review Executive Summary)

	DM	DBT+DM	Uncertainty
Recall rate /1,000	100-160	80-140	Moderate-high
Biopsy rate /1,000	14-22	12-27	Moderate
Cancer detection rate/1,000	3-5	4-6	Moderate-high
Positive biopsy among total biopsied	20-25%	25-30%	Low-moderate

The HTA review summary indicates that the 9 studies reviewed showed a substantial decrease in the recall rate with DBT vs. mammography and most found an increase in cancer detection. The evidence on biopsy rate was mixed, with the more recent studies showing an increase in the biopsy rate with DBT. Studies reporting on subgroups of women with dense and non-dense breasts found consistent findings.
There were limitations in the studies, including heterogeneity and differences among the screened populations, short follow-up duration, and lack of large prospective studies with patient outcomes. In addition, the only 2 prospective studies were conducted overseas, where the patterns of recall differ from that in the US. *Kaiser Interregional New Technologies Committee (INTC), November 2014* the evidence reviewed by the committee included 8 published comparative studies of DBT + mammography vs. mammography alone for routine screening (from a previous review) plus four more recent comparative studies. There were no published studies that investigated the impact of DBT screening on mortality or other health outcomes among women at low, average or high risk of breast cancer. The review concluded that there is insufficient evidence to determine that breast

 Back to Top

tomosynthesis is appropriate for screening asymptomatic women for breast cancer. The estimated absolute benefits in cancer detection and reduction in recall are small and the overall evidence is of low-to moderate quality. The review also concluded that the positive results observed may not translate to outcomes and there is insufficient evidence to determine that DBT prevents mortality or advanced disease from breast cancer, *Blue Cross Blue Shield/ Kaiser Permanente Technology Evaluation Center (TEC), January 2014* The addition of DBT to screening or diagnostic mammography did not meet the TEC criteria. The review included six studies that compared the use of mammography versus DBT with or without mammography for screening asymptomatic women. Four of the studies (Rose 2013, HAAS 2013, Skaane 2013, and Ciatto 2013) were also included in the HTA review. The two other studies included in the review were Rafferty et all's study (2013) and Good et all's study 2008 (Gur 2009). The TEC review did not include studies published in 2014 as the literature search was conducted in June 2013. TEC also evaluated the use of DBT for breast cancer diagnosis. The review concluded that the available evidence (at the time) on adding DBT to mammography for screening for breast cancer or to diagnostic mammography is insufficient to permit conclusions regarding the effect on health outcomes, or to determine the comparative benefit of adding DBT to mammography vs. mammography alone. *More recent published evidence after the HTA 2015 review* The literature search for more recently published studies identified a large (N=7,060) retrospective reading study embedded in a prospective study (TOMMY trial, Gilbert et al, 2015) that compared DBT plus 2D mammography vs. mammography alone, and a small (n=150) retrospective study (Thomassin-Naggara 2015) that evaluated the value of adding one view DBT to mammography to characterize breast lesions. TOMMY trial (Gilbert et al 2015 [Health Technology Assessment, NHS] Evidence table 1). This was a large retrospective reading study conducted by the UK National Institute for Health Research in six UK centers to compare the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography among 6,021 women 47-73 years of age, for further assessment after routine breast screening, and 1,040 women 40-49 years with moderate/high risk of developing breast cancer attending annual mammography screening. All participants underwent a two-view 2D mammography of both breasts and two-view DBT imaging. Image-processing software generated a synthetic 2D mammogram from the DBT data set. Blinded readers reviewed 2D or 2D+DBT, or synthetic 2D+ DBT images for each case without access to the original screening mammograms or prior examinations. Sensitivities and specificities were calculated for each reading arm and by subgroup analyses. Overall, the results indicate that the specificity of DBT plus 2D mammography was statistically significantly higher than that of 2D mammography alone. The improvement in sensitivity by adding DBT to 2D mammography was minimal and statistically insignificant among all participants combined. Subgroup analyses however, showed significantly higher sensitivity with DBT+2D mammography vs. 2D mammography for women in the age range of 50-59 years, women with invasive tumors 11-20mm in diameter, those with breast density >50%, and in women with grade 2 invasive tumors. The analysis suggests that there was no significant difference in specificity of synthetic 2D +DBT versus 2D +DBT. As regards the sensitivity of synthetic 2D+DBT, subgroup analysis suggested that it had higher sensitivity than 2D alone in the detection of 11-20 mm invasive cancers, but lower sensitivity than 2D or 2D+DBT in the detection of microcalcifications and DCIS (ductal carcinoma in situ) 11-20mm in size. The study included women recalled for suspicious lesions on 2D mammography (only 5% of the screened women were recalled) as well as younger women at high risk. DBT was not used for 95% of the women screened by 2D mammography who were not recalled. This inherent selection bias of the study could overestimate the true effect of adding DBT to 2D mammography on the specificity and underestimate its impact on the sensitivity. The study was not a screening trial and its results cannot be generalized to screening populations. Thomassin-Naggara and colleagues' study (2015) found that adding DBT to mammography improved reproducibility and diagnostic performance especially for radiologists with lower experience in reading mammography. Conclusion: There is insufficient evidence to determine the comparative benefit of screening with DBT versus conventional mammography. The published studies suggest that the addition of DBT to DM has no or minimal effect on improving sensitivity especially with experienced film readers. The studies, however, suggest that the addition of DBT to DM may reduce the recall rates, but that would depend on the reading protocol, recall policy and experience of radiologists reading the images. There is no published evidence, to date, to determine the benefit of using DBT alone or in addition to digital mammography on long-term health outcomes.

Articles: The literature search revealed over 130 articles on digital breast tomosynthesis published after the last MTAC review. DBT technology was recently assessed by TEC for breast cancer screening or diagnosis in January 2014, by INTC in November 2014, and more recently by HTA in January 2015, for breast cancer screening in patients with dense breasts. The search for additional large screening studies published after the literature search dates of these reviews identified one large retrospective reading study (TOMMY trial) that compared the diagnostic accuracy of DBT in conjunction with 2D mammography or synthetic 2D mammography vs. standard 2D mammography, a small retrospective study (N=150) on the added value on DBT combined with DM according to reader experience, a post hoc analysis of the STORM study by Ciatto and colleagues' 2013 study (included in the HTA review), and a recent meta-analysis on the use of DBT as a diagnostic not a

 Back to Top

screening test. The TOMMY trial was selected for critical appraisal. Gilbert FJ, Tucker L, Gillan MG, et al. The TOMMY trial: a comparison of TOMosynthesis with digital MammographY in the UK National Institute for Health Research (NHS) Breast Screening Programme - a multicentre retrospective reading study comparing the diagnostic performance of digital breast tomosynthesis and digital mammography with digital mammography alone. Health Technol Assess. 2015 Jan;19(4):1-136. See Evidence Table.

The use of Digital Breast Tomosynthesis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medical necessity review no longer required

CPT or HCPC code	Description
77061	Diagnostic digital breast tomosynthesis; unilateral
77062	Diagnostic digital breast tomosynthesis; bilateral
77063	Screening digital breast tomosynthesis; bilateral
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral *(List separately in addition to 77065 or 77066)*

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/03/2012	01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 04/20/2015[MPC], 06/02/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC], 10/04/2022[MPC], 10/03/2023[MPC]	02/28/2017

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/23/2015	Added CPT and HCPC codes
04/27/2015	Added April 2015 MTAC review
06/02/2015	MPC approved policy of insufficient evidence
08/25/2015	Added Medicare MLN MM8774 clarifying language
6/27/2017	Added WESCU rider language
02/28/2017	Medical necessity review no longer required.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Discography (Discogram) for Low Back Pain

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***Discography (Discogram) for Low Back Pain***, for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Low back pain is a great and growing problem in the Western countries as well as other parts of the world. It is the most common cause of disability in patients younger than 45 years old, and the loss of work, medical and disability costs can add up to at least $50 billion per year in the Unites States. Many factors are associated with back pain, but the exact causes of severe pain are unclear especially in the absence of a diagnosed anatomic pathology such as infection, tumor, deformity, or instability (Carragee 2001, 2004, Willems 2007).

Currently, there is no clinical test that could be used as a diagnostic gold standard for discogenic pain, and it is not possible to determine with absolute certainty that a particular disc is the spinal pain generator. Imaging methods such as radiography, magnetic resonance imaging (MRI), and computed tomography (CT) may detect disc degeneration but cannot confirm if it is symptomatic and relevant to the patient's pain syndrome. Plain radiographs provide data on bony alignment and deformity, signs of instability, and the general state of lumbar degeneration. Nuclear medicine scans may exclude tumors, fractures and infection, and magnetic resonance imaging (MRI) is used for the diagnosis lumbar degenerative disorders. MRI is considered the morphological imaging study of choice in patients with low back pain. It is non-invasive and allows assessment of more levels in one test. MRI findings might also provide some information to indicate that a positive test increases the likelihood of the disc as a source of patients' symptoms, yet the current evidence is insufficient to allow making an accurate prediction (Saal 2002, Hancock 2007, Willems 2007). Surgical exposure can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain.

Back to Top

Date Sent: 4/29/24

Lumbar discography was first introduced in the late 1940s as a morphologic test. The term discography used to describe the technology, implies a strictly anatomic evaluation. Discograms do not image pain and hence do not provide insight into which neural pathways mediate discogenic pain. Imaging of intervertebral discs morphology usually does not change within a short interval, but discographic images may change after only 2 weeks. Concerns about the invasiveness of discography, radiation exposure, risk of infection, and the recent advances made in the high-resolution multi-detector CT and MRI of the disc, minimized the role of discography as an imaging tool. However, the frequent recurrence of familiar back pain during the discography led to the use of the test in evaluating lumbar discs as the origin of chronic low back pain, as well as pain in the cervical spine. Currently discography is used as a provocative test alleged to correlate symptoms with pathology (Buenaventura 2007).

Provocative discography is an invasive diagnostic procedure performed by the injection of a nonirritating radio-opaque dye, under x-ray guidance, into the nucleus of one or more lumbar discs. The dye is slowly injected into the center of the nucleus pulposus by a 22-25-gauge needle. The patient must be awake and cooperative and is supposed to be blinded to the time and level of injection. The distribution of the dye is noted, and the patient is asked whether each injection seems painful, and if the pain is similar “concordant” to the usual back pain he experiences. The patient is also asked to rate the pain on a visual analogue scale (VAS) or pain thermometer from 0-10 (or 0 to 5), with 0 denoting no pain and the higher end being unbearable pain. A completely intact disc will retain the dye in a central globular pattern, and is usually not very uncomfortable, even at high pressures. With more advanced disc degeneration on the other hand, patients may experience varying degrees of discomfort and pain as the dye is injected. A post discogram CT scan is often performed, and allows for a more thorough visualization, assessment, and identification of disc abnormalities (Saal 2002, Carragee 2001, Cohen 2005, Rowles 2005).

Discography has always been described as one of the most controversial tests in the management of degenerative painful lumbar spine conditions. Unlike MRI or CT scans, discography is used as a provocative test alleged to correlate symptoms with pathology. It seeks to confirm an impression that the back pain is discogenic and originating from a certain intervertebral disc. Some researchers found that healthy, previously pain free, patients can develop both back and leg pain from a provocative discogram as a result of the injection of irritants at different sites in motion segments. They also found that placement of the needle and injecting contrasts in the annulus fibrosus rather than the nucleus pulposus may induce back pain which should be regarded as false positive discography. Also, pain response to the discograms may vary widely among patients with chronic pain and somatization disorders. According to several investigators, psychological distress and pre-existing chronic pain processes may be stronger predictors of low-back pain than painful disc injections (Saal 2002, Carragee 2004, and Lander 2005).

One of the most feared complications of discography is discitis because of the poor blood supply of the intervertebral discs. Other reported adverse events include injury to the intervertebral disc, headache due to neuroaxial leak of the contrast, convulsions, meningitis, subdural or epidural abscesses, intrathecal hemorrhage, and others. Also, as indicated earlier discography may cause or worsen low back pain especially in patients with somatization disorder (Cohen 2005).

The suggested clinical indications for discography are wide-ranging and highly individualized (Carragee 2004). Guidelines published by specialized groups recommend that discography be reserved for use in patients with equivocal or inconsistent findings from MRI or other tests. Some investigators suggest its use for the evaluation of patients with chronic back pain for whom a surgical intervention is being considered.

Discography is being reviewed by MTAC based on a request from Dr. Kyle Kim. Considered as a procedure, discography is not regulated by the FDA; however, the devices and agents used for the test require FDA approval. Several of these devices and contrast material have been approved by the FDA.

Medical Technology Assessment Committee (MTAC)

Discography

10/01/2007: MTAC REVIEW

Evidence Conclusion: *Reliability of discography for patients with chronic lumbar disc disease:* There is no current consensus in the spine community of what constitutes a positive disc injection (Carragee & Hannibal 2004). In general, a positive discogram depends mainly on the production of the usual or concordant pain, which is a subjective measure and might not be a proper validation tool. Observer variability and bias in reading a discogram, as well as inter and intraobserver validation of pain response were evaluated only in a few studies. In a prospective trial involving 47 patients (Carragee 2000), the authors found that patients with abnormal

Back to Top

psychological profiles have significantly higher rates of positive disc injections than either asymptomatic volunteers or symptomatic subjects with normal psychological screening. Agorastides and colleagues (2002) found an excellent interobserver and intraobserver agreement in applying Adams classification for discogram morphology but did not study the reliability of the test in diagnosing discogenic pain. These, as well as other published studies were small, had methodological flaws, and do not provide sufficient evidence to determine the reliability of discography. Diagnostic accuracy of discography: As indicated earlier there is no clinical test that could be used as a diagnostic gold standard for discogenic pain. Several studies investigated the accuracy of discogram and/or CT discograms in detecting disc disease based on surgical confirmation of the pathology. Other researchers evaluated the technology by comparing, and /or correlating its results with those obtained by various other techniques including CT, myelography, and MRI. Small series where experimental discograms (with no surgical confirmation) were performed on asymptomatic patients showed that the test might be associated with high false positive rates. Accuracy based on surgical confirmation of findings: Results of studies with surgical confirmation of disc degeneration (Jackson 1989, Bernard 1994, and others) showed that CT discography was more accurate than standard discography in identifying disc herniation. CT discography had a sensitivity ranging from 74% to 92% and specificity ranging from 60% to 80%, versus sensitivity around 80% and specificity as low as 31% for standard discography. Compared to other diagnostic modalities, CT discography seemed to be more accurate in identifying disc abnormalities. Combining it with MRI improved its sensitivity, but not the specificity in Bernard's study (See attached appendix table 1). Birney et al, 1992 (See evidence table) compared the findings of discography with MRI using surgical confirmation of disc herniation/degeneration as a gold standard among 90 patients (264 discs). All participants underwent an awake discogram by one radiologist and an MRI exam by another radiologist. 57 patients with 76 discs underwent surgical intervention. The study had its advantages and limitations. The authors evaluated discography as a morphologic test to examine the disc abnormality, but not as the cause of discogenic pain. The results of the study show 86% agreement between MRI and discogram. MRI was found to be more accurate in detecting disc herniation, while discogram was more accurate in detecting disc degeneration. The authors concluded that MRI and discography are equivalent in detecting degenerative disc disease; however, the study was not designed nor powered to detect equivalence. These studies determined the accuracy of discography in diagnosing disc pathology but did not confirm that the disc is the source of discogenic pain. Identifying a disc abnormality is not equal to identifying the cause of pain or that the disc is suitable for surgical intervention. Correlation of discography with MRI without surgical confirmation:
Studies that compared discography with MRI showed a varying agreement between the two tests. (See appendix table 2) Lim and colleagues (2005) studied the correlation between MRI and CT discography findings with pain response at provocative discography in 47 patients with discogenic back pain. MRI and discogram findings were analyzed based on concordant pain at discography. The study was small and had several limitations. Overall the authors reported a 68-89% accuracy of MRI in predicting pain, vs. 61% for discograms. Earlier in 1998, Ito and colleagues showed a 57% correlation between the two technologies in predicting pain. Several other investigators e.g. Gibson 1986, Linson 1990, Simmons 1991, Osti 1992, (See appendix table 2) as well as others studied the correlation between MRI and discograms in diagnosing a disc abnormality. The studies were small and had their limitations. Agreement rates were reported per patients, and/ or per discs. For patients it ranged from 55-75%, and for discs it ranged between studies from 71-94%. It is hard to determine if the lack of agreement between the tests was due lack of sensitivity (false negatives) or lack of specificity (false positives) in one or the other test. Diagnostic and therapeutic impact of discography on health outcomes: There were a number of published prospective and retrospective studies that aimed at correlating discography findings to surgical outcomes. The population sizes in these studies were small, and the mean duration of follow-up ranged from <2-6 years. Abnormal discogram was the basis for surgery, which was mainly spinal fusion, a procedure which is considered by many investigators as a controversial treatment. Willems and colleagues' (2007) study (see evidence table) evaluated whether preoperative status of the adjacent discs, as determined by provocative discography, had an impact on the clinical outcome of lumbar fusion in patients with chronic low back pain (LBP). The study included 209 patients with chronic LBP. They underwent outpatient routine diagnostic tests including radiography, MRI, CT, and provocative discography to determine the levels considered for lumbar fusion. The patients then underwent temporary external transpedicular fixation trial which was the final decisive factor for fusion. The latter was performed on 82 patients. They were followed up for a mean of 80 months and the primary outcome was the individual changes in pain on a visual analog scale (VAS), and patient satisfaction. A successful outcome was defined as 30% or more pain reduction. This rate was arbitrary, and according to the authors debatable. The study had other methodological flaws, and its overall results indicate that provocative discography had no significant impact on the clinical outcome after lumbar fusion. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum

Back to Top

acceptable outcome was 43%. Earlier in 2002, Madan and colleagues studied the outcome of spinal arthrodesis among 73 patients with discogenic low back pain refractory to nonoperative management. Chronologically the first 41 patients had not undergone discography while the following 32 patients underwent surgery based on discographic findings. The primary outcome was satisfactory clinical outcome based on a visual analogue scale and other questionnaires including the Oswestry Disability Questionnaire after a mean follow-up of 2.4-2.8 years. The results showed that 75.6 % of the patients in the discography group had satisfactory outcomes versus 81% of those who did not have a preoperative discography. This observed difference in improvement was not statistically significant. The other published studies had their limitations, had potential selection, spectrum and observation bias, and used subjective measures as their outcomes. They also had conflicting results all of which makes it hard to determine if preoperative discography is of value in selecting patients for surgical intervention and/or predicting surgical outcomes. Conclusion: There is insufficient evidence to determine the reliability of discography in the diagnosis of discogenic pain among patients with chronic low back pain. There is insufficient evidence to determine that that discography is accurate for the diagnosis of discogenic pain. There is insufficient evidence to conclude whether or not the use of discography can improve selection of patients, predict or improve surgical outcomes in those with discogenic chronic low back pain.

Articles: The search yielded over 500 articles some of which dated back to 1966. There were three systematic reviews of the literature with no meta-analyses, and several small prospective or retrospective studies that aimed at determining the reliability, calculating the diagnostic accuracy, comparing, or correlating the findings of discography with MRI, CT scanning, myelograms or radiographs in symptomatic or asymptomatic patients. The search also revealed several relatively small studies that utilized health outcomes as a method for assessing the efficacy of discography. The ideal study would be a blinded independent comparison of discogram with a gold standard. However, to date, there is no known gold standard for discogenic pain. Some researchers determined the accuracy of discography by comparing it to other diagnostic modalities. Others used surgical findings and pathological disc morphology as their standard to confirm discographic results. These can confirm the presence of disc degeneration but cannot definitely confirm that it is the source of discogenic pain. Other groups suggested using clinical results of fusion as a gold standard to confirm whether the positive discogram injections were in fact true positives. Still many disagree on using a “controversial “treatment as the spinal fusion as a gold standard for a diagnostic test. One study that correlated discogram findings with MRI, and another that sought to measure its efficacy based on health outcomes were presented in evidence tables. Several other studies were grouped in table forms (see appendix tables 1 and 2) and/or discussed in the reviewer’s evidence summary section.
The studies critically appraised in evidence tables are Birney TJ, White JJ, Berens D, et al. Comparison of MRI and in the diagnosis of lumbar degenerative disc disease. J Spinal Disord 1992;5:417-423 See Evidence Table.
Willems PC, Elmans L, Anderson PG, et al. Provocative discography and lumbar fusion. Is preoperative assessment of adjacent discs useful? Spine 2007;32:1094-1099 See Evidence Table.

The use of discography in the treatment of lower back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Discography

12/14/2011: MTAC REVIEW

Evidence Conclusion: In 2007 we reviewed the evidence for lumbar provocative discography, and there was insufficient evidence to determine the benefits of the procedure. A quick literature search did not reveal any good quality or large studies on analgesic discography. The only more recent study discussed in that article is the Cooper et al's study presented in a meeting and not published in a peer reviewed journal.
There was a systematic review with no meta-analysis of studies on lumbar discography (Manchianti 2009) that concluded that the level of evidence on the technology is II-2 (i.e. evidence obtained from at least one properly designed small diagnostic accuracy study). The review indicated that there is a lack of literature, poor methodological quality and very few studies using IASP criteria. Carragee (2006) compared 5-year outcomes of two cohorts: 1 Discography (presumed discogenic pain) cohort, n=30, and 2: Unstable spondylolisthesis cohort of 32 patients used as a control group. The gold standard used for the diagnosis of discogenic pain by discography was clinical outcome after surgical intervention. Outcome measures included VAS for back and leg pain, Modems Lumbar Questionnaires, analgesic usage, work status, reoperation, and complications. The results show a surgical success rate of 27% among the patients with discography positive test, compared to a 72% success rate in the control group. The calculated positive predictive value of discography for achieving at least the minimum acceptable outcome was 43%.

Articles: A quick literature search did not reveal any good quality or large studies on analgesic discography. The only more recent study discussed in that article is the Cooper et al's study presented in a meeting and not published in a peer reviewed journal. There was an systematic review with no meta-analysis of studies on lumbar discography (Manchianti 2009) that concluded that the level of evidence on the technology is II-2 (i.e. evidence obtained from at least one properly designed small diagnostic accuracy study). The review indicated that there is a lack of literature, poor methodological quality and very few studies using IASP criteria.

Back to Top

The use of discography in the treatment of lower back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

CPT® or HCPC Codes	Description
62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/18/2007	10/01/2007, 10/15/2007 MDCRPC, 1/3/2012 MDCRPC, 2/7/2012 MDCRPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC , 02/01/2022MPC, 02/07/2023MPC	05/02/2017

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
05/02/2017	Adopted KPWA policy for Medicare members

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Device, Equipment and Supplies

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Durable Medical Equipment Reference List (280.1).
Local Coverage Determinations (LCD) Local Coverage Article (LCA)	Oxygen and Oxygen Equipment (L33797) "Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment." Oxygen and Oxygen Equipment – Policy Article (A52514) "Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the beneficiary's treatment." Patient Lifts (L33799) Patient Lifts – Policy Article (A52516) **Please note that many individual DME items may have their own specific LCD and/or LCA.*
Kaiser Permanente Medical Policy	PureWick™ Urine Collection System Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Device, Equipment and Supplies"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

Noridian Jurisdiction D DME Supplier Manual
Noridian Same or Similar Chart

Please refer to Kaiser Permanente payment policy Durable Medical Equipment for reimbursement clarification

For Non-Medicare Members

Durable Medical equipment (DME) also known as home medical equipment (HME) may be considered medically necessary when **ALL** of the following criteria are met:

Back to Top

- The patient has a documented physical functional impairment or disability due to disease, trauma, congenital anomaly or prior therapeutic intervention and requires accommodation for basic activities of daily living (ADLs) that can be met by using a DME item; and
- Documentation in the medical record contains a clinical assessment and rationale for the requested DME item (see Required Documentation below); and
- The DME is prescribed by a health care practitioner; and
- It is an item with a published HCPCS code; and
- The piece of equipment meets the definition of DME (see Policy Guidelines) and
- The requested DME item is not considered to be not medically necessary, investigational or unsafe by a regulatory agency, excluded by plan benefits or contract exclusion; and
- When specific criteria exist, the patient has also met those criteria.

The following are considered not medically necessary:

- Accessory add-ons and upgrades when a basic DME item meets the member's functional needs
- Athletic/exercise/physical fitness equipment (e.g. treadmills, stationary bikes)
- Comfort or convenience items (e.g., OTC compression sleeve-like garments/soft brace)
- Comfort or convenience items added to basic equipment
- Deluxe equipment when basic (standard) equipment is available and meets the member's functional needs
- Duplicate equipment (e.g. a rolling walker, when the member has a properly fitted cane)
- Equipment and modifications/upgrades to equipment when used primarily for leisure or recreational activities (e.g. special wheelchair wheels for sport activities, prosthetic adaptations for beach use, skiing and others)
- Equipment used for environmental control or to enhance the environmental surroundings (e.g. air conditioners, air filters, humidifiers, allergy protective pillow/mattress covers, furniture [e.g. recliner chairs, over-bed tables], and others)
- First aid or precautionary equipment (e.g. automatic external defibrillator (AED), portable oxygen to back up an in-home oxygen system)
- Home modifications (e.g. bath grab bars, electronic door openers, elevators, Jacuzzi/whirlpools, ramps,)
- Institutional equipment (e.g. any DME that is used only in a medical facility and is not suitable for use in the home setting)
- Same/similar or back-up DME item(s) not used as the primary device to meet the member's functional needs (ie more than one of the same item of durable medical equipment).
- Devices that do not meet the definition of durable medical equipment (DME), because they are not primarily intended for medical purposes (e.g. desktop/laptop computers, smartphones, tablets, internet, phone services, any modification to a patient's residence for DME use)

*See below for specific exclusions

Required Documentation

Documentation from the clinical evaluation should include the following:

- An order/prescription from the physician/health care provider responsible for the patient's care that states the therapeutic purpose of the DME
- Details of the patient's physical functional impairment related to completing activities of daily living (ADLs) without the home medical equipment/DME; and
- The patient's medical condition that requires DME for long term use (i.e. 6-12 months or more) when applicable; and
- What assistive devices (e.g., canes, walkers, manual wheelchairs) the device has been trialed and found to be inadequate/unsafe or contraindicated to completely meet the patients functional needs (when applicable)

Note: Even when a provider orders or prescribes DME and deems the equipment necessary for the patient's functional needs, that does not mean that the item meets the criteria as listed in the policy. It also does not guarantee that the item will be considered medically necessary.

Definition of Terms

Back to Top

Activities of daily living (ADLs) – ADLs are self-care activities done daily within a member's place of residence and includes

- Dressing/bathing
- Eating
- Ambulating (walking)
- Toileting
- Transferring
- Hygiene/grooming

Durable Medical Equipment (DME) – DME is:

- Primarily and customarily used to serve a medical purpose and
- Not useful to a person in the absence of illness or injury and
- Ordered or prescribed by a physician or other qualified provider and
- Reusable (non-disposable) and
- Designed to withstand repeated use (durable) and
- Not solely for the convenience of the patient or caregiver
- The equipment is not for use exclusively outside the home setting.

Prosthetics are covered if:

1. The device replaces all or part of an internal body organ or
2. Replaces all or part of the function of a permanently inoperative or malfunctioning internal body organ. **AND**
3. When specific medical criteria exist, the patient has also met those criteria.

The following items require review by Clinical Review:

1. Equipment with no HCPCS code
2. Equipment using miscellaneous code ****99, K0108, or L4205 in the absence of specific equipment/prosthetic codes
3. New technology
   a. Not yet FDA approved
   b. No specific HCPC for the service
   c. New FDA approval within 6 months
4. All equipment/prosthetics listed in Clinical Review Criteria
5. Duplicate items of equipment are being requested

Testicular prosthesis is considered medically necessary for replacement of congenitally absent testes, or testes lost due to disease, injury or surgery.
Testicular prosthesis may be covered when associated with transgender services when clinical criteria is met. Some plans do not cover transgender services.

ExoSyn Energy Storing AFO – CMS coding guidelines can be found here: Correct Coding - IDEO and ExoSym Energy Storing AFO
Medicare LCD L33686 – Ankle-Foot/Knee-Ankle-Foot Orthosis

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In 2012 Kaiser Permanente plans developed a reference list for DME/prosthetic equipment/devices that would be covered. The criteria above were developed to augment the list in the determination of coverage for DME/prosthetic items in the absence of a specific medical policy document.

Back to Top

Evidence and Source Documents

Member contract

Applicable Codes

*To verify authorization requirements for specific DME items, please use the **Pre-authorization Code Check**.

Considered non-covered personal convenience item/not separately reimbursable in the home setting:

CPT® or HCPC Codes	Description
A4467	Belt, strap, sleeve, garment, or covering, any time **Should use a more specific code*
A9270	Noncovered item or service
	Air Conditioners or Cleaners
A9280	Alert or alarm device, not otherwise classified
L3000-L3090	Arch support
E0160	Sitz type bath or equipment, portable, used with or without commode
E0161	Sitz type bath or equipment, portable, used with or without commode, with faucet attachment(s)
E0162	Sitz bath chair
E0235	Paraffin bath unit, portable
A4265	Paraffin, per pound
E0240	Bath/shower chair, with or without wheels, any size
E0241	Bathroom wall rail
E0242	Bathroom rail, floor base
E0243	Toilet rail
	Bed Baths (home type)
E0273	Bed board
	Bed Lifters (bed elevators)
	Beds-Lounges (power or manual)
E0270	Hospital bed, institutional type includes: oscillating, circulating and Stryker frame, with mattress (not on Exclusions list in the General Criteria)
E0462	Rocking bed, with or without side rails
	Dehumidifiers
K1004	Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories
	Disposable sheets and bags
A4553	Non-disposable underpads, all sizes
A4554	Disposable underpad, all sizes
	Electric air cleaners
	Electrostatic machines
	Elevators
A9300	Exercise equipment
	Face masks (surgical)
E0218	Fluid circulating cold pad with pump, any type
E0191	Heel or elbow protector, each
A9273	Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type
	Humidifiers (not associated with PAP equipment, oxygen, IPPB, and Cool Air mist set ups)
A4520	Incontinence garment, any type (e.g., brief, diaper), each
E0221	Infrared heating pad system
A4639	Replacement pad for infrared heating pad system, each
E0481	Intrapulmonary percussive ventilation system and related supplies
L8499	Leg cover, realistic (Unlisted procedure for miscellaneous prosthetic services)
A9285	Inversion/Eversion correction device
	Leotards (does not include the burn leotards)
	Massage devices
A9270	Non-covered service

Back to Top

CPT® or HCPC Codes	Description
E0274	Over-bed table
	Parallel bars
E0625	Patient lift, bathroom or toilet, not otherwise classified
E0635	Patient lift, electric with seat or sling
E0640	Patient lift, fixed system, includes all components/accessories
E0639	Patient lift, moveable from room to room with disassembly and reassembly, includes all components/accessories
E0300	Pediatric crib, hospital grade, fully enclosed, with or without top enclosure
	Portable room heaters
A9281	Reaching/grabbing device, any type, any length, each
E0710	Restraints, any type (body, chest, wrist or ankle)
E0700	Safety equipment, device or accessory, any type
	Sauna Baths
E0172	Seat lift mechanism placed over or on top of toilet, any type
	Spare tanks of oxygen
	Speech teaching machines
	Stairway elevators
E0638 & E0641-E0642	Standing frame/table
A4490-A4510	Surgical stockings
	Telephone alert systems
E0203	Therapeutic light box, minimum 10,000 lux, table top model
E0244	Raised toilet seat
E0245	Tub stool or bench
E0246	Tub rail attachment for transfer
E0247	Transfer bench for tub or toilet with or without commode opening
E0248	Transfer bench, heavy-duty, for tub or toilet with or without commode opening
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
	Treadmill exercisers
L8510	Voice amplifier
E0249	Pad for water circulating heat unit, for replacement only
E0950	Wheelchair tray
E1310	Whirlpool, nonportable (built-in type)
E1300	Whirlpool, portable (overtub type)
	White Canes
A9282	Wigs
A9286	Hygienic item or device, disposable or non-disposable, any type, each
A4606	Oxygen probe for use with oximeter device, replacement
E0445	Oximeter device for measuring blood oxygen levels noninvasively
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
V5275	Ear impression, each
V5281	Assistive listening device, personal FM/DM system, monaural (1 receiver, transmitter, microphone), any type
V5282	Assistive listening device, personal FM/DM system, binaural (2 receivers, transmitter, microphone), any type
V5283	Assistive listening device, personal FM/DM neck, loop induction receiver
V5284	Assistive listening device, personal FM/DM, ear level receiver
V5285	Assistive listening device, personal FM/DM, direct audio input receiver
V5286	Assistive listening device, personal blue tooth FM/DM receiver
V5287	Assistive listening device, personal FM/DM receiver, not otherwise specified
V5288	Assistive listening device, personal FM/DM transmitter assistive listening device

Back to Top

CPT® or HCPC Codes	Description
V5289	Assistive listening device, personal FM/DM adapter/boot coupling device for receiver, any type
V5290	Assistive listening device, transmitter microphone, any type
K1006	
A7001	Canister, non-disposable, used with suction pump, each **not covered when used with disposable external urine management system*
A7002	Tubing, used with suction pump, each **not covered when used with disposable external urine management system*
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	External urinary catheter; non-disposable, for use with suction pump, per month
E2001	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system
E0936	**Effective May 1, 2024** Continuous passive motion exercise device other than knee
E0445	**Effective May 1, 2024** Oximeter device for measuring blood oxygen levels noninvasively
A4606	**Effective May 1, 2024** Oxygen probe for use with oximeter device, replacement

Effective July 1, 2024

Codes without payment methodology by Medicare that we have reimbursed but will no longer reimburse:

CPT® or HCPC Codes	Description
L2999	Lower extremity orthoses, not otherwise specified **There are more specific codes that should be used*
L3999	Upper limb orthosis, not otherwise specified **There are more specific codes that should be used*

Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E2601	General use wheelchair seat cushion, width less than 22 in, any depth
E2602	General use wheelchair seat cushion, width 22 in or greater, any depth
E2603	Skin protection wheelchair seat cushion, width less than 22 in, any depth
E2604	Skin protection wheelchair seat cushion, width 22 in or greater, any dept
E2605	Positioning wheelchair seat cushion, width less than 22 in, any depth
E2606	Positioning wheelchair seat cushion, width 22 in or greater, any depth
E2607	Skin protection and positioning wheelchair seat cushion, width less than 22 in, any depth
E2608	Skin protection and positioning wheelchair seat cushion, width 22 in or greater, any depth

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Creation Date	Review Dates	Date Last Revised
01/22/2004	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 10/01/2013[MPC], 06/03/2014[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 02/13/2024[MPC]	02/13/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Back to Top

Revision History	Description
10/1/2015	Added 2 Noridian links
10/27/2015	Added testicular prosthesis information
02/02/2016	Expanded the policy for DME
09/28/2017	Added A9285 to non-covered
11/16/2017	Added ExoSyn language
02/28/2017	Added A4265 to non-covered list
05/23/2018	Added V codes for assistive listening devices to the non covered list
08/04/2020	Added devices not primarily intended for medical purposes (computers/phones/tablets, etc.) to the not medically necessary section
06/07/2022	MPC approved to add Home Pulse Oximetry codes to the DME list; 60-day notice required
10/26/2022	Retitled non covered item list
10/28/2022	Added E0765; Relief Band Device to the DME non-covered list
05/31/2023	Added Purewick Urinary Collection System to the DME non-covered list
12/09/2023	MPC approved to endorse a position of non-coverage in the ambulatory setting, aligning with CMS payment methodology.
12/13/2024	MPC approved DME billing codes that have been reimbursed historically but will no longer have payment methodology will be listed on DME page: L2999, L3999

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Driving Skills Assessment

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	Billing and Coding: Therapy Driving Evaluations (A52772) *Medicare does not reimburse evaluations performed solely to assess a beneficiary's ability to drive a vehicle. In order for a service to be covered, the service must have a benefit category in the statute Title 18 of the Social Security Act (SSA), it must not be excluded, and it must be reasonable and necessary. There is no benefit category for driving evaluations.*

For Non-Medicare Members

Treatments and/or therapies that are intended to specifically improve what are known as Instrumental Activities of Daily Living (IADL) are not covered because they are not considered treatment of disease. This includes driving skills assessments.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

OT is generally covered for members with eligible conditions that require improvement in Activities of Daily Living (ADLs). These include, but may not be limited to
bathing, communication, dressing, feeding, grooming, mobility, personal hygiene, self-maintenance, skin management, and toileting.

Treatments and/or therapies that are intended to specifically improve what are known as Instrumental Activities of Daily Living (IADL) are not covered because they are not considered treatment of disease. These include, but are not limited to: community living skills including balancing a checkbook, use of public transportation; home management skills including meal preparation, laundry; leisure activities including hobbies, sports or recreation of all types even if suggested as part of an OT treatment plan; motor vehicle driving evaluations and driving instruction - this includes automobiles, trucks, motorcycles and bicycles; or personal safety preparedness. This does not mean that a driving evaluation might not be helpful for a given patient, rather that the patient or family would be responsible for the cost.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/07/2020	04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	04/07/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt new non-coverage criteria, effective 08/01/2020.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dry Needling for Myofascial Pain

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Acupuncture (30.3) Acupuncture for Fibromyalgia (30.3.1) Acupuncture for Osteoarthritis (30.3.2) Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Myofascial pain syndrome (MPS) is a fairly common form of pain that arises from muscles or related fascia. The syndrome is usually characterized by palpable muscle tenderness and trigger points (myofascial trigger points or MTrPs). These are highly localized, hyperirritable spots in a palpable taut band of skeletal muscle fibers. When compressed, MTrPs can cause local and/or referred tenderness and pain, aggravation of existing pain, and /or autonomic phenomena. They can also contribute to impaired range of motion and increased sensitivity to stretch. Active MTrPs are associated with spontaneous local or referred pain and/or pain on movement, while latent MTrPs require direct stimulation to trigger pain symptoms. Palpating a trigger point or inserting a needle into it may elicit a localized twitch response, a brisk contraction of muscle fibers in and around the MTrPs. Trigger points may develop anywhere in the body in response to sudden injury, muscle overload, or repetitive microtrauma. Frequently affected sites include trapezius, supraspinatus, infraspinatus, teres muscle, lumbar paraspinals, gluteus, and pectoralis muscles. It is postulated that the injured muscle fibers shorten forming taut bands in response to the excessive amounts of calcium released from the damaged fibers or to the excessive amounts of acetyl choline released from the corresponding motor end plate. There are no laboratory or imaging tests to establish the diagnosis of MPS or to locate the trigger points. It has been suggested that spot tenderness, taut band, and pain recognition are the three important criteria for the diagnosis of MTrP, and that referred pain and local twitch response can be confirmatory signs for the diagnosis (Chou 2012, Dıraçoğlu 2012, Furlan 2005, Kietrys 2013, Ay 2010, Tekin 2013 Tough 2009).

Back to Top

The primary goal of treating MPS is to inactivate the trigger points and loosen the taut bands. The most important strategy is to treat the underlying etiological lesion that causes activation of MTrPs. If the underlying pathology is not appropriately and completely treated, the MTrP is inactivated only temporarily not completely. Several treatment modalities have been used to alleviate the chronic myofascial pain, but no single strategy proved to be universally successful. These include the use of non-steroidal anti-inflammatory drugs (NSAIDs), NSAID gel or patch, thermotherapy, massage, physical therapy, spray and stretch techniques, exercise, ischemic compression, laser therapy, acupuncture, or local injections of substances as steroids or lidocaine. Trigger point injection with local anesthetic, saline, steroid, botulinum toxin, or even dry needling is believed to be the most effective method for treating MPS (Ay 2010, Chou 2012, Kalichman 2010).

Dry needling (DN) was initially developed to treat musculoskeletal disorders. It was widely used for the treatment of MTrPs in the last three decades after some investigators indicated that needling effect is distinct from that of the injected substance. Trigger-point DN (also called biomedical acupuncture) is different from acupuncture and is not based on the insertion of needles in traditional acupuncture meridian sites. DN is a procedure in which an acupuncture-like needle is inserted into the skin and muscle in the location of an MTrPs without the use of saline or any other liquid agent or medication. The needle is not left in situ but is removed after the muscle has finished twitching and the trigger point inactivated. This should be followed by exercises, usually stretching or ergonomic adjustments, in order to establish a painless full range of motion. It has been suggested that DN is most effective when local twitch responses are elicited, probably because of rapid depolarization of the involved muscle fibers which manifest as local twitches. The actual mechanism by which DN may produce an effect is being debated and several explanations were postulated. Some investigators explain that the localized twitch response that often occurs may interrupt the motor end-plate noise, producing an analgesic effect, while others suggest that eliciting a localized twitch response and stretching exercises relax the actin-myosin bonds in the tight bands. It is also postulated that the mechanical damage of the muscle fibers and nerve terminations leads to an increase of extracellular potassium, depolarization of nerve fibers, inhibition of central feedback mechanisms, local dilution of nerve-sensitizing substances, increasing vasodilatation, and formation of necrosis in trigger point area. A number of other mechanisms were postulated by different researchers. Adverse events associated with the DN include soreness after needling, local hemorrhages at the needling site, and syncopal responses (Ay 2010, Furlan 2005, Kalichman 2010, Kietrys 2013).

Several schools and theoretical models of DN have been developed during the last three decades. The most common are the radiculopathy (also known as intramuscular stimulation) and MTrP models. Dry needling techniques include superficial or deep needling and needling with or without paraspinal needling. In the superficial needling the needle is only inserted into the tissue overlying the MTrP to a depth of 5-10 mm for 30 seconds. At this level the needle does not necessarily reach the MTrP and local twitches are not expected. In the technique that involved paraspinal needling, needles are inserted at the trigger point as well as in the paraspinal muscle of the same segment that innervates the painful muscles. These last two techniques were the least investigated (Kalichman 2010).

DN is a minimally invasive skilled intervention performed by physical therapists (where allowed by state law) and requires advanced training. The states allowing the procedure to have to follow guidelines for education and competency standards for performing it.

Medical Technology Assessment Committee (MTAC)

Dry Needling for Myofascial Pain

02/10/2014: MTAC REVIEW

Evidence Conclusion: The results of the published randomized controlled trials (RCTs) and meta-analyses do not provide sufficient evidence to determine that DN is superior or equivalent to acupuncture, physical therapy, injections with lidocaine or botulinum toxin in reducing myofascial pain or increasing the range of motion. The published randomized controlled trials that compared the effect of DN to sham injections, injections with lidocaine, botulinum toxin, acupuncture, or physical therapy had small sample sizes, and insufficient power to detect significant differences between the study groups. The majority of trials were unblinded, had methodological limitations, and none was designed as an equivalence trial. The overall results of the studies show some improvement in pain and range of motion with lidocaine or botulinum toxin injections, physical therapy, or acupuncture, and some or no improvement with DN. Improvements were observed when the comparisons were made between pre-and post-treatment within each of the study groups. There were no significant between groups differences in the outcomes studied. Many of the authors interpreted the lack of difference between the study groups as equal effects. As indicated earlier, none of the trials were designed as equivalence study, and a lack of significant differences between study groups cannot be interpreted as equal effects as it might be due to the small sample sizes and insufficient power of the trials.

 Back to Top

Kietrys et al's (2013) meta-analysis (evidence table 1) pooled the results of 12 trials with a total of 696 participants that compared DN to either sham therapy or other active therapies (lidocaine injection, botulism toxin injection, or acupuncture) for upper quarter myofascial pain. The pooled results of the analysis indicate that DN may be superior to sham needling but less effective than the other active therapies. Tough and colleagues' (2009) meta-analysis pooled the results of 7 small trials, with significant heterogeneity, that studied the effect of acupuncture and DN of the MTrPs compared to no additional intervention, indirect local DN, or a sham therapy. Four of the included studies were rated to have poor methodological quality. The authors could perform a MA only for 4 (N=134 participants) studies that compared DN to sham needling. The pooled results of these trials showed that DN was not superior to sham therapy in reducing the myofascial pain (standardized mean difference =14.09 (95% CI, -5.81 to 33.99). The results of the two meta-analyses have to be interpreted with caution due to the small number and size of the trials as well as their methodological limitations, and significant heterogeneity between studies.
Conclusion: There is insufficient published evidence to determine that dry needling has a superior or equivalent effect as acupuncture, other therapies, or injections in reducing pain and improving range of motion (ROM) in patients with myofascial pain syndrome (MPS). The results of trials comparing DN to sham needling are conflicting, and may only provide weak evidence that DN performed by experienced physiatrists may be superior to sham needling in reducing the pain, but not improving the ROM. There is insufficient published evidence to determine the appropriate number of points to be injected. There is insufficient published evidence to determine the duration of pain relief after the injection. There is insufficient evidence to determine whether the patients would need to undergo another needling procedure, and the most appropriate interval between re-injections if needed.
Articles: The literature search revealed a number of small randomized controlled trials and 4 systematic reviews with or without meta-analyses (MA) on the use of DN in the management of myofascial pain. Kietrys and colleagues' 2013 meta-analysis examined the effectiveness of DN for the treatment of upper quarter myofascial pain. Tough et al's 2009 MA updated an earlier 2001 MA on the effect of DN on MPS in any location in the body. A Cochrane review (Furlan et al, 2005) pooled the results of studies on acupuncture and DN for low back pain. The three meta-analyses included the majority of the published RCTs that compared DN to sham needling, physical therapy, or injection of local anesthesia used for the treatment of myofascial syndrome in different locations in the body. The following most recent and larger meta-analysis and selected RCTs included or not included in the meta-analyses were critically appraised. Selection of the RCTs was based on their size, control groups, and methodological quality. Ay S, Evcik D, Tur BS. Comparison of injection methods in myofascial pain syndrome: a randomized controlled trial. *Clin Rheumatol*. 2010; 29:19-23. Dıraçoğlu D, Vural M, Karan A, et al. Effectiveness of dry needling for the treatment of temporomandibular myofascial pain: a double-blind, randomized, placebo-controlled study. *J Back Musculoskelet Rehabil*. 2012; 25:285-290. Irnich D, Behrens N, Gleditsch JM, et al. Immediate effects of dry needling and acupuncture at distant points in chronic neck pain: results of a randomized, double-blind, sham-controlled crossover trial. *Pain*. 2002; 99:83-89. Kietrys DM, Palombaro KM, Azzaretto E, et al. Effectiveness of Dry Needling for Upper-Quarter Myofascial Pain: A Systematic Review and Meta-analysis. *J Orthop Sports Phys Ther*. 2013; 43:620-34. Rayegani SM, Bayat M, Bahrami MH, et al. Comparison of dry needling and physiotherapy in treatment of myofascial pain syndrome. *Clin Rheumatol*.2013 Dec 19.DOI 10.1007/s10067-013-2448-3.Tough EA, White AR, Cummings TM, et al. Acupuncture and dry needling in the management of myofascial trigger point pain: a systematic review and meta-analysis of randomised controlled trials. *Eur J Pain*. 2009; 13:3-10. Tekin L, Akarsu S, Durmuş O, et al. The effect of dry needling in the treatment of myofascial pain syndrome: a randomized double-blinded placebo-controlled trial. *Clin Rheumatol*. 2013; 32:309-315.

The use of dry needling for myofascial pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Assessment

For dry needling (DN), typically coupled with exercise or stretching, for the treatment of adults with mechanical neck and/or trapezius muscle pain associated with trigger points (TrPs).

Conclusion

An overall low-quality body of evidence suggests that DN appears to be safe and may be somewhat effective for the treatment of neck and/or trapezius pain when combined with exercise, but it is unclear whether it provides additional benefits beyond those provided by standard therapy alone.

- Two sham-controlled trials found no difference in improvement in pain or physical function between DN plus exercise relative to sham DN plus exercise. This suggests that DN does not confer benefits beyond those attained by exercise or stretching.

Back to Top

- In 6 studies, DN coupled with exercise resulted in statistically and clinically significant improvement in pain relative to pretreatment levels; findings in 5 of these studies were mixed as to whether use of DN improved physical function relative to baseline.
- In 4 studies, DN coupled with exercise resulted in improved pain and function relative to exercise alone, but there were no differences between DN alone or coupled with exercise and manual therapy relative to manual therapy alone. The clinical significance of these results is unclear.

Additional studies are needed to address the remaining questions regarding the clinical significance of DN treatment, its long-term effectiveness, and its effectiveness versus other standard therapies.

Hayes Rating: C

Hayes. Hayes Technology Assessment. Dry Needling for Mechanical Neck and/or Trapezius Muscle Pain in Adults. May 18, 2023. Retrieved May 23, 2023, from https://evidence.hayesinc.com/report/dir.needling2835

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/01/2014	04/01/2014[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC], 03/12/2024[MPC]	05/23/2023

[MPC] Medical Policy Committee

Revision History	Description
06/02/2020	Added NCD's: Acupuncture for Chronic Lower Back Pain (cLBP) (30.3.3) and Acupuncture (30.3)
05/23/2023	Added Hayes Technology Assessment for Dry Needling for Mechanical Neck and/or Trapezius Muscle Pain in Adults

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Radiation Therapy for Palmar Fibromatosis

- Radiotherapy
- Dupuytren's Contracture

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Radiation Therapy for Palmar Fibromatosis," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dupuytren's contracture (DC) is a fibrotic tissue disorder affecting the hands. It is a benign condition characterized by thickening connective tissue in the palm eventually progressing to the formation of nodules and cords. Symptoms typically occur in both hands and progress gradually over time at variable rates. The lumps or dermal pits can be present for extended periods of time before a cord may develop causing the fingers to contract. The contracture, however, may not become troublesome for years or may never progress at all.

DC has a global prevalence of 3-6% primarily affecting males and Caucasian populations. Most patients will present with symptoms in middle age (Rizzo, Stern et al. 2013). Typically diagnosed upon physical examination, the etiology of DC is unknown, however, there is believed to be a strong genetic component as it most commonly occurs in people of Northern European or Scandinavian ancestry and often runs in families. The literature has also suggested associations with diabetes, seizures, smoking, alcohol, trauma and beta-blockers.

At present, there is no cure for DC. Available treatment options include both invasive and noninvasive modalities and typically focus on managing the disability and preventing progression (NICE 2010). Stretching, massage and splinting are frequently recommended while corticosteroid injections and fasciectomy have been used in more

Back to Top

Date Sent: 4/29/24

extreme and developed cases. In any case, most treatment options have limited effectiveness as 20% of patients experience recurrence of symptoms.

Radiation therapy or radiotherapy (RT) is a non-surgical treatment option that is reported to halt or slow the progression of DC in its early stages. Aimed to prevent or postpone the need for surgical intervention, the mechanism for action is unclear, but it is thought to affect the development and growth rate of fibroblasts within the palmar fascia. RT treatment of the affected nodules and cords can be performed with either superficial x-rays or electron beams. The technique is typically carried out over several consecutive visits until the intended radiation dose has been achieved.

Medical Technology Assessment Committee (MTAC)

Radiotherapy for Dupuytren's Contracture

10/20/2014: MTAC REVIEW

Evidence Conclusion: The most recent study, published by Zirbs and colleagues in September of 2014, included 355 patients with DC who had undergone soft X-ray between 1999 and 2008 at one of two sites in Germany. Participants were asked to respond to a structured questionnaire addressing family history, predisposing factors, occupation, disease characteristics, progression, treatments, effects, side-effects, and satisfaction using a visual analogue scale (VAS). Over half (58%) of patients responded to the questionnaire and, of those, almost 80% reported no progression of symptoms after receiving treatment and were satisfied with therapy. The investigators noted a significantly higher improvement in patients with who had experienced symptoms for less than 20 months, supporting the hypothesis that early stages of DC are treated more effectively. Ultimately, the authors concluded that radiotherapy was well-tolerated and prevented further disease progression in most patients (Zirbs, Anzeneder et al. 2014). In the only RCT identified, Seegenschmiedt and colleagues compared two different radiation techniques with the overall aim of optimizing radiation dose. The study included 129 patients (198 hands) who were randomly assigned to receive one of two RT schedules (30 Gy vs. 21 Gy). Subjective responses, DC stage, nodule number, size and consistency, as well as, cords and finger mobility were assessed at two follow-up appointments. At one year, the investigators reported that objective symptom assessment showed indications of regression in over half (56%) of the hands treated with 30 Gy of radiation. Similarly, of the group treated with 21 Gy of radiation, 53% of hands showed signs of regression. Subjective symptom assessment also indicated regression of DC in both groups with 65% and 53% of patients in groups A and B, respectively. The investigators, however, do not indicate if this difference was significant. Ultimately, the authors conclude that both tested regimens are well accepted and tolerated by patients. (Seegenschmiedt, Olschewski et al. 2001). Betz and colleagues present a case series of 135 patients (208 hands) who were irradiated with orthovoltage in two courses of five daily fractions of 3.0 Gy (total dose of 30 Gy) separated by a six to eight-week interval. The investigators were able to follow-up 76% of hands treated at 13 years and reported complete relief of symptoms in 16% of patients, good relief in 18% and minor relief in 32% patients. Ultimately, the investigators concluded that radiotherapy is effective in prevention of disease progression and improves patient's symptoms in early stage DC. (Betz, Ott et al. 2010). In terms of safety, theoretical adverse events could be anything that we already know to be associated with radiation such as skin dryness, scarring/hand stiffness, and long-term potential for developing radiation induced cancer. The included studies list both acute and chronic symptoms such as dryness and desquamation, skin atrophy, lack of sweating, telangiectasia and sensory affection. Seegenschmeidt and colleagues also detailed a higher acute toxicity in the low-dose group receiving (21Gy) when compared to the medium-dose group (30 Gy) siting the dose-time factor as the cause. In any case, all three studies ultimately concluded that the radiation therapy was well tolerated. On the whole, the body of evidence is limited and should be interpreted with caution. First and foremost, none of the included studies used an adequate comparator. In two of the selected studies no comparison group was used, and in the one study that did make comparisons, no sham group was included. To add to this, each study utilized different radiation doses at different regimens without identifying an ideal or standard dose. The inclusion criteria may also be a limiting factor as all three of the studies included patients who had previously received treatment limiting the ability to exclude the effects of prior treatment. Finally, only one of the studies, by Betz and colleagues, provides adequate follow up (13 years) to assess progression of symptoms and long-term safety. Conclusions: There is insufficient evidence to support the effectiveness of radiation therapy for patients with DC. There is insufficient evidence to support the safety of radiation therapy for the treatment of DC.

Articles: The literature was searched for publications assessing the safety and effectiveness of RT for DC. Several publications were revealed, many of which were published in languages other than English (primarily German). There were no randomized controlled trials (RCTs) comparing the effectiveness of RT with surgical intervention or any other medical intervention for that matter. One RCT was discovered that compared the effectiveness of two different radiation doses. In addition, two recent case series were included to address safety. The following articles were selected for critical appraisal: Zirbs M, Bruckbauer AH, Hoffman H, et al., Radiotherapy with soft X-rays in Dupuytren's disease – successful, well-tolerated and satisfying. European

Back to Top

Academy of Dermatology and Vernereology. 2014. See Evidence Table 1. Seegenschmiedt MH, Olschewski T, Guntrum F. Radiotherapy optimization in early-stage dupuytren's contracture: first results of a randomized clinical study. Int J Radiation Oncology Biol Phys. 2001; 49(3):785-798. See Evidence Table 2. Betz N, Ott OJ, Adamietz B, et al. Radiotherapy in early-stage Dupuytren's contracture. Strahlenther Onkol. 2010;186(2): 82-90. See Evidence Table 3.

The use of Radiotherapy for Dupuytren's Contracture does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
Effective September 1st, 2024 **77412**	**Effective September 1st, 2024** Radiation treatment delivery, => 1 MeV; complex
With diagnosis code	
M72.0	Palmar fascial fibromatosis [Dupuytren]

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/28/2014	11/07/2014MPC, 09/01/2015MPC, 06/07/2016MPC, 04/04/2017MPC, 02/06/2018MPC, 01/08/2019MPC, 01/07/2020MPC, 01/05/2021MPC, 01/04/2022MPC, 01/10/2023MPC, 04/02/2024MPC	04/17/2024

MPC Medical Policy Committee

Revision History	Description
12/24/2019	Added guidelines for Medicare members to use commercial criteria.
4/17/2024	Added code 77412. Requires 60-day notice, effective 9/1/2024.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dynamic Spinal Visualization

- Cineradiography
- Digital Fluoroscopic Video of the Spine
- Dynamic Motion X-ray
- Spine Digital Motion X-ray

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Dynamic Spinal Visualization***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dynamic spinal visualization addresses different imaging techniques that allow the simultaneous visualization of movement of internal body structures with corresponding external body movement. These include dynamic or digital motion x-rays and video fluoroscopy (also known as digital fluoroscopic video or cineradiography). These imaging technologies use x-rays to create images either on film, video monitor, or computer screen.

Video fluoroscopy is a procedure that uses fluoroscopy to create real-time video images of internal structures of the body. Unlike standard x-rays that take one picture at a time, fluoroscopy provides motion pictures of the body that can be displayed on a video monitor during the procedure and also recorded for further or later evaluation. Digital motion X-ray is a fluoroscopic x-ray that integrates today's digital and optic technology to produce an x-ray movie of the body while in motion. It involves the use of either film x-ray or computer-based x-ray snapshots taken in sequence as the patient moves; to image the cervical spine; for example, patients are asked to perform flexion, extension, right and left lateral flexion and left and right rotation exercises to document range of motion. The

Back to Top

snapshots are then digitized, put in order using a computer program and played on a video monitor creating a moving image of the inside of the body. Both digital motion x-rays and video fluoroscopy can either be examined by the physician with or without using special computer software to evaluate several aspects of the body's structure such as intervertebral flexion and extension, to determine the presence or absence of abnormalities.

The technology has been used for decades in the diagnosis of various conditions, mainly swallowing disorders, and have been proposed for the evaluation of spinal disorders including low back pain, and segmental lumbar spinal instability to determine the presence or absence of abnormalities.

Medical Technology Assessment Committee (MTAC)

Dynamic Spinal Visualization

10/17/2011: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence, to date, to determine the clinical utility of dynamic spinal visualization for the diagnosis or management of patients with spinal disorders. The published studies mainly evaluated the spine kinematics and motion patterns of the lumbar segments in symptomatic patients and asymptomatic volunteers. Others studied the correlation of total sequence of movement observed by cineradiography with the conventional radiographs taken at the extremes of spinal motion. No studies examined the effect of using the technology on managing the patients, impact on health outcomes, or an incremental value over conventional imaging methods. Reviews made by other health plans including Blue Cross, Blue Shield, Regence, Anthem, and several others, all came to the same conclusion that dynamic spinal visualization is considered investigational, and that there is insufficient published data to support the use of digital motion x-rays or cineradiography/video fluoroscopy of the spine for any indication.

Articles: The literature search revealed a limited number of small studies that compared the spine kinematics in patients with neck or back pain versus asymptomatic controls. No studies evaluating the effect of using the technology on managing the patients with back pain or other spinal disorders were identified.

The use of dynamic spinal visualization does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	Description
76120	Cineradiography/videoradiography, except where specifically included
76125	Cineradiography/videoradiography to complement routine examination (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/01/2011	11/01/2011[MDCRPC],10/02/2012[MDCRPC],08/06/2013[MPC],06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC] ,07/10/2018[MPC], 07/09/2019[MPC] ,07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC]	11/01/2011

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Electroconvulsive Therapy (ECT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare National Coverage Determinations Manual, Chapter 1, Part 2 (Section 160.25)
National Coverage Determinations (NCD)	Multiple Electroconvulsive Therapy (MECT) 160.25
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Care Guideline: Electroconvulsive Therapy (B-802-T) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Electroconvulsive therapy (ECT) is a procedure where electrodes are positioned on the patient's scalp, and a measured electrical current is passed through to the brain, inducing generalized seizure activity. ECT is typically administered by a psychiatrist, with the patient under general anesthesia (provided by an anesthesiologist or anesthetist). The treatments are performed in either an inpatient or outpatient setting, depending on a variety of factors.1

ECT is not typically considered the first-line of treatment. It is most often used to treat patients with treatment-resistant depression, after a failure of a number of adequate medication trials over time. However, it may result in therapeutic effect more rapidly than medications and should be considered as a possible first line treatment in life threatening catatonia (e.g. with risk of death due to severe malnutrition/starvation) or in someone who is at extremely high risk of suicide.2 Patients with severe medical or psychiatric illness often start ECT on an inpatient basis, and as they improve, might switch to outpatient treatment. Continuation and maintenance ECT are usually provided on an outpatient basis.

Back to Top

Date Sent: 4/29/24

The mechanism of action for ECT remains unknown. However, many studies have shown a variety of changes in the central nervous system that might play a significant role in its therapeutic effect, including ECT prompting the release of neurotransmitters, and ECT causing the hypothalamus or pituitary gland to release hormones such as thyroid stimulating hormone and endorphins.2

ECT has been found to be an effective and safe mode of treatment for a number of behavioral health disorders/conditions, and is practiced widely in the United States.1 However, the treatment continues to have some stigma attached because of misperceptions about its use, a lack familiarity with the current treatment procedure and the current level of risk of adverse effects.2

There are few contra-indications or relative contra-indications to the treatment, so a pre-treatment medical review is required before initiating treatment.

Risks of ECT are primarily those associated with anesthesia. The mortality rate (about 2 to 4 deaths per 100,000 treatments) is mostly related to cardiopulmonary events, but the mortality rate is less than that reported for normal childbirth, and is associated with the anesthesia risks.3,4

Current ECT techniques use anesthesia and brief-pulse electrical stimuli that “virtually eliminate” the past risk of fractures and minimize the risk of developing transient cognitive dysfunction effects. Not all patients who receive ECT will obtain Cognitive dysfunction / memory loss from the treatment; however, when it occurs, it can present during or after the course of ECT. The memory effects from ECT can manifest as an acute confusional state, as anterograde amnesia or as retrograde amnesia.

The acute confusional state is considered a result of both the seizure and the anesthesia. It usually resolves 10-30 minutes after the procedure.5

Anterograde amnesia is a decreased ability to retain newly acquired information. It can occur during a course of ECT and usually resolves within 2 weeks after completing the course.6

Retrograde amnesia involves forgetting recent memories, forgetting events that occur during the course of ECT and for a period of weeks or months prior to the ECT. Patients tend to retain knowledge about themselves but might forget public knowledge or information about world events. This retrograde amnesia tends to recover more slowly.7,8

ECT is most commonly used to treat severe or treatment-resistant depression. ECT has also been shown to be effective for bipolar mood disorders (depression, mania or mixed states), schizoaffective disorder, schizophrenia and catatonia.2

ECT has been found to be particularly effective in treating patients with depression with prominent suicidal ideation or patients with psychotic depression. Response rates have been found to range from 50-80% for patients with treatment-resistant depression, and maintenance medication management or maintenance ECT may significantly decrease the relapse rate.9,10

For patients with bipolar disorder, ECT has been used for treatment of severe and psychotic depression, especially if refractory to medication management.11,12

For patients with schizophrenia or schizoaffective disorders, ECT may be considered when a rapid global improvement with reduction in symptoms is needed.13 ECT might also be used in the treatment of catatonia.14

ECT may be warranted for patients who are in an acutely life-threatening situation (e.g. high risk for suicide attempt, unremitting self-injury, catatonia, starvation, intractable manic excitement, or neuroleptic malignant syndrome). ECT might also be indicated when patients have a coexisting medical condition, where ECT is considered a safer therapeutic alternative than behavioral medication management (e.g. pregnant or elderly patients), and for patients who have previously responded well to ECT or who are unwilling or unable to take medications.1,2,15,16,17

For patients who have obtained a positive therapeutic response with ECT, but who are unable to sustain the response with post-ECT behavioral health medication management, ECT as maintenance treatment may be considered, and is generally administered with decreased frequency (e.g. weekly, biweekly, monthly), and might be provided as long-term maintenance treatment, when discontinuation or further reduction in the treatments is likely to lead to a relapse.1,18

Back to Top

Evidence and Source Documents

1. Lisanby SH. Electroconvulsive therapy for depression. N Engl J Med. 2007; 357(19):1939.
2. Kellner CH, Greenberg RM, Murrough JW et al. ECT in treatment-resistant depression. Am J Psychiatry. 2012; 169(12):1238.
3. Fink M, Taylor MA. Electroconvulsive Therapy. Evidence and Challenges. JAMA. 2007;298(3):330-332. http://jama.jamanetwork.com/article.aspx?articleid=207945
4. Abrams R. Electroconvulsive Therapy. 4th ed. New York, NY: Oxford University Press; 2002.
5. Tzabazis A, Schmitt HJ, Ihmsen H, et al. Postictal agitation after electroconvulsive therapy: incidence, severity, and propofol as a treatment option. J ECT 2013. 29:189.
6. Fink M, Abrams R, Bailine S., Jaffe R. Ambulatory electroconvulsive therapy: report of a task force of the association for convulsive therapy. Association for Convulsive Therapy. Convuls Ther 1996; 12:42.
7. Lisanby SH, Maddox JH, Prudic J, et al. The effects of electroconvulsive therapy on memory of autobiographical and public events. Arch Gen Psychiatry 2000; 57:581.
8. Sobin C., Sackeim HA, Prudic J, et al. Predictors of retrograde amnesia following ECT. Am J Psychiatry 1995; 152:995.
9. Allan CL, Ebmeier KP. The use of ECT and MST in treating depression. International Review of Psychiatry 2011;23(5):400-12.
10. Nordenskjold A, von Knorring L, Engstrom I. Predictors of the short-term responder rate of Electroconvulsive therapy in depressive disorders – a population-based study. BMC psychiatry 2012; 12:115.
11. Versiani M, Cheniaux E, Landeira-Fernandez J. Efficacy and safety of electroconvulsive therapy in the treatment of bipolar disorder: a systematic review. Journal of ECT 2011;27(2):153-64
12. Poon SH, Sim K, Sum MY, Kuswanto CN, Baldessarini RJ. Evidence-based options for treatment-resistant adult bipolar disorder patients. Bipolar disorders 2012;14(6):573-84.
13. Tharyan P, Adams CE. Electroconvulsive therapy for schizophrenia. Cochrane Database of Systematic Reviews 2005, (verified by Cochrane 2009 Apr), Issue 2. Art. No.: CD000076.
14. Hatta K, Miyakawa K, Ota T., Usui C, Nakamura H, Arai H. Maximal response to electroconvulsive therapy for the treatment of catatonic symptoms. Journal of ECT 2007;23(4):233-5.
15. Oral ET, et al. electroconvulsive therapy in psychiatric practice: a selective review of the evidence. Neuro Endocrinology Letters 2008;29 Suppl 1:11-32.
16. Nielsen RE, Damkier P. Pharmacological treatment of unipolar depression during pregnancy and breast-feeding – a clinical overview. Nordic Journal of Psychiatry 2012;66(3):159-66.
17. Wilkins KM, Ostroff R, Tampi RR. Efficacy of electroconvulsive therapy in the treatment of nondepressed psychiatric illness in elderly patients: a review of the literature. Journal of Geriatric Psychiatry and Neurology 2008;21(1):3-11.
18. Rapinesi C, et al. Prevention of relapse with maintenance electroconvulsive therapy in elderly patients with major depressive episode. Journal of ECT 2013;29(1):61-4.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
90870	Electroconvulsive therapy (includes necessary monitoring)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015MPC, 10/04/2016MPC, 08/01/2017MPC, 06/05/2018MPC, 06/04/2019MPC, 06/02/2020MPC, 06/01/2021MPC, 06/07/2022MPC, 06/06/2023MPC	12/21/2023

MPC Medical Policy Committee

Revision History	Description

Back to Top

06/05/2018	MPC approved to adopt MCG* B-802-T for ECT
12/21/2023	Added NCD Multiple Electroconvulsive Therapy (MECT) 160.25

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Neurobiofeedback & Brain Mapping

- Neurofeedback (EEG Biofeedback) and
- Neuropsychiatric EEG-Based Assessment Aid (NEBA) – ADHD
- Quantitative EEG (Brain Mapping)

Criteria

For Medicare Members

Source	Policy
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "*Attention Deficit Hyperactivity Disorder (ADHD)*"** for medical necessity determinations. Use the Non-Medicare Criteria below. Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "*Quantitative EEG (Brain Mapping)*"** for medical necessity determinations. Use the Non-Medicare Criteria below.

For Non-Medicare Members

Service	Criteria used
Neurofeedback for ADHD (biofeedback) Neuropsychiatric EEG-Based Assessment Aid (NEBA)	See MCG* A-0330: *Biofeedback Inconclusive or Non-Supportive Evidence* For attention-deficit hyperactivity disorder in children, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefits vs. harm; additional research is recommended. For adolescents, there is insufficient evidence in the published medical literature to show that this service/therapy provides better outcomes than current standard services/therapy. There was no literature reported for adults with attention-deficit hyperactivity disorder at the time of the review. *For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access
EEG, Quantitative (Brain Mapping)	Kaiser Permanente has elected to use the EEG, Quantitative (Brain Mapping) (A-1050) MCG* Care Guideline for medical necessity determinations. This is not covered per MCG*. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

Back to Top

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Attention Deficit Hyperactivity Disorder (ADHD) is a common chronic neurobehavioral condition affecting approximately 5% of children worldwide. A child with ADHD may present as: 1) predominantly hyperactive, 2) predominantly inattentive, or 3) both hyperactive and inattentive. ADHD is often accompanied by impaired social adjustment, academic problems, and lower adaptive functioning in major life activities which may persist to adolescence and adulthood (Benner-Davis 2007, Gevensleben 2009, Lansbergen 2011).

Medication, particularly psychostimulants, is the primary treatment for ADHD. Psychostimulants work quickly, improve attention, and reduce hyperactivity and impulsitivity in about 70% of all children. However, their effect on academic achievement, family relation, and social skills is small. There are also some concerns regarding their side effects, and their long-term benefits have not been established. Behavioral therapy has been shown to reduce ADHD symptoms, but may not be sufficiently effective especially in terms of generalization and long-term effects (Leins 2007, Gevensleben 2009, Lansbergen 2011).

In searching for additional or alternative treatments for children with ADHD, neurofeedback (NF) emerged as a promising option. NF is a type of biofeedback that uses electroencephalography (EEG) to provide a signal that can be used by a person to receive feedback about brain activity. It is based on the rationale that there is a relationship between surface EEG and the underlying thalamocortical mechanism responsible for its rhythms and frequency modulations. Lubar was the first to report on EEG and behavioral changes in a hyperkinetic child. He explained that ADHD children differ from others in that their brain waves tend to be of larger amplitude. Specifically, the EEG shows excess theta activity along with lower amounts of beta activity. This pattern of brain wave activity usually indicates a sleep or daydreaming state, rather than an alert and focused state. The goal of EEG biofeedback training is to alter these abnormal brain waves by decreasing theta waves, while simultaneously increasing beta waves (i.e. theta suppression/beta enhancement). This would potentially help the child acquire self-control over certain brain activity patterns, derive self-regulation strategies, and apply the gained self-regulation skills in daily life (Lubar 1976, Lubar 1991, Bakhshayesh 2011).

In EEG biofeedback training, the therapist explains to the child the connection between what is happening in his/her cortex and what is recorded on the EEG and helps him/her learn how to gain control over the brain activity patterns. The EEG biofeedback equipment is connected to the individual with sensors that are placed on the scalp and ears. Once connected, the brainwave activity can be observed on a computer monitor. Individuals are then taught to play computerized games using their brainwave activity. Changes in the individual's brainwave activity are then fed back to the individual through visual and/or auditory information by the computer. During a typical 45-minute session, the child is seated in front of a computer, electrodes are connected to his head, and then a therapist starts up a videogame or movie on the child's screen and monitors his brain waves on another screen. The child then locks his eyes on the action, concentrating on sending the kind of brain waves that will keep a virtual airplane flying, or perhaps a favorite movie rolling. If his attention wanders or he begins to fidget, the plane slows or the movie screen darkens, and the therapist encourages him to regain focus using techniques such as slow, deep breathing. Children may also practice maintaining learned brainwave states when engaged in school- or work-related tasks (Gevensleben 2009).
In the last three decades many studies compared brain activity using electro-encephalography (EEG) among children with ADHD versus the brain activity of normal controls in an attempt to study the underlying neurophysiology of ADHD; and to investigate subtypes of the disorder and their response to treatment. The EEG frequency bands of most interest in ADHD research are the theta, beta, and alpha bands either alone or in relation to one another such as the theta/beta power or amplitude ratio. Alpha band activity is typically observed during rest when the eyes are closed and is negatively associated with central nervous system arousal. Beta band activity on the contrary, generally accompanies mental activity and concentration. Cortical theta is observed frequently in young children, but in older children and adults, it tends to appear during meditative, drowsy, or sleeping states. Researchers suggest that most

Back to Top

children with ADHD display EEG differences in their brain electrical activity as compared to normal children, particularly with respect to their increased frontocentral theta activity primarily during the resting state. This indicates decreased cortical activity that may be associated with underarousal. A theta /beta ratio (TBR) due to increased theta is reported by many investigators as a consistent characteristic of ADHD. Some groups recommend using the TBR during eyes-opened or eye-closed resting condition as an add-on for the diagnosis and monitoring of ADHD. However, it is reported that the true functional significance of this measure is still unknown, and an elevated theta activity may be a nonspecific marker of cortical dysfunction common to other disorders such as epilepsy, bipolar disorder, and polysubstance abuse (Arns 2013, Liechti 2013, Loo 2012).

A number of studies examined the accuracy and diagnostic value of the theta power and TBR in discriminating normal children from children with learning disorders, ADD, and ADHD. In 2005, Boutros and colleagues performed a review and meta-analysis to estimate the strength and effect size of increased theta activity in ADHD patients. Based on their findings they concluded that the increased EEG theta activity in ADHD is promising and should be further developed as a diagnostic test for ADHD. Around the same time another group of investigators (Snyder and Hall, 2006) also conducted a meta-analysis to investigate the theta and beta powers and their ration (TBR) and concluded that the pooled results support the finding that an increase in the theta/beta ratio is a commonly observed trait in ADHD relative to normal controls. They however, cautioned that theta/beta ratio trait may arise with other conditions, and that a prospective study covering differential diagnosis would be required to determine generalizability to clinical applications (Arns 2013, Boutros 2005, Loo 2012 Snyder 2006).

Based on this EEG technology, the Neuropsychiatric EEG-Based Assessment Aid (NEBA) System (NEBA Health, Augusta, GA) was developed and recently received Food and Drug Administration (FDA), in July 2013, to help assess ADHD in children and adolescents 6-17 years of age. It is not to be used as a stand-alone diagnostic test, but as a conjunctive tool for diagnosing ADHD. NEBA is a non-invasive test that calculates the ratio of theta and beta waves frequencies in 15-20 minutes (FDA and NEBA websites accessed January 15, 2014).

According to the FDA, the use of the device together with the complete medical and psychological examination, can help confirm an ADHD diagnosis or a clinician's decision that further diagnostic testing should focus on ADHD or other medical or behavioral conditions that lead to symptoms similar to ADHD. The FDA reviewed the NEBA System through a de novo classification process, a regulatory pathway for some low- to moderate-risk medical devices that are not substantially equivalent to an already legally marketed device (FDA website accessed January 15, 2014).

Medical Technology Assessment Committee (MTAC)

Neurofeedback for ADHD

10/17/2011: MTAC REVIEW

Evidence Conclusion: A number of small randomized and nonrandomized controlled trials included in Arns and colleagues' meta-analysis (evidence table 1) and the pooled results of available data indicate that NF may have some beneficial effects on a number of ADHD measures. However, when compared with stimulant therapy, NF did not prove to have an equivalent or superior effect on ADHD core symptoms. None of the studies monitored potential adverse effects of NF. The small study sizes, their short duration, lack of a valid control group, mixed and multiple interventions used, lack of double-blinding, additional time spent with the therapists for NF, as well as other study methodological limitations make it hard to determine the efficacy of the neurofeedback used alone or in addition to other interventions for the treatment of children with ADHD. Gevensleben and colleagues' trial (evidence table 2) conducted by a group of researchers in a university hospital in Germany, compared NF training to computerized attention skills training. This may be considered as a more valid comparison as it controls for therapist time and attention training. The primary endpoint was improvement in attention and reduced hyperactivity as rated by the parents. No measures of children's academic functioning or classroom performance were collected. The results of the trial showed that symptoms improved in both groups; however, the score of the primary outcome measure (parents' rating of FBB-HKS [a German rating scale]) was significantly higher in children in the NF group. The trial was randomized and controlled, but was not blinded, and the NF training program was developed by the study group. After the training period 18% of the children were started on a medication. Six months follow-up data, available for only two thirds of the participants, showed that the behavioral improvements were maintained at 6 months, but the difference between the two interventions did not reach a statistically significant level. The investigators attributed the lack of significant difference to insufficient statistical power due to the smaller number of children with follow-up data. They authors concluded that NF training may help some children, but more research is needed to replicate the findings and identify which children with ADHD are more likely to benefit from NF training. Well conducted randomized trials with a sham neurofeedback control,

Back to Top

double-blinding, and long-term follow-up are needed to establish the efficacy and safety of neurofeedback in improving the core symptoms of ADHD.
Articles: The search revealed one meta-analysis on the efficacy of neurofeedback treatment in ADHD and a number of RCTs that were included in the meta-analysis. Three small RCTs published after the meta-analysis, as well as a report on 6 months follow-up of an earlier RCT were also identified. The meta-analysis as well as the largest trial, which had a more valid design and longer follow-up, were selected for critical appraisal. Arns M, de Ridder S, Strehl U, et al. Efficacy of neurofeedback treatment in ADHD: the effects on inattention, impulsitivity and hyperactivity; a meta-analysis. Clin EEG Neurosci 2009; 40:180-189. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Is neurofeedback an efficacious treatment for ADHD? A randomized controlled trial. J Child Psychol Psychiatry. 2009; 50:780-789. See Evidence Table. Gevensleben H, Holl B, Albrecht B, et al. Neurofeedback training in children with ADHD: 6-month follow-up of a randomized controlled trial. Eur Child Adolesc Psychiatry 2010; 19:715-724. See Evidence Table.

The use of Neurofeedback for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/20/2016: MTAC REVIEW
Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD)
Evidence Conclusion: EEG-NF versus placebo, sham: EEG neurofeedback (EEG-NF) treatments in children with ADHD: an updated meta-analysis of randomized controlled trials: (Micoulaud-Franchi et al., 2014) (Evidence table 1) On parent assessment (probably unblinded assessment), the overall ADHD scores (-0.49 [-0.74, -0.24], $p < 0.001$) as well as the inattention and hyperactivity/impulsivity scores were significantly improved (-0.46 [-0.76, -0.15], $p = 0.003$); -0.34 [-0.59, -0.09], $p = 0.007$) in patients receiving EEG NF compared to controls. On teacher assessment (probably blinded assessment), only the inattention score was significantly improved (Effect size of -0.30 [-0.58, -0.03] with p=0.03). Based on the findings, EEG-NF may improve core ADHD symptoms. However, the major limitation lies in the heterogeneity of EEG-NF protocols across individual studies. Other limitations include: 1) the small number of studies, 2) small size of individuals RCTs, 3) the exclusion of relevant RCTs in the meta-analysis, 4) the lack of blinded parent assessment and 5) the lack of evaluation of study quality. These result in low quality of evidence. Due to the aforementioned limitations, result should be interpreted with caution. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma et al., 2013) (Evidence table 2) In both groups, and based on investigator assessment, ADHD symptoms decreased over time ($F= 26.56$, $p < .001$) to a similar degree. According to teacher assessment, significant improvement of symptoms over time ($F= 13.54$, $p = .001$) was reported, without a difference between groups ($F= 0.45$, $p = .509$). On the CGI-I scale, symptoms did not worsen. On CGAS, score increased similarly in both groups ($F= 1.96$, $p = .169$).
On PSERS, the total number of adverse events decreased significantly over time ($F= 6.30$, $p = .016$) and decreased similarly in the two groups ($F= 0.10$, $p = .754$). The SDQ assessment showed that sleep problems decreased significantly over time ($F= 5.42$, $p = .025$) in both groups. Overall, no differences in improvements between the groups were reported. However, several limitations are worth noted: 1) the small sample size limiting statistical power; 2) the therapist was not blinded; 3) the use of medications by some participants could have biased the outcomes of NF; 4) no follow-up data was available to assess the short or long term effects of NF; 5) generalizability might have been compromised since the sample is composed of white children. Studies with larger sample size and long follow-up are warranted to confirm these findings. Neurofeedback versus stimulant Medication: Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel et al., 2014) (Evidence table 3) Regarding pre-post comparison, ADHD symptoms and functional impairment improved in general in both groups. Academic performance was only improved (except for math and oral expression) in NF group. Concerning pre-follow-up comparisons, similar results were observed. NF group-maintained symptoms achievement at 2 & 6 months after treatment completion. Inattention improved more than hyperactivity/impulsivity across evaluators, time & treatment. The major limitations are the small sample size and lack of longer follow-ups. In addition, patients were not blinded, and allocation concealment was not discussed. The risk of bias is therefore high. However, no major differences in symptom improvement were observed. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Orem & Hestad, 2013) (Evidence table 4) After treatment, there was a significant difference between the two groups with improvement observed in the medication groups. There were significant differences after treatment between the groups on inattention, Visual Continuous Performance Test (VCPT) & reaction time measures on patient assessment. All were in favor of the medication groups. Similar findings were observed on teacher assessment. In addition, higher positive changes were observed with the medication groups. The results indicate that medication led to better symptoms control on both parent and teacher assessment, particularly on inattention, VCPT & reaction time measures and that NF did not produce positive changes. However, this pilot study has several limitations: 1) generalizability of the findings may have been compromised
 Back to Top

because of the non-use of standard protocols, 2) small sample size 3) blinding was not discussed, 4) 59% of patients had learning disabilities making harder to achieve a positive outcome. Overall, the risk of bias is high, and results should be interpreted with caution. A randomized controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li et al., 2013) (Evidence table 5) In terms of Core symptoms and behavioral problems, significant improvement was noted for combination group compared to the control group. For social function assessments, the combination group performance was significantly better than that of the control group after 40 sessions of treatment ($p < 0.001$). Regarding brain function assessment, the dominant probability of 8 Hz wave decreased significantly in the combination group. Adverse events correlate with methylphenidate dosage. The authors conclude that the combination of neurofeedback and methylphenidate is effective in improving the symptoms of ADHD in children. They also demonstrated that this combination is superior in enhancing core symptoms, behavioral issues, and brain function. However, limitations reside in small sample size limiting statistical power; the lack of long-term follow-up. One of the authors had financial tie with the Janssen Pharmaceutical. Therefore, results should be interpreted with caution.
Additional study: A placebo-controlled neurofeedback study (Arnold et al., 2012) did not demonstrate superiority of NF on ADHD core symptoms.
Conclusion:

- The body of evidence is of low quality.
- Variations in the characteristics of EEG-NF protocols, the use of medications while receiving NF treatment, the small sample size, the lack of blinding in a number of studies and the short follow-up periods may have biased the findings.
- Neurofeedback may improve the core symptoms of ADHD in children but did not demonstrate superiority or was not equivalent to pharmacological therapy in reducing ADHD symptoms in children.
- There is insufficient evidence to determine whether Neurofeedback in combination with methylphenidate is effective in reducing the core symptoms of ADHD in children.

Articles: The literature revealed a number of articles, but the following articles were selected for critical appraisal: EEG neurofeedback treatments in children with ADHD: an updated meta-analysis of randomized controlled trials (Micoulaud-Franchi et al., 2014) See Evidence table 1. A randomized placebo-controlled trial of electroencephalographic (EEG) neurofeedback in children with attention-deficit/hyperactivity disorder (van Dongen-Boomsma, Vollebregt, Slaats-Willemse, & Buitelaar, 2013) See Evidence table 2. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Meisel, Servera, Garcia-Banda, Cardo, & Moreno, 2014) See Evidence table 3. Effects of Neurofeedback versus stimulant Medication in Attention-Deficit/Hyperactivity Disorder: A Randomized pilot study (Ogrim & Hestad, 2013) See Evidence table 4. A randomised controlled trial of combined EEG feedback and methylphenidate therapy for the treatment of ADHD (Li, Yang, Zhuo, & Wang, 2013) See Evidence table 5.

The use of Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Neuropsychiatric EEG-Based Assessment Aid (NEBA)

02/10/2014: MTAC REVIEW

Evidence Conclusion: There is no published evidence to date to determine the safety, accuracy, or clinical utility of NEBA system in discriminating between children with or without ADHD. The FDA approval was based on a clinical study of 275 children and adolescents with attention and/or behavioral concerns. The study was conducted by the manufacturer of the NEBA system and has not been published in a peer reviewed journal to date. The observational studies on the correlation between the theta/beta ratios (TBR) had their limitations, and their results were inconclusive. In addition (according to Loo, 2012) there are wide variation in EEG instrumentation that can make it very hard to compare or generalize results of studies using different EEG hardware and software.
Articles: The literature search did not reveal any published study on the NEBA system; it only identified several observational studies that investigated brain activity using EEG in children with ADHD compared with normal controls, as well as three meta-analyses that pooled the results of a number of these studies.

The use of NEBA does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Biofeedback—

Considered Not Medically Necessary:

Back to Top

CPT® Codes	Description
90875	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 30 minutes
90876	Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (eg, insight oriented, behavior modifying or supportive psychotherapy); 45 minutes
90901	Biofeedback training by any modality
Dx Codes	**Description**
F90.0-F90.9	Attention-deficit hyperactivity disorder

Brain Mapping—

Considered Not Medically Necessary:

CPT® Codes	Description
95961	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of attendance by a physician or other qualified health care professional
95962	Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of attendance by a physician or other qualified health care professional (List separately in addition to code for primary procedure)
95999	Unlisted neurological or neuromuscular diagnostic procedure
S8040	Topographic brain mapping

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/01/2011	11/01/2011[MDCRPC], 10/02/2012[MDCRPC,] 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	09/05/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/20/2016	Added Electroencephalography (EEG) Neurofeedback (NF) for Attention deficit hyperactivity disorder (ADHD) MTAC review
08/10/2016	Merged NEBA criteria into same document
09/06/2016	Added KPWA policy for Medicare members
10/03/2017	MPC approved to adopt MCG A-0330 summary of findings as criteria language
09/05/2023	MPC approved to adopt EEG, Quantitative (Brain Mapping) MCG A-1050. Requires a 60-day notice; effective February 1, 2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Elective Surgical Procedures (Level of Care Policy)

- Bariatric
- Cardiac Catheterization
- ENT
- General Surgery
- Gynecology
- Orthopedic
- Pacemaker
- Spine
- Urology

Criteria

For Medicare Members

Source	Policy
Code of Federal Regulations (CFR)	42 CFR 412.3
CMS Coverage Manuals	Hospital Outpatient Regulations and Notices
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Elective Surgical Procedures"*** for *level of care medical necessity determinations*. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

When requesting Inpatient Level of Care for certain *elective* surgical procedures (not those typically done in an ambulatory surgery center), the request will be reviewed for coverage in the most appropriate, safe, and cost-effective level of care. A member's clinical presentation may be appropriate for an alternate level of care such as a hospital-based outpatient setting.

Examples include but are not limited to Pacemaker Placement or Cardiac Catheterization, Bariatric Surgery Procedures, and General Surgery Procedures.

Some elective surgical procedures may also be subject to medical necessity review in addition to level of care criteria below:

Bariatric Surgery
Cardiac Defibrillators
Cardiac Pacemakers
Cervical Fusion
Lumbar Fusion

Back to Top

Minimally Invasive Lumbar Decompression
Total Hip Arthroplasty
Total Knee Arthroplasty

A planned elective admission for certain surgeries or procedures is considered medically necessary at an inpatient level of care when any of the following criteria is met:

- Medical conditions increasing the risk of major post-operative complications:
  - Advanced liver disease (MELD Score >8)
  - Cognitive status that warrants inpatient stay
  - Severe renal disease (GFR ≤ 30mL/min
  - Severe valvular heart disease
  - Stroke or TIA within the last 3 months
  - Symptomatic chronic lung disease (e.g., asthma, COPD)
  - Symptomatic coronary artery disease or heart failure
  - Unstable medical condition (e.g., poorly controlled diabetes)
- Procedure related factors that may increase the risk of complications:
  - Anesthetic risk
    - American Society of Anesthesiologists class III or greater
    - Age 85 years or older
    - High risk for thromboembolism
    - Moderate (AHI 15-30) to severe (AHI >30) sleep apnea
    - Persistent electrolyte abnormalities unresponsive to treatment (e.g., hyperkalemia, hyponatremia
    - Risk of postoperative airway compromise (e.g., open neck procedure, airway surgery)
  - Complexity of surgical procedure
    - Complex surgical approach (e.g., unusually extensive dissection needed)
    - Complex post-operative wound care (e.g., complex drain management, open wound, previous local tissue injury resulting from factors such as radiation, previous surgery, impaired circulation, sustained pressure)
    - Difficult approach because of previous operation
    - Extensive or prolonged (longer than the usual time frame) surgery
- The need for preoperative diagnostic studies that cannot be performed as an outpatient
- Procedural related event that may require an inpatient stay as indicated by the following:
  - Acute Kidney Injury
  - Altered mental status that is severe or persistent
  - Ambulatory or appropriate activity level status is not achieved
  - Conversion to open or complex procedure that requires inpatient care
  - Excessive drainage or bleeding from the operative site
  - Hemodynamic instability
  - Longer postoperative monitoring or treatment is needed due to preoperative use of drugs (e.g., cocaine, amphetamines)
  - Pain, fever, or vomiting not appropriate for ambulatory or observation level of care
  - Severe complications of procedure (e.g., bowel injury, airway compromise, vascular injury)
  - Unstable clinical status

Definitions

ASA physical Status Classification System Risk Scoring tool: The American Society of Anesthesiologists (ASA) physical status classification system was developed to offer clinicians a simple categorization of a patient's physiological status that can be helpful in predicting operative risk. The ASA score is a subjective assessment of a patient's overall health that is based on five classes. Current Definitions and ASA-Approved examples found HERE.

Apnea Hypopnea Index (AHI): The number of apneas plus the number of hypopneas during the entire sleeping period, times 60, divided by total sleep time in minutes; unit: event per hour

Acute Kidney Injury: Acute Kidney Injury is defined as any of the following:

- Increase in the serum creatinine value of ≥ 0.3 mg/dL (26.52 micromol/L) in 48 hours

Back to Top

- Increase in serum creatinine of ≥ 1.5 times baseline within the prior 7 days
- Reduction of more than 50% in estimated glomerular filtration rate from baseline
- Urine volume < 0.5 mL/kg/hour for 6 hours (KDIGO, 2021)

Hemodynamic Instability:

Hemodynamic instability, as indicated by **1 or more** of the following:

- Vital sign abnormality not readily corrected by appropriate treatment, as indicated by **1 or more** of the following:
    - Tachycardia that persists despite appropriate treatment (eg, volume repletion, treatment of pain, treatment of underlying cause)
    - Hypotension: systolic blood pressure <90 mm hg or decrease in systolic blood pressure >40 mm hg
    - Mean arterial pressure less than 70 mm Hg
    - Orthostatic hypotension that persists despite appropriate treatment (eg, volume repletion)
    - Altered level of consciousness
    - Shortness of breath

If requesting this these services, for inpatient level of care, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Attending provider must provide documentation in the prior authorization request that supports the need to have an overnight stay of greater than 2 midnights.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Surgery may safely be performed in various settings. Some of the common settings used are an inpatient hospital or medical center, an off-campus outpatient hospital or medical center, or an on campus outpatient hospital. Costs for surgical procedures may vary among these different settings. To encourage the use of the most safe and appropriate, cost effective sites of service for certain medically necessary outpatient surgical procedures, prior authorization is required for the site of service for the surgical procedures listed below.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific contract and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Bariatric Surgery codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Laparoscopic Roux-en-Y **Requires separate medical necessity review with Bariatric Surgery criteria*		
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	X

Back to Top

43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	X
Lap Band Procedure **Requires separate medical necessity review with Bariatric Surgery criteria*		
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only	X
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	
Laparoscopic Gastric Sleeve **Requires separate medical necessity review with Bariatric Surgery criteria*		
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)	X

Cardiac Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Cardiac Catheterization		
0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)	
92928	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; single major coronary artery or branch	
92929	Percutaneous transcatheter placement of intracoronary stent(s), with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	
92933	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	
92934	Percutaneous transluminal coronary atherectomy, with intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (List separately in addition to code for primary procedure)	
92937	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	
92938	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (List separately in addition to code for primary procedure)	
92943	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; single vessel	
92944	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (List separately in addition to code for primary procedure)	

Back to Top

92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)	
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)	
93451	Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed	
93452	Left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	
93453	Combined right and left heart catheterization including intraprocedural injection(s) for left ventriculography, imaging supervision and interpretation, when performed	
93454	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation;	
93455	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography	
93456	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right heart catheterization	
93457	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) including intraprocedural injection(s) for bypass graft angiography and right heart catheterization	
93458	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	
93459	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	
93460	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed	
93461	Catheter placement in coronary artery(s) for coronary angiography, including intraprocedural injection(s) for coronary angiography, imaging supervision and interpretation; with right and left heart catheterization including intraprocedural injection(s) for left ventriculography, when performed, catheter placement(s) in bypass graft(s) (internal mammary, free arterial, venous grafts) with bypass graft angiography	
93462	Left heart catheterization by transseptal puncture through intact septum or by transapical puncture (List separately in addition to code for primary procedure)	
93505	Endomyocardial biopsy	
93563	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective coronary angiography during congenital heart catheterization (List separately in addition to code for primary procedure)	
93564	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective opacification of aortocoronary venous or arterial bypass graft(s) (eg, aortocoronary saphenous vein, free radial artery, or free mammary artery graft) to one or more coronary arteries and in situ arterial conduits (eg, internal mammary), whether native or used for bypass to one or more coronary arteries during	

Back to Top

	congenital heart catheterization, when performed (List separately in addition to code for primary procedure)	
93565	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective left ventricular or left atrial angiography (List separately in addition to code for primary procedure)	
93566	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)	
93567	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)	
93568	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for pulmonary angiography (List separately in addition to code for primary procedure)	
93569	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, unilateral (List separately in addition to code for primary procedure)	
93571	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)	
93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress; initial vessel (List separately in addition to code for primary procedure)	
93573	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary arterial angiography, bilateral (List separately in addition to code for primary procedure)	
93574	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary venous angiography of each distinct pulmonary vein during cardiac catheterization (List separately in addition to code for primary procedure)	
93575	Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective pulmonary angiography of major aortopulmonary collateral arteries (MAPCAs) arising off the aorta or its systemic branches, during cardiac catheterization for congenital heart defects, each distinct vessel (List separately in addition to code for primary procedure)	
93593	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; normal native connections	
93594	Right heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone; abnormal native connections	
93595	Left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone, normal or abnormal native connections	
93596	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); normal native connections	
93597	Right and left heart catheterization for congenital heart defect(s) including imaging guidance by the proceduralist to advance the catheter to the target zone(s); abnormal native connections	
93598	Cardiac output measurement(s), thermodilution or other indicator dilution method, performed during cardiac catheterization for the evaluation of congenital heart defects (List separately in addition to code for primary procedure)	
Pacemaker Placement		
33206	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial	
33207	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); ventricular	

Back to Top

33208	Insertion of new or replacement of permanent pacemaker with transvenous electrode(s); atrial and ventricular	
33210	Insertion or replacement of temporary transvenous single chamber cardiac electrode or pacemaker catheter (separate procedure)	
33211	Insertion or replacement of temporary transvenous dual chamber pacing electrodes (separate procedure)	
33212	Insertion of pacemaker pulse generator only; with existing single lead	
33213	Insertion of pacemaker pulse generator only; with existing dual leads	
33214	Upgrade of implanted pacemaker system, conversion of single chamber system to dual chamber system (includes removal of previously placed pulse generator, testing of existing lead, insertion of new lead, insertion of new pulse generator)	
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode	
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator	
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator	
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator	
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator	
33221	Insertion of pacemaker pulse generator only; with existing multiple leads	
33223	Relocation of skin pocket for implantable defibrillator	
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator)	
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (eg, for upgrade to dual chamber system) (List separately in addition to code for primary procedure)	
33226	Repositioning of previously implanted cardiac venous system (left ventricular) electrode (including removal, insertion and/or replacement of existing generator)	
33227	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; single lead system	
33228	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; dual lead system	
33229	Removal of permanent pacemaker pulse generator with replacement of pacemaker pulse generator; multiple lead system	
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads	
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads	
33233	Removal of permanent pacemaker pulse generator only	
33234	Removal of transvenous pacemaker electrode(s); single lead system, atrial or ventricular	
33235	Removal of transvenous pacemaker electrode(s); dual lead system	
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead	
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy	X
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber	
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system	
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system	
33264	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; multiple lead system	
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed **Requires separate medical necessity review with Cardiac Defibrillators Clinical Review Policy*	

Back to Top

33271	Insertion of subcutaneous implantable defibrillator electrode **Requires separate medical necessity review with Cardiac Defibrillators Clinical Review Policy*	
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed **Requires separate medical necessity review with Pacemaker Clinical Review Policy*	
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular, including imaging guidance (eg, fluoroscopy, venous ultrasound, ventriculography, femoral venography), when performed **Requires separate medical necessity review with Pacemaker Clinical Review Policy*	

ENT Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Thyroidectomy		
60200	Excision of cyst or adenoma of thyroid, or transection of isthmus	
60210	Partial thyroid lobectomy, unilateral; with or without isthmusectomy	
60212	Partial thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmusectomy	
60220	Total thyroid lobectomy, unilateral; with or without isthmusectomy	
60225	Total thyroid lobectomy, unilateral; with contralateral subtotal lobectomy, including isthmusectomy	
60240	Thyroidectomy, total or complete	
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	
60254	Thyroidectomy, total or subtotal for malignancy; with radical neck dissection	X
60260	Thyroidectomy, removal of all remaining thyroid tissue following previous removal of a portion of thyroid	
60270	Thyroidectomy, including substernal thyroid; sternal split or transthoracic approach	X
60271	Thyroidectomy, including substernal thyroid; cervical approach	
Parathyroidectomy		
60500	Parathyroidectomy or exploration of parathyroid(s);	
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	

General Surgery Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Laparoscopic Appendectomy		
44960	Appendectomy; for ruptured appendix with abscess or generalized peritonitis	X
44970	Laparoscopy, surgical, appendectomy	
Laparoscopic Cholecystecomy		
47562	Laparoscopy, surgical; cholecystectomy	
47563	Laparoscopy, surgical; cholecystectomy with cholangiography	
47564	Laparoscopy, surgical; cholecystectomy with exploration of common duct	
47570	Laparoscopy, surgical; cholecystoenterostomy	X
Hernia Repair (non-hiatal)—Femoral, inguinal, and umbilical		

Back to Top

49505	Repair initial inguinal hernia, age 5 years or older; reducible	
49507	Repair initial inguinal hernia, age 5 years or older; incarcerated or strangulated	
49520	Repair recurrent inguinal hernia, any age; reducible	
49521	Repair recurrent inguinal hernia, any age; incarcerated or strangulated	
49525	Repair inguinal hernia, sliding, any age	
49550	Repair initial femoral hernia, any age; reducible	
49553	Repair initial femoral hernia, any age; incarcerated or strangulated	
49555	Repair recurrent femoral hernia; reducible	
49557	Repair recurrent femoral hernia; incarcerated or strangulated	
49650	Laparoscopy, surgical; repair initial inguinal hernia	
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	
49659	Unlisted laparoscopy procedure, hernioplasty, herniorrhaphy, herniotomy	
Lumpectomy; Partial or Complete Mastectomy		
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy);	
19302	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy); with axillary lymphadenectomy	
19303	Mastectomy, simple, complete	
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	
Laparoscopic Nissen Fundoplication or Esophagogastric Fundoplasty		
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, Nissen, Toupet procedures)	
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	
Lysis of adhesions by laparoscopy (without bowel ischemia, systemic toxicity) Laparotomy is Inpatient procedure		
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	
44005	Enterolysis (freeing of intestinal adhesion) (separate procedure)	X

Gynecology Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Laparoscopic Hysterectomy		
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less	
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g	
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less	
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g	
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less	
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g	

Back to Top

58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	
58575	Laparoscopy, surgical, total hysterectomy for resection of malignancy (tumor debulking), with omentectomy including salpingo-oophorectomy, unilateral or bilateral, when performed	X
Vaginal Hysterectomy		
58260	Vaginal hysterectomy, for uterus 250 g or less	
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)	
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	
58267	Vaginal hysterectomy, for uterus 250 g or less; with colpo-urethrocystopexy (Marshall-Marchetti-Krantz type, Pereyra type) with or without endoscopic control	X
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	
58275	Vaginal hysterectomy, with total or partial vaginectomy	X
58280	Vaginal hysterectomy, with total or partial vaginectomy; with repair of enterocele	
58290	Vaginal hysterectomy, for uterus greater than 250 g	
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	
Anterior or Posterior Colporrhaphy		
57240	Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele, including cystourethroscopy, when performed	
57250	Posterior colporrhaphy, repair of rectocele with or without perineorrhaphy	
57260	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed;	
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair	
Laparoscopic Surgical Myomectomy, Oophorectomy, and/or salpingectomy		
58545	Laparoscopy, surgical, myomectomy, excision; 1 to 4 intramural myomas with total weight of 250 g or less and/or removal of surface myomas	
58546	Laparoscopy, surgical, myomectomy, excision; 5 or more intramural myomas and/or intramural myomas with total weight greater than 250 g	
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)	
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method	
58670	Laparoscopy, surgical; with fulguration of oviducts (with or without transection)	
58671	Laparoscopy, surgical; with occlusion of oviducts by device (eg, band, clip, or Falope ring)	
58672	Laparoscopy, surgical; with fimbrioplasty	
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)	
58679	Unlisted laparoscopy procedure, oviduct, ovary	
59150	Laparoscopic treatment of ectopic pregnancy; without salpingectomy and/or oophorectomy	
59151	Laparoscopic treatment of ectopic pregnancy; with salpingectomy and/or oophorectomy	
Bladder Sling—vaginal approach		
51840	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); simple	X
51841	Anterior vesicourethropexy, or urethropexy (eg, Marshall-Marchetti-Krantz, Burch); complicated (eg, secondary repair)	X
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra)	

Back to Top

51990	Laparoscopy, surgical; urethral suspension for stress incontinence	
51992	Laparoscopy, surgical; sling operation for stress incontinence (eg, fascia or synthetic)	
57288	Sling operation for stress incontinence (eg, fascia or synthetic)	
57289	Pereyra procedure, including anterior colporrhaphy	

Orthopedic Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Total Knee Arthroplasty **Requires separate medical necessity review with Total Knee Arthroplasty Criteria*		
27438	Arthroplasty, patella; with prosthesis	
27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment	
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	X
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	X
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	X
Total Hip Arthroplasty **Requires separate medical necessity review with Total Hip Arthroplasty Criteria*		
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	X
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	X
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	X
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	X
Total Shoulder Arthroplasty		
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	X
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	X

Spine Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Lumbar Discectomy, Foraminotomy, or Laminotomy (when elective and not at multiple levels)		

Back to Top

62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar **Requires separate medical necessity review with Minimally Invasive Lumbar Decompression criteria*	
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar	
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)	
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar	
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)	
Cervical Discectomy or Microdiscectomy, foraminotomy, laminotomy		
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical	
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)	
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)	
Cervical Laminectomy		
0274T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic **Requires separate medical necessity review with Minimally Invasive Lumbar Decompression criteria*	
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical	
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments;	X
63051	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [eg, wire, suture, mini-plates], when performed)	X
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment	X
63082	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment (List separately in addition to code for primary procedure)	X
63185	Laminectomy with rhizotomy; 1 or 2 segments	X

Back to Top

63190	Laminectomy with rhizotomy; more than 2 segments	X
63191	Laminectomy with section of spinal accessory nerve	X
63250	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; cervical	X
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical	X
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical	X
Lumbar Laminectomy (when elective and without significant comorbid conditions)		
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar **Requires separate medical necessity review with Minimally Invasive Lumbar Decompression criteria*	
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis	
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)	
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)	
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (eg, far lateral herniated intervertebral disc)	
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)	
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment	X
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)	X
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment	X
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)	X
63185	Laminectomy with rhizotomy; 1 or 2 segments	X
63190	Laminectomy with rhizotomy; more than 2 segments	X
63200	Laminectomy, with release of tethered spinal cord, lumbar	X
63252	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracolumbar	X

Back to Top

63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	
63272	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar	X
Cervical Fusion—Anterior		
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2 **Requires separate medical necessity review with Cervical Fusion (Anterior or Posterior) criteria*	
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure) **Requires separate medical necessity review with Cervical Fusion (Anterior or Posterior) criteria*	
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2 **Requires separate medical necessity review with Cervical Fusion (Anterior or Posterior) criteria*	
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure) **Requires separate medical necessity review with Cervical Fusion (Anterior or Posterior) criteria*	X
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)	
Cervical Fusion—Posterior **Requires separate medical necessity review with Cervical Fusion (Anterior or Posterior) criteria*		
22600	Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment	X
22614	Arthrodesis, posterior or posterolateral technique, single interspace; each additional interspace (List separately in addition to code for primary procedure)	
Single Level Lumbar Fusion **Requires separate medical necessity review with Lumbar Fusion criteria*		
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	X
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	X
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace **Requires separate medical necessity review with Medically necessary services criteria*	X
22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)	
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar	
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar	
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace	

Back to Top

	(other than for decompression), single interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)	

Urology Procedure Codes—
Non-Medicare: Requires review when submitted as an inpatient level of care
Medicare: Medicare inpatient only procedures indicated with an "X" below, and this policy does not apply

CPT® or HCPCS Codes	Description	Medicare *IP Only List*
Percutaneous Nephrostomy		
50080	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (eg, stone[s] up to 2 cm in single location of kidney or renal pelvis, nonbranching stones)	
50081	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (eg, stone[s] > 2 cm, branching stones, stones in multiple locations, ureter stones, complicated anatomy)	
50432	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation	
50433	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access	
50695	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy), and all associated radiological supervision and interpretation; new access, with separate nephrostomy catheter	
52334	Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde	
Transurethral Resection of the Prostate (TURP)		
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included)	
Orchiectomy **May require separate medical necessity review with Gender Affirming Surgeries criteria*		
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach	
54522	Orchiectomy, partial	
54530	Orchiectomy, radical, for tumor; inguinal approach	
54535	Orchiectomy, radical, for tumor; with abdominal exploration	
54690	Laparoscopy, surgical; orchiectomy	
Laparoscopic Nephrectomy **May require separate medical necessity review with Kidney/Pancreas Transplant OR Kidney Transplant criteria*		
50543	Laparoscopy, surgical; partial nephrectomy	

Back to Top

50545	Laparoscopy, surgical; radical nephrectomy (includes removal of Gerota's fascia and surrounding fatty tissue, removal of regional lymph nodes, and adrenalectomy)	X
50546	Laparoscopy, surgical; nephrectomy, including partial ureterectomy	X
50547	Laparoscopy, surgical; donor nephrectomy (including cold preservation), from living donor	X
50548	Laparoscopy, surgical; nephrectomy with total ureterectomy	X
Pyeloplasty		
50544	Laparoscopy, surgical; pyeloplasty	
Vesicovaginal Fistula Repair		
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	
Prostatectomy		
55810	Prostatectomy, perineal radical	X
55812	Prostatectomy, perineal radical; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	X
55815	Prostatectomy, perineal radical; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes	X
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy	X
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes	X
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/1/2022	11/01/2022[MPC], 11/07/2023[MPC]	07/11/2023

[MPC] Medical Policy Committee

Revision History	Description
11/01/2022	MPC approved the new Elective Surgical Procedures (Level of Care) criteria. Cardiac Catheterization/Pacemaker is the first approved elective procedure to be done on an outpatient basis. 60-day notice is required; effective April 1, 2023.
03/22/2023	Updated effective date to April 25th, 2023.
07/11/2023	MPC approved to expand the scope of our current policy which has been restricted to two procedures to date. Requires 60-day notice. Effective date 12/01/2023
10/06/2023	Effective date changed to 12/05/2023.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Electrical Stimulation and Devices

- Electrical Stimulation for the Treatment of Dysphagia
- Functional Neuromuscular Stimulation Unit (FNS or ENS)
- Galvanic Stimulation Device
- Gastric Electrical Stimulation (Enterra)
- H-wave Stimulation Device
- Microcurrent Stimulation Device (MENS)
- NESS Stimulators for Foot Drop and Paralyzed Hands
- Neuromuscular Electrical Stimulation Unit (NMES)
- Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis
- Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
- ReBuilder System
- Transcutaneous Electrical Nerve Stimulation (TENS) Unit
- Transcutaneous Electrical Joint Stimulation Devices (TEJSD)
- WalkAide System for Patients with Foot Drop
- Peripheral Nerve Stimulation

A Separate Criteria Document Exists for the Following Devices:

Central Nervous System Electrical Nerve Stimulator: Spinal Cord Stimulators for Pain, Deep Brain Stimulation
Electrical Stimulation for Treatment of Wounds (Wound Care Treatments)
Hypoglossal Nerve Stimulation (Treatments for Obstructive Sleep Apnea)
Osteogenic (Bone) Stimulators
Sacral Nerve Stimulator for Fecal and Urinary Incontinence
Deep Brain Stimulation
Vagus Nerve Stimulation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Electrical Nerve Stimulators 160.7 Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy 160.7.1 Neuromuscular Electrical Stimulation (NMES) (160.12) Non-Implantable Pelvic Floor Electrical Stimulator (230.8) Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES) (160.13) Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (10.2) Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (160.27)

Back to Top

	Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2)
Local Coverage Determinations (LCD)	Transcutaneous Electrical Nerve Stimulators (TENS) (L33802) Peripheral Nerve Stimulation (L37360) Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821) *references code E0762 External upper Limb Tremor Stimulation Therapy (L39591) (References E0734, A4552)
Local Coverage Article	Transcutaneous Electrical Nerve Stimulators (TENS) (A52520) Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (A52713)

For Non-Medicare Members

Device	Criteria
TENS unit	**Effective until September 1, 2024** Kaiser Permanente has elected to use the MCG* (KP-0241) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **Effective September 1, 2024** Kaiser Permanente has elected to use coverage guidance from Medicare's Local Coverage Determination (LCD)Transcutaneous Electrical Nerve Stimulators L33802 and Policy Article Transcutaneous Electrical Nerve Stimulators (TENS) (A52520) **If requesting this service, please send the following documentation to support medical necessity:** • Last 6 months of clinical notes from requesting provider or specialist to include any medications that were tried for pain relief • This service is dependent upon other measures of pain relief having been tried
External Upper Limb Tremor Stimulator Therapy (e.g., Cala Trio)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
NMES Unit – Neuromuscular Electrical Stimulation	Must meet **ALL of the following:** 1) Has durable medical equipment benefit 2) Treatment of muscle atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other neurological reasons for disuse atrophy

Commented [DP1]: I changed this we are not adopted MCG we are adopting medicare.

Back to Top

Device	Criteria
FES unit – Functional Electrical Stimulation (e.g. Parastep I System)	Must meet **ALL of the following:** 1. Has durable medical equipment benefit 2. Spinal cord injury patients to achieve walking and not reverse or retard muscle atrophy with all of the following characteristics: a) Persons with intact lower motor units (L1 and below) (both muscle and peripheral nerves); b) Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently; c) Persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction; d) Persons that possess high motivation, commitment and cognitive ability to use such device for walking; e) Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes; f) Persons that can demonstrate hand and finger function to manipulate controls; g) Persons with at least 6-month post-recovery spinal cord injury and restorative surgery; h) Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and i) Persons who have demonstrated a willingness to use the device long-term. j) Persons without one of the following conditions: i) Cardiac pacemaker; ii) Severe scoliosis or severe osteoporosis; iii) Skin disease or cancer at area of stimulation; iv) Irreversible contracture; v) Autonomic dysreflexia
Gastric Electrical Stimulation for the Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)	Kaiser Permanente has elected to use the FDA Humanitarian Device Exemption approved indications for Diabetic Gastroparesis: • Chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years
Gastric Electrical Stimulation for the Treatment of Gastroparesis (other than diabetic gastroparesis)	Kaiser Permanente has elected to use the MCG* Gastric Stimulation, Electrical (A-0395) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access. **If requesting this service, please send the following documentation to support medical necessity:** • Last 2 years of gastroenterology notes • Most recent clinical note from requesting provider
Electrical Stimulation for the Treatment of Dysphagia	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Galvanic Stimulation Device	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

Back to Top

Device	Criteria
H-wave Stimulation Device	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Microcurrent Stimulation Device (MENS)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
NESS Stimulators for Foot Drop and Paralyzed Hands	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
ReBuilder System Threshold electrical stimulation	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
WalkAide System for Patients with Foot Drop	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies
Peripheral Nerve Stimulator (i.e., StimRouter, Stimwave, Nalu)	Peripheral nerve stimulation is not covered for any indication at this time. Under evidence review. All requests must be reviewed by the Medical Director.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Back to Top

Background

A transcutaneous electrical nerve stimulator (TENS) is a device that utilizes electrical current delivered through electrodes placed on the surface of the skin to decrease the patient's perception of pain by inhibiting the transmission of afferent pain nerve impulses and/or stimulating the release of endorphins.

These are not the same as neuromuscular electrical stimulators (NMES), which are used to directly stimulate muscles and are used to prevent disuse atrophy (not address pain).

The transcutaneous electrical nerve stimulator is a well-established technique with limited effect and efficacy for the control of chronic painful disorders. Patients with chronic pain are best treated with a multi-disciplinary approach that includes increasing their activity. A TENS unit may be useful for a few weeks to assist a patient in becoming more active. It is not recommended for acute pain management as medication is much more effective and is safe for short-term management. It may be used occasionally to assist with pain control in patients with acute pain.

Medical Technology Assessment Committee (MTAC)

Transcutaneous Electrical Nerve Stimulation (TENS)

06/30/1998: MTAC REVIEW

Evidence Conclusion: Jarzem et al., Transcutaneous Electrical Nerve Stimulation for Patients with Chronic Backpain, presented at the annual meeting of the American Academy of Orthopedic Surgeons, San Francisco, 1997. 350 patients with chronic back pain, randomized into 4 groups; (1) daily treatment with conventional TENS; (2) treatment with nu-wave form TENS; (3) treatment with acupuncture TENS; (4) and treatment with sham TENS. In addition, all underwent an identical exercise program by a single therapist, blinded. 26 patients dropped out. All patients improved over time, but there were no significant differences among treatment groups.

Electrical Stimulation for the Treatment of Dysphagia

BACKGROUND

Dysphagia is the subjective sensation of difficulty or abnormality of swallowing. The term is derived from the Greek dys for bad or disorder, and phago for eat. Swallowing is a complex sensory-motor behavior that involves more than 25 pairs of muscles, 6 cranial nerves, and 2 cervical nerve roots to transport saliva, ingested solids, and fluids from the oral cavity to the stomach. It consists of three sequential, physiologically interconnected phases: oral preparatory and propulsive phase, pharyngeal phase, and esophageal phase. Dysphagia occurs when there is a problem with any part of this swallowing process. It can affect any age group, and may result from congenital abnormalities, stroke, head injury, neoplasms, and/or other medical conditions. Its incidence is higher in the elderly, in patients who have had strokes, and in patients who are admitted to acute care hospitals or chronic care facilities. Some may have trouble swallowing food, liquids, or saliva, and others are completely unable to swallow. Dysphagia can be a serious health threat due to the risk of aspiration pneumonia, bronchospasm, airway obstruction, pulmonary fibrosis, malnutrition, dehydration, and death (Leelamanit 2002, Blumenfeld 2006, Shaw 2007, Bulow 2008, Humbert 2012, Tan 2013). Functional dysphagia therapy aims at reducing the risk of aspiration and improving the physiology of the impaired swallowing mechanism to restore function. The traditional therapy incorporates diet modification, position adjustment, speech therapy, and exercise to alter the muscle structure and function. Percutaneous endoscopic gastronomy tubes are often used in the management of dysphagia. Thermal tactile stimulation by the application of cold to the anterior faucal arch is also being used with some success. Existing treatments for dysphagia are usually unable to restore the complete swallow function among patients with the most severe disorders (Freed, 2001, Miller 2013, Tan 2013). Transcutaneous electrical stimulation (ES) that involves the application of electric current across the skin to stimulate nerve or muscle tissue during a functional task is commonly used in physical and rehabilitation therapy. It is used to strengthen muscles after surgery, prevent disuse atrophy of denervated muscles, decrease spasticity, and accelerate wound healing. There are several variants of electrical stimulation therapy. Transcutaneous electrical nerve stimulation (TENS) is mainly used in an attempt to alleviate neuropathic or chronic musculoskeletal pains. This can be used on atrophied or denervated muscles but does not cause muscle

 Back to Top

contraction. Functional electrical stimulation (FES) is the application of electrical current to excitable tissue to supplement or replace function that is lost in neurologically impaired individuals e.g. after spinal cord injury. Neuromuscular electrical stimulation (NMES) therapy is used on innervated muscles to recruit motor units and increase muscle strength. It selectively targets healthy innervated muscle fibers but does not always stimulate atrophied or denervated muscle. NMES may be considered as a FES in situations when a muscle contraction is facilitated during a functional task (Peckham 2005, Carnaby-Mann 2007, Tan 2013). Over the last 2-3 decades, NMES therapy has been proposed as a treatment option for pharyngeal dysphagia to initiate or re-establish the act of swallowing. The therapy involves the application of electric stimulation through a pair of surface electrodes located on the neck. These are usually placed in one of two configurations: one electrode above the lesser horn of the hyoid bone and the other roughly 4 cm below it, or both electrodes above the lesser hyoid bones bilaterally. Electric pulses are then delivered continuously at 80Hz for duration of 300 µs and intensity ranging from 2.5 to 25 mA depending on the patient's tolerance. The therapy is usually given for 60-minutes session every day, 5 days a week until swallowing has been restored or until the patient cannot tolerate it (Steele 2007). NMES has received great interest and raised much controversy since it was introduced. Over 9,000 speech pathologists in the US have been trained to use the technology. However, the underlying neurophysiologic basis for using the procedure that involves surface electrode placement on the external lateral neck is poorly defined. Challenge in designing a neuromuscular stimulation device for swallowing include selecting which muscles to target in the swallowing sequence, designing a device that triggers a chain of successive muscle excitations and inhibitions similar to normal swallowing process. Some scientists have argued that the current intensity delivered by NMES at the submental region is greatest at the skin surface and diminishes with depth through the platysma underlying the skin and subcutaneous fat. The deeper muscles which would pull the hyoid bone up and toward the mandible, and those that elevate the larynx to the hyoid bone, are much less likely to be activated by surface stimulation (Ludlow 2007, Steele 2007). Potential risks of NMES include arrhythmia, hypotension, laryngospasm, burns, glottic closure, and interference with pacemakers. The therapy is contraindicated in patients with pacemakers, superficial metal implants or orthotics, skin breakdown, cancer, history or cardiac disorders, seizures, impaired peripheral conduction system, pregnancy, significant reflux due to use of a feeding tube, or dysphagia due to drug toxicity (Leelamanit 2002, Blumenfeld 2006, Huckabee 2007).
Two NMES devices, the Freed Bioelectric Dysphagia Treatment Device and the Chattanooga VitalStimTM system, were cleared by the FDA for marketing in June 2001 and December 2002 respectively. Both are equivalent external electrical stimulation devices intended for re-education of the throat muscles, necessary for pharyngeal contraction, for the treatment of dysphagia from any etiology other than mechanical causes requiring surgery. The therapy treatment sessions last for 60 minutes and are most commonly administered by a speech and language pathologist. The FDA approval came with a warning that: 1.The long-term effects of chronic electric stimulation are unknown, 2. Stimulation should not be applied over the carotid sinus nerves, 3. Improper placement of the electrodes or improper use of recommended frequency, intensity or pulse, may cause laryngeal or pharyngeal spasm which may close the airway or cause difficulty in breathing.

04/14/2004: MTAC REVIEW
Electrical Stimulation for the Treatment of Dysphagia
Evidence Conclusion: The study reviewed provides insufficient evidence on the use of electrical stimulation in patients with dysphagia. It had potential selection and observation bias. The investigators compared electrical stimulation to tactile stimulation in a controlled study where patients were not randomized, but alternately assigned to electric stimulation using the Freed Bioelectric Dysphagia Treatment Device, or thermal tactile stimulation. Overall, the results of the study show that both treatment groups improved, but the final swallow scores were higher among the electrical stimulation group. The study has potential selection and observation biases and does not provide sufficient data on the long-term effectiveness of the treatment.
Articles: The search yielded 11 articles on electrical stimulation for the treatment of dysphagia. There was a longitudinal study with a control group, on electrical stimulation for swallowing disorders caused by stroke (Freed et al 2001), and another on effects of electrostimulation on salivary function of Sjogren's syndrome patients (Talal 1992). In the latter study, treatment aimed at increasing the production of saliva by an electrostimulation device placed on the tongue, which is different from the transcutaneous electric stimulating of the pharyngeal muscles. The search also revealed one case series with 23 patients, four small case reports, and four review articles. A larger study with 892 patients was submitted to the FDA but has not been published in a peer reviewed medical journal to date. *An evidence table was created for the following study:* Freed ML, Freed L, Chatburn RL et al. Electrical stimulation for swallowing disorders caused by stroke. Respir Care 2001;46:466-474. See Evidence Table

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/04/2008: MTAC REVIEW
 Back to Top

Electrical Stimulation for the Treatment of Dysphagia

Evidence Conclusion: VitalStim was reviewed earlier by MTAC in April 2004. The best evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke. The study had its limitations and biases and did not provide sufficient evidence on the safety and effectiveness of neuromuscular electrical stimulation in treating dysphagia.

Articles: There is still a lack of published literature on the use of NMES for swallowing. The best published evidence to date is a very small (N=25) recent RCT with several limitations and a meta-analysis that included one small controlled trial (Freed, et al 2001), a retrospective study with a control group, and small case series. The results of the published controlled studies and case series are conflicting. Several case series with non-blinded subjective measures reported some improvement in swallowing. This positive effect was however not observed when more objective outcomes were used and blindly measured. The only published randomized controlled trial showed no significant differences between NMES and traditional swallowing therapy in treating patients with swallowing difficulties due to stroke. The trial was too small, unblinded, had insufficient statistical power, and no long-term follow-up. These limitations together with other methodological flaws do not allow making conclusions on the efficacy and safety of the therapy. In conclusion, there is insufficient published evidence to determine: 1. Whether patients treated with VitalStim will show more improvement in the oral and pharyngeal phases of swallowing compared to the traditional therapies used in the management of dysphagia. 2. If patients treated with VitalStim would have fewer dietary consistency restrictions compared to those receiving traditional means for dysphagia management, or 3. If patients treated with VitalStim would progress more rapidly from nonoral to oral nutrition compared to those receiving traditional means for dysphagia management.

The search yielded just over 30 articles on electrical stimulation for the treatment of dysphagia. Many were reviews and opinion pieces. There was one meta-analysis of non-randomized controlled studies and case series studies, a more recent small randomized controlled trial, and a number of case series on the effect of NMES therapy on improving swallowing. The literature search did not reveal any study on the effect of therapy on dietary restrictions, or progress from nonoral to oral nutrition. The meta-analysis and the RCT were selected for critical appraisal. Carnaby-Mann GD, Crary MA. Examining the evidence on neuromuscular electric stimulation for swallowing. A meta-analysis. Arch Otolaryngol Head Neck Surg.2007;133:564-571. See Evidence Table Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. Dysphagia April 2008. See Evidence Table Bulow M, Speyer R, Baijens L, et al. Neuromuscular electrical stimulation (NMES) in stroke patients with oral and pharyngeal dysfunction. Dysphagia April 2008. See Evidence Table

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/16/2014: MTAC REVIEW

Electrical Stimulation for the Treatment of Dysphagia

Evidence Conclusion: NMES was reviewed earlier by MTAC in 2004 and 2008 and did not pass the evaluation criteria due to the lack of evidence on its safety and efficacy in the management of dysphagia. The best published evidence at the time was the Freed et al (2001) nonrandomized controlled trial that compared electrical stimulation to tactile stimulation for the treatment of 110 patients with swallowing disorders caused by stroke, a very small RCT with 25 patients (Bulow 2008) and a meta-analysis of small nonrandomized studies comprising 225 patients. More recently a number of randomized or quasi randomized RCTs were conducted to assess the efficacy of NMES in patients with dysphagia due to variable etiologies. The studies were small in size, had short follow-up durations, and varied widely in the patient selection, electrode positioning, stimulation protocols, combination with other therapies, and outcome measures. The results of the published trials as well as a meta-analysis of 7 trials are conflicting (evidence tables 1&2). Baijens, et al (2013) found no additional clinical benefit when submental NMES used in addition to the traditional dysphagia therapy in patients with dysphagia secondary to Parkinson's disease. Kushner, et al (2013) reported significantly better outcomes with NMES combined with traditional therapy vs. traditional therapy alone for patients with dysphagia following stroke. On the other hand Tan and colleagues' 2013 meta-analysis of RCTs suggest that NMES may be more effective than traditional therapy in patients with dysphagia due to different etiologies, except for post-stroke dysphagia. The conflicting results of the published studies, different stimulation protocols used, various underlying pathological conditions, and short follow-up durations, makes it hard to determine whether NMES provides additional therapeutic benefit for patients with dysphagia.

Articles: The literature search for studies on NMES published after the last 2008 MTAC review, revealed over 50 articles. There were two meta-analyses, 6 small randomized controlled trials, and a number of observational small studies related to the current review. One of the two meta-analyses (Geeganage et al, 2012) assessed feeding and swallowing treatment strategies including NMES in stroke patients and the other (Tan et al, 2013) evaluated NMES in patients with dysphagia caused by non-stroke conditions. The published RCTs identified by the search

 Back to Top

examined the effect of NMES on treating dysphagia due to stroke, Parkinson's disease, or cancer. The following meta-analysis and the RCTs were selected for critical appraisal. Baijens LW, Speyer R, Passos VL, et al. Surface electrical stimulation in dysphagic Parkinson patients: a randomized clinical trial. Laryngoscope. 2013;123:E38-44. See Evidence Table Heijnen BJ, Speyer R, Baijens LW, et al. Neuromuscular electrical stimulation versus traditional therapy in patients with Parkinson's disease and oropharyngeal dysphagia: effects on quality of life. Dysphagia. 2012; 27:336-345. See Evidence Table Lim KB1, Lee HJ, Lim SS, et al. Neuromuscular electrical and thermal-tactile stimulation for dysphagia caused by stroke: a randomized controlled trial. J Rehabil Med. 2009;41:174-178. See Evidence Table Long YB, Wu XP. A randomized controlled trail of combination therapy of neuromuscular electrical stimulation and balloon dilatation in the treatment of radiation-induced dysphagia in nasopharyngeal carcinoma patients. Disabil Rehabil. 2013;35:450-454 See Evidence Table Permsirivanich W, Tipchatyotin S, Wongchai M, et al. Comparing the effects of rehabilitation swallowing therapy vs. neuromuscular electrical stimulation therapy among stroke patients with persistent pharyngeal dysphagia: a randomized controlled study. J Med Assoc Thai. 2009;92:259-265. See Evidence Table Ryu JS, Kang JY, Park JY, et al. The effect of electrical stimulation therapy on dysphagia following treatment for head and neck cancer. Oral Oncol. 2009;45:665-668. See Evidence Table Tan C, Liu Y, Li W, et al. Transcutaneous neuromuscular electrical stimulation can improve swallowing function in patients with dysphagia caused by non-stroke diseases: a meta-analysis. J Oral Rehabil. 2013; 40:472-480. See Evidence Table Xia W1, Zheng C, Lei Q, Tang Z, et al. Treatment of post-stroke dysphagia by VitalStim therapy coupled with conventional swallowing training. J Huazhong Univ Sci Technolog Med Sci. 2011;31:73-76. See Evidence Table.

The use of electrical stimulation in the treatment of dysphagia does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)

BACKGROUND

Gastroparesis (GP) is a gastric motility disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. The most common etiologies of GP are diabetes mellitus, post-surgical often as the result of damage to the vagal nerve, and idiopathic. Other causes include Parkinson's disease, collagen vascular disorder, and any disease process that interferes with the neuromuscular function of the stomach. The characteristic symptoms of gastroparesis include early satiety, nausea, vomiting, bloating, and abdominal pain. These symptoms are typically driven by meal intake but can also be present continually at varying degrees of intensity. A severe gastroparesis can result in impaired quality of life, recurrent hospitalizations, malnutrition, and even death (Velanovich 2008, McCollum 2011). The standard medical management of gastroparesis involves dietary modification, glycemic control, and the use of antiemetic therapy combined with prokinetic agents such as metoclopramide and erythromycin. These therapies are generally effective for the symptomatic relief in the majority of patients with GP. However, some patients do not respond to, or cannot tolerate drug treatment, and may require palliative endoscopic or surgical therapies. Surgical options include feeding jejunostomy tubes, decompressing gastrotomy tubes, pyloroplasty, and gastrectomy as a last resort (McKenna 2008, Velanovich 2008, McCallum 2010). In the last decade, high frequency gastric electrical stimulation (GES) emerged as a potential treatment option for patients with medically refractory gastroparesis. The therapy involves delivering low-energy electrical stimuli in the muscularis propria of the stomach at a frequency significantly higher than the normal gastric slow wave frequency. This is different from gastric pacing that delivers high energy stimuli at a frequency slightly above the intrinsic slow wave activity. The Enterra® Therapy System (Medtronic, Minneapolis, MN), a stimulation device delivering high-frequency GES, was granted Humanitarian Device Exemption by the US Food and Drug Administration in 2000 for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic in origin (O'Grady 2009, Chu 2012). The Enterra® system consists of three main elements: a pair of leads, a pulse generator, and a programming system. The leads and pulse generator are implanted surgically via laparotomy or laparoscopically. The two leads are surgically implanted about 1 cm apart in the muscle wall of the greater curvature of the stomach, approximately 10 cm from the pylorus. They are anchored in place then connected to a pulse generator placed in a subcutaneous pocket created in the abdominal wall generally in the superior quadrant of the abdomen. The pulse generator is controlled by an external programmer that allows for interrogation and programming of stimulation via a radio-telemetry link. The battery life of the pulse generator is 5-10 years depending on the neurostimulator setting. It is sealed in the generator and thus the device must be replaced when the battery is depleted. The leads can be left in place and reused with the new pulse generator. The Enterra system produces intermittent bursts of high-frequency (~14 cycles per second) short duration pulses (~ 330 µs) that are three to four times faster than the native gastric slow wave frequency (Chu 2012, Guerci 2012, Soffer 2012). GES therapy is not without complications; researchers reported that 7-10% of the patients treated with the Enterra® system experience an adverse event mainly infection of the subcutaneous pocket. Other events include erosion of the abdominal wall by the device, leads dislodgment or penetration through the gastric wall, or tangling of wires in the generator pocket

 Back to Top

and formation of adhesions (Soffer 2012). This technology was approved by the FDA as a humanitarian device based on data from one study consisting of 33 patients that was not published in the peer-reviewed literature at the time.

02/14/2001: MTAC REVIEW
Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)
Articles: There are currently no peer-reviewed articles on this technology. Therefore, it is not possible for the MTAC committee to review the Gastric Electrical Stimulation Enterra™ Therapy System at this time.
No published evidence found.

The use of Gastric Electrical Stimulation Enterra Therapy System in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* as there was no published evidence to review.

02/11/2013: MTAC REVIEW
Gastric Electrical Stimulation for Treatment of Medically Refractory Diabetic Gastroparesis (Enterra™)
Evidence Conclusion: There is insufficient published evidence to determine that gastric electrical stimulation (GES) may improve refractory nausea and vomiting symptoms in patients with gastroparesis secondary to diabetes mellitus. There is also insufficient evidence to determine that GES improves gastric emptying, or that it is superior to other therapies for the treatment of GP. The three published RCTs on GES had their limitations, had negative results, and could not rule out the placebo effect of the therapy. There was no, or very short washout periods between the ON/OFF modes of the experimental phases of the trials, no comparisons were made between GES and other therapies, medical therapy was tried for only one month in some cases, and the prokinetic/antiemetic agents and other therapies were not discontinued during the study periods. The Worldwide Anti-Vomiting and Electrical Stimulation Study (WAVESS) conducted by Abell and colleagues, 2003 (Evidence table 1) was the first published RCT that evaluated the efficacy of the implanted GES system for highly symptomatic patients with drug refractory nausea and vomiting secondary to gastroparesis of diabetes or idiopathic etiology. This trial together with two other observational studies were the basis for the US Food and Drug Administration Humanitarian Device Exemption approval of Enterra® Therapy System for patient with chronic drug refractory nausea and vomiting secondary to gastroparesis of diabetes mellitus or idiopathic origin. The study was a very small RCT with limitations. It was powered to enroll 80 subjects but could only recruit 33, and was changed from a RCT to an observational study after 2 months of randomization. After implantation of the device, patients were randomized to an ON or OFF stimulation of the device for one month, after which, they were crossed-over to the alternative ON/OFF mode without a washout period. All patients were kept on the prokinetic, antiemetic and other therapies they were using for the duration of the randomized and observational phases of the study. Overall, the results of the trial showed a significant decrease in the weekly vomiting frequency for all the patients combined, but not for the diabetic or idiopathic subgroups. It is to be noted that the published outcome data are different from the data presented to the FDA where no significant differences were found in the mean or median vomiting episodes between the ON and OFF modes. The total Symptom Scores (TSS) did not improve significantly during the RCT phase but showed significant improvement in the open-label phase. Side effects included infection, pacer migration, and stomach wall perforation. Another crossover RCT conducted by McCallum and colleagues, 2010 (evidence table 2) also had its methodological limitations and did not allow examining the placebo effect of GES. All study participants underwent GES for 1.5 months before randomization. There was no washout period after the initial GES or between the ON and OFF modes in the experimental randomized phases. The results of the study showed no significant difference in the (weekly vomiting frequency) WVF or other symptoms between the ON versus OFF periods but showed a significant improvement in WVF in the first 6-week unblinded period after implantation vs. baseline, which could have been carried over to the randomized phase, especially with a lack of washout period. There was a high rate of adverse events, many of which were serious, and three patients requires surgical intervention for infection requiring removal of the device, lead dislodgement, or device migration. At one year after the implant, when all patients had the device switched on, the WFV remained lower than baseline. One meta-analysis (Grady, 2009) combined the results of the first RCT (Abell 2003) together with 12 case series with no control groups, and a second meta-analysis (Chu 2012) pooled the results of two RCTs (Abell 2003, and McCallum 2010) together with 8 case series with no controls. The pooled results showed significant improvement in gastroparesis symptoms. The authors of the two meta-analyses indicated that the results of the analyses should be interpreted with caution due to the limitations and design of the studies included. The three most important complications reported were infection in the subcutaneous pocket affecting, electrodes detachment or displacement, and pulse generator migration, all of which require surgical intervention. Due to the unpredictable response of patients to GES, Abell and colleagues, 2011 (evidence table 3) investigated the effects of temporary electrical gastric stimulation therapy on gastroparesis symptoms to assess the response after a few days of therapy as a predictor of response to long-

 Back to Top

term therapy with GES. The trial included 55 patients among whom only 13 had diabetes mellitus as the cause of GP. The study was a crossover RCT with only one day washout period between the two sessions in which the device was alternately turned ON and OFF. In the first 3 days after implantation of the electrodes (session 1) both groups experienced a significant improvement in vomiting, nausea, and all symptom scores, irrespective of stimulation, which may indicate a placebo effect. In conclusion, larger studies with a parallel group design, sufficient power, and long-term follow-up are needed to more accurately determine the efficacy and safety of gastric stimulation therapy for gastroparesis of diabetes mellitus or idiopathic etiology.

Articles: The literature search revealed over 100 articles on gastric electrical stimulation in patients with gastroparesis. The majority were review articles, articles on technical aspects of the therapy, or observational studies and case series with no comparison groups. The search identified three randomized controlled trials and two meta-analyses that pooled the results of case series together with the randomized controlled trial. The three RCTs were selected for critical appraisal. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterol. 2003; 125:421-428. See Evidence Table McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. 2010; 8:947-954. See Evidence Table Abell TL, Johnson WD, Kedar A, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis: Gastrointest Endosc. 2011; 74:496-503. See Evidence Table

The use of Gastric Electric Stimulation for the Treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

NESS Stimulators for Foot Drop and Paralyzed Hands

BACKGROUND

Foot drop is a motor deficiency caused by partial or total paralysis of the muscles innervated by the peroneal nerve. It is not a disease but a symptom of an underlying problem. It is often caused by an injury to the peroneal nerve but can also be associated with a variety of conditions such as stroke, dorsiflexor injuries, neuropathies, drug toxicities, or diabetes. The problem may be temporary or permanent depending on the cause. Foot drop is characterized by the lack of voluntary control of ankle dorsiflexion, and subtalar eversion. Patients with foot drop are unable to walk on their heel, flex their ankle, or walk with the normal heel-toe pattern. They usually exhibit an exaggerated or high-steeping walk called steppage gait or foot drop gait in order to compensate for toe drop. This unnatural walking motion may result in subsequent damage to the hip, back or knee (Voigt 2000). Management of patients with foot drop varies and is dependent on the underlying cause. Some patients may be fitted with of ankle-foot orthoses (AFO) brace, which typically limit ankle plantarflexion to enhance foot clearance during swing. Patients may also undergo physical therapy for gait training. Surgery may be an option when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as “functional electrotherapy” because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and “natural” sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. It contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. It is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury, and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience seizures should not use WalkAide (FDA materials; Innovative Neurotronics website). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord. The NESS L300 is another electrical stimulation system that received FDA clearance (in 2006) to provide ankle dorsiflexion in individuals with drop foot following an upper motor neuron injury or disease. It has the same intended use and same principal of operation as the WalkAide. The main technological difference however between the two systems, is the RF wireless communications between the components of NESS L300 versus the wired communication in the WalkAide system. NESS L300 is a neuroprothesis device that consists of four main parts 1. A lower leg orthosis containing electrodes and a controlled stimulation unit, 2. A heel sensor 3. A control unit that is carried in the pocket, mounted on the waist, or on a neck strap, and 4. PDA to be used by the clinician to configurate the control unit with functional parameters as appropriate for every patient. The system is intended

 Back to Top

to provide ankle dorsiflexion in individuals with foot drop following an upper motor neuron injury or disease. During the swing phase of gait, the NESS L300 electrically stimulates muscles in the affected leg to provide dorsiflexion of the foot. According to the manufacturer it may also facilitate muscle reduction, prevent/retard disuse atrophy, maintain or increase joint range of motion and increase local blood flow (FDA materials; Ness 300 website). NESS H200 or Bioness is another new muscle stimulation device developed Bioness Inc. to restore function to paralyzed muscles. It is a brace like apparatus, equipped with electrodes to stimulate and activate muscles that have been affected by stroke, injury, multiple sclerosis or cerebral palsy. The H 200is worn on the forearm and hand and holds the hand in a functional position. According to the manufacturer, the functional electrical stimulation is used to move affected areas through repetitive exercises which would strengthen the muscles, reduce spasticity, improve blood flow, and increase range of movement. A microprocessor allows the therapist to program the device with a sequence of exercises customized to each patient. The system may be also used in the home setting (Bioness Inc. web page). Stroke is one of the leading causes of disability and impairment in the United States. It is reported that only 12-18% stroke survivors will regain complete functional recovery of the upper extremity, and that about 30% to 66% of those with paretic arms will still have an impaired upper limb function after six months with routine rehabilitation. Arm dysfunction impairs the daily activities of the individual as writing, dressing, bathing, self-care, and in turn reduces the functional independence, occupational performance, and quality of life (de Kroon 2002, Meilink 2008, and Kwakkel 2008). Loss of upper extremity function following stroke is a major rehabilitation challenge. Occupational and physical therapies which are commonly used in the rehabilitation of stroke patients have not always been satisfactory in improving the reaching, grasping, holding, or releasing functions of the paralyzed limb. Investigators are now focusing on therapies that will lead to regaining and improving upper extremity functional activity rather than only minimizing the impairment (Alon 2008). Electrical stimulation (ES) has been studied and used clinically for about 40 years in different neurological conditions such as cerebrovascular accidents, multiple sclerosis, cerebral palsy, and other events. Its use for the upper limb is getting increased attention as a therapeutic modality in poststroke rehabilitation. It provides continuous low voltage stimuli which enable repetitive exercise to the neuromuscular system. ES has two modalities: 1. Therapeutic electrical stimulation (TES) which applies higher frequency (36 Hz) with the aim of activating the reduced muscle strength and preventing or lowering the pain and spasticity of the muscles, and 2. Functional electrical stimulation (FES) which applies lower frequency ES (18 HZ) in order to improve activity during the stimuli. TES includes neuromuscular electrical stimulation (NMES), EMG-triggered electrical stimulation, positional feedback stimulation training (PFST), and transcutaneous electrical nerve stimulation (TENS). These have different indications, mechanisms of action, and are applied by multiple devices with a range of possibilities for the adjustment of stimulation parameter (Berner 2004, Kroon 2002). FES on the other hand, is the application of neuromuscular electrical stimulation concurrently with the training of task specific or functional activity i.e. provoking muscle contraction in order to assist the performance of functional activities during stimulation. In the last decades, several research groups have been working on the development of FES systems for the upper extremity, and currently multiple devices aiming at restoring the upper limb function are commercially available (Snoek 2000, Alon 2008). The NESS H200, formerly known as “The Handmaster”, (NESS Ltd Ra’anana, Israel) is a portable, non-invasive, hybrid wrist/hand orthosis and electrical stimulation device that is designed to be used in hemiplegic as well as C5 tetraplegic patients. It provides an instrument for both the treatment at the level of impairment (neuromuscular and articular properties) and disability (functional handgrip with stabilized wrist). The system contains an external control unit connected by a cable to a below the elbow splint. The splint contains a body with front spiral end and a wing which pivots about the body and can be opened by lifting a release handle. Five surface electrodes are attached to the splint and correspond with the motor points in finger and thumb muscles. The control unit allows the user to select from among three exercise modes and three functional modes. The exercise modes provide stimulation to the targeted finger and thumb extensor and flexor muscles. The functional mode provides sequential key grip or palmer grasp and release patterns. The spiral design of the system allows wrist stabilization in a functional position of 10 -20o of extension. The system is also designed to permit reproducible accurate electrode positioning by the patient. Once fitted into the orthosis, the electrodes remain in position for all subsequent applications and allow consistent replication of the grasp, hold and release hand functions. The patient is provided with a progressive home exercise program and is required to follow a conditioning paradigm using the system’s exercise modes. Training periods start at 10 minutes twice daily and gradually increase to 45 minutes 2 times a day (Hara 2008, Snoek 2000). The NESS system and the Handmaster device received FDA clearance in September 2002, and August 2003 respectively, to be used to maintain or increase the range of motion, reduce muscle spasm, prevent retardation of disuse atrophy, muscle reduction, increase local blood circulation, and provide hand active range of motion and function in patients suffering from upper limb paralysis due to C5 spinal cord injury, or hemiplegia due to stroke.

12/03/2007: MTAC REVIEW
NESS Stimulators for Foot Drop and Paralyzed Hands

Back to Top

Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the Ness L300 system for patients with foot drop. There is insufficient published evidence to determine the efficacy and safety of the Ness H200 system for the restoration of hand movements.
Articles: The search did not reveal any published studies, on Bioness, NESS L300, or NESS H200. Information about the devices was obtained from the FDA and/or the manufacturer's Web sites.

The use of the NESS L300 or NESS H200 in the treatment of foot drop or paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/06/2008: MTAC REVIEW
NESS Stimulators for Foot Drop and Paralyzed Hands
Evidence Conclusion: The two published RCTs (Alon 2007, and Alon 2008) were conducted by the same group of investigators in the same center, using the same eligibility criteria, procedures, and outcome measures. One of the studies (Alon 2007) included patients with mild/moderate paresis (Fugl- Meyer score 11-40), and the other (Alon 2008) included patients with severe motor loss of the upper extremity (Fugl-Meyer score 2-10). The two trials compared the standard physical and occupational therapies plus FES using NESS H200 versus the standard physical and occupational therapies alone. The trials were small, unblinded, and had no extended follow-up after the end therapy. Their overall results showed some improvement in movement and function in the patients randomized to the NESS H200. The observed differences vs. standard therapy were statistically significant in patients with mild/moderate paresis but not in those with severe motor loss (Alon 2008). The lack of statistical power in the latter study, as well as open-label design, short duration, and absence of follow-up do not allow making any definitive conclusion regarding the effectiveness of the therapy or the persistence of the improvements observed in patients with severe motor impairment. Ring and colleagues' trial (2005) were a comparative study with blinded assessment of outcomes, but had the disadvantage of inappropriate randomization, small number of patients, and absence of follow-up after the six weeks of therapy. The authors categorized the participants into those with or without active voluntary motion of the fingers and wrist at baseline. Patients were assigned to receive rehabilitation with or without NESS Handmaster. The overall results of the trial showed significant improvement in spasticity, motion, and function in all participants receiving the NESS Handmaster device vs. those who did not receive the device. The observed differences were statistically significant for all variables studies for patients who had active partial range of movement at baseline. For those with no active voluntary motion in the fingers and wrist at baseline, decrease in finger spasticity was the only statistically significant improvement observed.
Conclusion: There is poor evidence to determine that the use of NESS H200 may improve upper extremity function in patients with mild or moderate paresis/paralysis with similar eligibility criteria as those in the trials, compared to standard physical and occupational therapies. There is insufficient evidence to determine whether the benefits observed would persist after therapy is ended. There is insufficient published evidence to determine that the use of NESS H200 would improve function in patients with severe motor loss in the upper extremity. There is insufficient published evidence to determine if the use of NESS H 200 would lead to a faster motor and functional recovery vs. standard therapy alone. There is fair evidence that NESS H200 is safe to use among patients with upper limb impairment due to stroke, and who has eligibility criteria similar to those of the published studies.
The search revealed a large number of published articles on the use of FES in general, but very limited publications on use the use NESS H200 (NESS Handmaster) for patients with cervical spinal cord injury or stroke. The majority of studies on NESS H200 were case reports or case series with less than 30 patients. There were two small (N=15, and N= 26) randomized controlled trials and one quasi-randomized study, that compared the outcomes of FES using NESS H200 or NESS Handmaster devices in addition to the standard rehabilitation vs. standard rehabilitation alone in stroke survivors with impaired upper extremity. All three were critically appraised.
Articles: Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation (FES) may modify the poor prognosis of stroke survivors with severe motor loss of the upper extremity. Am J Rehabil Med 2008;87:627-636 See Evidence Table Alon G, Levitt AF, McCarthy PA. Functional electrical stimulation enhancement of upper extremity functional recovery during stroke rehabilitation: A pilot study. Neurorehabil Neural Repair 2007;21:207-215 See Evidence Table Ring H, and Nechama Rosenthal. Controlled study of neuroprosthetic functional electrical stimulation in sub-acute post-stroke rehabilitation. J Rehabil Med 2005;37:32-36 See Evidence Table

The use of the NESS H200 in the treatment of paralyzed hands does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System
BACKGROUND
The Vertis percutaneous neuromodulation therapy (PNT) system, manufactured by Vertis Neuroscience, is a minimally invasive, nonsurgical therapy. It is based on the premise that chronic back pain is caused by increased

 Back to Top

sensitization of the nerve cells that transmit pain signals. The Vertis PNT system delivers electrical stimulation to the deep tissues near the spine to alter the "hypersensitivity" of nerve pathways that cause persistent pain. Treatment consists of a series of outpatient treatment sessions performed in a clinic setting. It is intended for use by a physician or other clinician (e.g. physical therapist), not for patient use. The device includes three major components: Control unit - A software driven, five-channel, AC powered nerve stimulator which generates the electrical stimulus, Sterile, needle electrodes, A cable that connects the needles to the control unit. The FDA approved Verdis PNT in September 2001 for the following indications: Symptomatic relief and management of chronic or intractable low back pain and/or as an adjunctive treatment in the management of post-surgical low back pain and post-traumatic low back pain.

10/09/2002: MTAC REVIEW
Percutaneous Neuromodulation Therapy (PNT) for Back Pain - Vertis PNT System
Evidence Conclusion: There is insufficient evidence to determine the effect of percutaneous neuromodulation therapy on back pain.
Articles: There were no published articles evaluating the effect of PNT on back pain. Two articles that were submitted for publication were identified on the manufacturer's website. The manufacturer indicated that the articles are not yet published.

The use of percutaneous neuromodulation therapy in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
BACKGROUND
There are three main types of arthritis that can affect the knee joint: osteoarthritis, rheumatoid arthritis and post-traumatic arthritis. Osteoarthritis, the most common type, is generally a slowly progressing degenerative disease that involves the gradual wearing away of the joint cartilage. Symptoms include pain and swelling. Pain often increases after activities such as walking and stair climbing and is the principal symptom for which patients with osteoarthritis seek medical attention. The main goal of treatment is pain control, although maintaining and/or improving joint function are also goals. A stepwise approach to management of osteoarthritis of the knee is generally recommended. Initial conservative measures include weight reduction, exercise, and the use of supportive devices. Medications, including anti-inflammatories and corticosteroids, can be used to supplement the conservative approaches. For patients who fail medical management, surgical treatments are available. Pulsed electrical stimulation is a potential non-invasive alternative to surgery for patients who do not respond to medical treatment. The BioniCare Stimulator has been approved by the FDA as an adjunctive treatment for osteoarthritis of the knee. It is a portable battery-operated device that delivers a low frequency (100 Hz) electrical signal to the knee via skin electrodes. Other types of electrical stimulation including electro-acupuncture, transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES) with the Respond Select device have also been used to treat osteoarthritic knee pain.

08/01/2005: MTAC REVIEW
Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee
Evidence Conclusion: There was one randomized controlled trial on BioniCare for treating osteoarthritis (Zizic et al. 1995). The authors reported that the active treatment group had significantly better outcomes than the placebo group two weeks after completing a 4-week treatment period. However, the statistical analysis may have been biased. The authors used a one-sided p-value at $p<0.05$. If they had used the commonly accepted method of dividing the p-value in half for a one-sided p-value (in this case $p<0.025$), two of the three primary efficacy variables would not have been significant. Another limitation of the study is that, although the authors reported statistically significant differences, the clinical significance is unclear. There was approximately a 10% difference in the change from baseline in patient perception of pain and patient perception of function (approximately 30% change in the treatment group and 20% change in the placebo group for each outcome variable).
Articles: The single RCT was published in 1995 and has not been replicated. In addition, no studies were identified that compared BioniCare to other treatments such as medication or TENS. Patients in the Zizic study were not required to have failed other treatments. One empirical study on the BioniCare system was identified (Zizic, 1995). This was a placebo-controlled randomized controlled trial and was critically appraised. No studies were identified that compared BioniCare to other treatments such as exercise or medication, or to different forms of electrical stimulation such as TENS. *The Zizic study was critically appraised:* Zizic TM, Hoffman KC, Holt PA et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. *J Rheumatol* 1995; 22: 1757-1761. See Evidence Table

The use of Pulsed electrical stimulation in the treatment of osteoarthritis of the knee does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*
 Back to Top

ReBuilder System

BACKGROUND

Peripheral neuropathy is a disorder of the peripheral nervous system characterized by impaired function of sensory, motor and/or autonomic nerves. It results from damage to the cell body, nerve fiber, or to the surrounding myelin sheath of peripheral nerves. Manifestations include pain, numbness, tingling, extreme sensitivity to touch, lack of coordination, muscle weakness or paralysis, and bowel or bladder problems. Treatment relies on addressing the underlying cause and various treatments for pain. ReBuilder is a handheld, battery-powered nerve stimulator that delivers an electrical impulse, similar to a normal nerve signal, to specific regions of the body to alleviate pain, burning, tingling, and numbness from a variety of conditions. The ReBuilder is an FDA class II, neurologic therapeutic medical device that first received FDA 510(k) approval in 1987 for marketing as a TENS unit for pain relief. In 1989, the FDA cleared ReBuilder for other indications. The FDA approval is for the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain relief, relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle reeducation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motions. The FDA has written warning letters to manufacturer of ReBuilder against marketing the device for any off-label indications, including peripheral neuropathy.

12/19/2011: MTAC REVIEW

ReBuilder System

Evidence Conclusion: The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). Conclusion: There is insufficient evidence to determine the safety or efficacy of the ReBuilder System for the treatment of chronic intractable pain for any condition.

Articles: The literature studies did not identify any studies that evaluated the ReBuilder System for any indication. The search did identify a 2011 technology assessment from Kaiser Permanente. Their literature search also did not identify any studies that evaluated the safety or efficacy of the ReBuilder System (Kaiser 2011). See Evidence Table.

The use of ReBuilder System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

WalkAide System for Patients with Foot Drop

BACKGROUND

Foot drop is defined as a significant weakness in the muscles involved in flexing the ankle and toes (dorsiflexion). The specific muscles affected include the tibialis anterior, extensor hallucis longus and extensor digitorum longus. These muscles allow the toes to swing upward during the beginning of a walking stride and the planting of the heel towards the end of the stride. In patients with foot drop, the foot droops or drags along the ground during the swing phase. The condition is also called steppage gait because patients often raise their thigh excessively high to compensate for toe drop, and they appear as though they are walking up stairs. The unnatural walking motion may result in subsequent damage to the hip, back or knee. Foot drop is associated with a number of conditions such as peripheral nerve injuries, stroke, diabetes, neuropathies and drug toxicity. The causes can be divided into three categories, which may overlap: nerve damage, muscle damage, and/or a skeletal or anatomic abnormality. The conventional treatment for foot drop is the use of ankle-foot orthoses (AFO). These typically limit ankle plantar flexion to enhance foot clearance during swing. Disadvantages of AFOs are that they can be uncomfortable and limiting to wear. Surgery is sometimes beneficial when the cause of foot drop is muscular or neurologic. Electrical stimulation was first proposed as a treatment for foot drop by Liberson in 1961. Liberson referred to the treatment as “functional electrotherapy” because its purpose was to replace a functional movement that was lost after injury or illness. There has been extensive development of functional stimulation devices since the early 1960s. The first devices were hard-wired surface stimulators, followed by hard-wired implanted electrical stimulators, and then microprocessor-based surface and implanted systems. In the 1990s, artificial and “natural” sensors were developed as a replacement for the foot-switch. More recently, testing has been done on a device in which both the sensor and stimulator are implanted (Lyons et al. 2002). The WalkAide system is an external neuromuscular functional stimulator. The system contains a control unit attached to a flexible cuff that contains two electrodes. The unit is placed on the leg below the knee, near the head of the fibula. According to FDA materials, WalkAide stimulates the common peroneal nerve which innervates the muscles that cause dorsiflexion of the ankle. This stimulation is intended to produce a more natural and stable walking stride. WalkAide is indicated for individuals with foot drop due to central nervous system conditions including cerebral palsy, multiple sclerosis, traumatic brain injury and cerebrovascular accident. It is contraindicated for patients with traumatic accidents to the leg, complications of back, hip or knee surgery, sciatica, peripheral neuropathy, spinal stenosis, post-polio syndrome and Guillain-Barre syndrome. In addition, patients with pacemakers or who experience

 Back to Top

seizures should not use WalkAide (FDA materials; Innovative Neurotronics Web site). The Innovative Neurotronics WalkAide System for foot drop was approved by the FDA in August 2005 to address the lack of ankle dorsiflexion in patients who have experienced damage to upper motor neurons or pathways to the spinal cord.

10/02/2006: MTAC REVIEW
WalkAide System for Patients with Foot Drop
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the Innovative Neurotronics WalkAide System for patients with foot drop. A randomized controlled trial comparing WalkAide to ankle-foot orthoses is underway. The only empirical study identified was a case study, reporting on one patient. The patient used a bionic nerve (BION) implant and a portable BIONic foot drop stimulator that the authors called a "WalkAide2". It is not clear whether this is the same technology as the Innovative Neurotronics WalkAide system.
Articles: There are no published randomized or non-randomized controlled studies. According to ClinicalTrials.gov and the Innovative Neurotronics website, an RCT is underway comparing the Innovative Neurotronics WalkAide System to an ankle-foot orthosis (AFO) in patients with cerebrovascular accident. No data from this study are available at this time.

The use of the WalkAide system in the treatment of foot drop does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

TENS--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0720	Transcutaneous electrical nerve stimulation (TENS) device, two-lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric)

External Upper Limb Tremor Stimulator Therapy (e.g., Cala Trio)
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare – Considered Not Medically Necessary- experimental, investigational or unproven

HCPC Codes	Description
A4542	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
E0734	External upper limb tremor stimulator of the peripheral nerves of the wrist

NMES/FES--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program

Back to Top

E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

Gastric Neurostimulation--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Other Electrical Stimulation--

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT/HCPC Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64580	Incision for implantation of neurostimulator electrode array; neuromuscular
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Peripheral Nerve Stimulator- i.e., StimRouter--

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare – Considered Not Medically Necessary *****All requests must be reviewed by the Medical Director*

 Back to Top

CPT® Codes	Description
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64575	Incision for implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)

Electrical Stimulation for the Treatment of Dysphagia
Galvanic Stimulation Device
H-wave Stimulation Device
Microcurrent Stimulation Device (MENS)
Percutaneous Neuromodulation Therapy (PNT) for Back Pain
Vertis PNT System
ReBuilder System Threshold Electrical Stimulation--

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

Pulsed Electrical Stimulation for Treatment of Osteoarthritis of the Knee--

Medicare: Considered Not Medically Necessary - experimental, investigational or unproven
Non-Medicare: Considered Not Medically Necessary

HCPC Codes	Description
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/30/1998	02/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 01/03/2012[MDCRPC], 08/07/2012[MDCRPC], 03/05/2013[MDCRPC], 04/02/2013[MDCRPC], 01/07/2014[MPC], 07/01/2014[MPC], 05/05/2015[MPC], 03/01/2016[MPC], 01/03/2017[MPC], 11/07/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC], 02/13/2024[MPC]	04/12/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
06/14/2016	Added NCD 160.7.1
06/02/2015	TENS: MPC approved recommendation of adopting the MCG hybrid criteria
09/28/2017	Added Gastric Neurostimulation codes
06/28/2018	Removed G0283
07/12/2018	Corrected the FES and NMES criteria

Back to Top

10/03/2018	Added LCD L37360 Peripheral Nerve Stimulator
06/24/2020	Added HCPC code C1823 (ESD)
09/01/2020	Removed HCPC codes A4570, C1823, E0766, E0769, G0281 and G0282. Removed CPT codes 63650, 63655, 63685, 64550, 64565, 95971, 95972, 95973, 95974, 95975, 95976, 95977, 95978 and 95979. Added HCPC code E0762. Removed Hypoglossal Nerve Stimulation indications – noted on *Sleep Apnea Treatments* criteria.
11/06/2023	Updated Medicare coverage links. Added L34821 transcutaenous Electrical Joint Stimulation Devices (TEJSD)
03/18/2024	Added new LCD External upper Limb Tremor Stimulation Therapy (L39591) (E.g., Cala Trio)
04/02/2024	MPC approved the to adopt the Medicare Local Coverage Determination L33802 for TENS units for commercial members; Requires a 60-day notice. Effective September 1, 2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Electromagnetic Navigation Bronchoscopy (ENB)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Electromagnetic Navigation Bronchoscopy (ENB)"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members4

Service	Criteria
Endobronchial Ultrasound	Kaiser Permanente has elected to use the Endobronchial Ultrasound (A-1049) MCG* Care Guideline for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under *Quick Access*.
Biopsy of peripheral lesions	When used with endobronchial ultrasound, electromagnetic navigation bronchoscopy is considered medically necessary.
Fiducial marker placement	via electromagnetic navigation bronchoscopy is not considered medically necessary, as there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Flexible bronchoscopy (FB) is a minimally invasive procedure that is used for the diagnosis and treatment of lung cancer. Research suggests that the sensitivity of FB is approximately 88% for diagnosing central lesions and 78% for diagnosing peripheral lesions (most commonly defined as lesions that are not visible beyond the visual

Back to Top

Date Sent: 4/29/24

segmental bronchi). However, the sensitivity of FB is dependent on lesion size. FB does not perform as well for smaller peripheral lesions. It has been estimated that for peripheral lesions less than 2 cm in diameter the sensitivity of FB is approximately 34% (Rivera 2007).

Electromagnetic navigation bronchoscopy (ENB) is a relatively new bronchoscopic tool that combines CT-generated virtual bronchoscopy and electromagnetic tracking of a steerable probe to allow physicians to perform biopsy of peripheral lesion that are not accessible through conventional bronchoscopy. It has also been suggested that mediastinal lymph nodes can be biopsied using ENB. Other uses of ENB include implantation of fiducial markers for radiotherapy, implantation of brachytherapy seeds or catheters, and dye marker placement for surgical resection.

Several ENB systems have received FDA approval. ENB using the superDimensions I Logic™ System (superDimensions, Inc. Minneapolis, MN) is performed in three phases – planning, registration, and navigation and biopsy (Bechara 2011, Schwartz 2010).

1. Planning: A three-dimensional image of the patient's lungs with anatomical landmarks is constructed using previously taken CT scans and proprietary software.
2. Registration: The steerable navigation catheter is inserted through the bronchoscope. The three-dimensional image with anatomical landmarks created in the planning phase is viewed and correlated with the actual image from the video bronchoscope. The position of each landmark is marked using a foot pedal.
3. Navigation and biopsy: The steerable catheter is used to navigate to the lesion. The location of the catheter's tip is displayed on the CT images. Once the catheter reaches the target, it is locked in place, and the working guide is retracted. Once the catheter is in place, any endoscopic tool can be inserted through the channel. This includes transbronchial forceps to biopsy the lesion or guide wire for the placement of fiducial markers.

Medical Technology Assessment Committee (MTAC)

Electromagnetic Navigation Bronchoscopy

08/20/2012: MTAC REVIEW

Evidence Conclusion: **Diagnostic yield** A recent RCT that included 118 subjects with evidence of peripheral lung lesions or solitary primary nodules on CT evaluated the diagnostic yield of endobronchial ultrasound (EBUS), electromagnetic navigation bronchoscopy (ENB), and combined EBUS/ENB. Results from this study suggest that combined EBUS/ENB improves diagnostic yield compared to either method alone. The pneumothorax rate was 5% in the EBUS and ENB alone groups and 8% in the combined group. There was no significant difference in pneumothorax rate between the three groups (Eberhardt 2007).

Diagnostic yield (Eberhardt 2007)		
EBUS	**ENB**	**Combined**
69%	59%	88%

A recent meta-analysis also evaluated the diagnostic yield of different guided bronchoscopy methods. Results from this meta-analysis suggest that the diagnostic yield of ENB is approximately 67%. Results from this meta-analysis should be interpreted with caution as the majority of the studies included in the meta-analysis were small case series (Wang Memoli 2012). Since the meta-analysis two additional case-series were identified. The first case-series included 112 subjects and evaluated the diagnostic yield of ENB combined with rapid on-site cytopathologic evaluation (ROSE). Overall, the diagnostic yield in this study was 84%. In lesions less than 2 cm, the diagnostic yield was 75.6% and 89.6% in lesions greater than 2 cm. There were two cases (1.8%) of pneumothorax (Lamprecht 2012). The second case-series included 101 subjects and also evaluated the diagnostic yield of ENB combined with ROSE. The diagnostic yield from this study was 85%. There were 6 cases (5.8%) of pneumothorax (Pearlstein 2012). **Fiducial marker placement** A small observational study evaluated the transcutaneous placement of fiducial markers using either CT or fluoroscopic guidance (N=15) or transbronchial placement using ENB (N=8) in patient with small, early-stage, non-small cell lung cancer. Pneumothorax occurred in 8 patients (53%) who underwent transcutaneous placement and no patients who underwent transbronchial placement. The fiducial markers did not show substantial migration during the course of treatment for either method (Kupelian 2007). Conclusion: Diagnostic yield: Results from a RCT, a meta-analysis of mainly small case-series, and two case-series suggests that the overall diagnostic yield of ENB is approximately 59 to 85%.
Safety: The pneumothorax rate in the studies ranged from 1.8 to 8%.

Back to Top

Fiducial marker placement: There is insufficient evidence to determine the safety and clinical utility of ENB for the placement of fiducial markers.

Articles: Several small observational studies, a randomized controlled trial (RCT), and a meta-analysis were identified that evaluated the use of ENB for diagnosing lung cancer. The meta-analysis and the RCT were selected for review. A few small observational studies were identified that evaluated fiducial marker placement using ENB. The number of patients receiving ENB for the placement ranged from 1 to 12. Due to the small sample size none of these studies were selected for review. A summary of the results from one of the more recent studies is presented below. The following articles were selected for review: Eberhardt R, Anantham D, Ernst A, Feller-Kopman D, Herth F. Multimodality bronchoscopic diagnosis of peripheral lung lesions: a randomized controlled trial. Am J Respir Crit Care Med. 2007;176:36-41. See Evidence Table. Wang Memoli JS, Nietert PJ, Silvestri GA. Meta-Analysis of Guided Bronchoscopy for the Evaluation of the Pulmonary Nodule. Chest. 2011. See Evidence Table.

The use of ENB for diagnosis does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of ENB for fiducial marker placement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Biopsy of peripheral lesions, Fiducial marker placement

CPT Codes	Description
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed, with computer-assisted, image-guided navigation (list separately in addition to code for primary procedure)
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s])

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Endobronchial Ultrasound

CPT Codes	Description
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to code for primary procedure[s])
C7512	Bronchoscopy, rigid or flexible, with single or multiple bronchial or endobronchial biopsy(ies), single or multiple sites, with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s), including fluoroscopic guidance when performed

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	09/05/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Back to Top

Revision History	Description
06/26/2020	Added “Kaiser Permanente Medical Policy” statement under Medicare section
02/06/2023	Added CPT code 31627 to criteria page
09/05/2023	MPC approved to adopt Endobronchial Ultrasound, MCG A-1049 for clinical coverage indications. Requires 60-day notice; effective February 1, 2024.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Superficial Radiation Therapy (Electronic Brachytherapy for Non-Melanoma Skin Cancer)

- "Xoft" Skin Treatments

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Noridian retired LCD Brachytherapy: Non-intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Nonmelanoma skin cancer (NMSC) is the most common malignancy in the Caucasian population and its incidence continues to rise. It is estimated that more than two million Americans are affected by NMSC each year. Basal cell carcinoma (BCC) represents approximately 75% of NMSCs and squamous cell carcinoma (SCC) 25%. These cancers have a low mortality rate and are rarely life threatening but can be disfiguring when not diagnosed and treated in a timely manner. They also have a significant impact on the health care delivery system (Alam 2011, Bhatnagar 2010 & 2013).

Date Sent: 4/29/24

Treatment options for NMSC include surgery, radiation therapy, chemotherapy, and photodynamic therapy. Surgery is considered the gold standard therapy; it provides the highest cure rates and has satisfactory cosmetic results. Surgical techniques include excision, curettage with electrodessication, and Mohs micrographic surgery. The choice of procedure depends on the histologic type, size, and location of the lesion. Some patients, however, are not suitable candidates for surgery because of their age, health condition, or potential disfigurement due to the location or type of cancer. Radiation therapy has been used for selected skin cancers, typically reserved as a second-line therapy for patients with surgical contraindications or as adjuvant therapy for high-risk lesions. It may also be a good alternative to surgery for lesions located in areas where surgery may be more difficult, lead to disfigurement, or affect structural function e.g. eyelid, ear, or nose. Radiation therapy techniques used for NMSC include superficial x-rays, orthovoltage x-rays and megavoltage photons, electron beam irradiation, and high-dose rate (HDR) brachytherapy with surface applicators or surface molds. HDR brachytherapy works via a precise, radioactive seed that delivers high dose radiation within specialized catheters to a targeted area within a shielded room. It is also commonly used for breast, lung, prostate and gynecologic cancers (Bhatnagar 2010 & 2013, Frakulli 2015, Linos 2015, Safigholi 2015).

Electronic brachytherapy (EBT) is a form of HDR brachytherapy that brings an electronic brachytherapy source in close proximity to the cancerous site. EBT has the potential benefit of providing shorter and more convenient form of radiotherapy without the use of radioactive isotopes, linear accelerators, or dedicated treatment vault, and with minimal shielding requirements due to the low energy used. Currently there are three different EBT systems available for clinical application: Axxent by Xoft Inc. (Fremont, CA), the Intrabeam Photon Radiosurgery Device by Carl Zeiss Surgical (Oberkochen, Germany), and the Esteya by Elekta (Esteya EBS, Elekta AB-Nucletron, Stockholm, Sweden). The main component in these systems is a miniature X-ray tube that produces bremsstrahlung (electromagnetic) radiation using electron energies ranging from 20-70keV. Treatment of skin cancers by these systems is performed using conical applicators developed by the manufacturers and provided in different sizes (1cm, 2 cm, 3.5 cm, and 5 cm) Bhatnagar 2013, Safigholi 2015).

Medical Technology Assessment Committee (MTAC)

Electronic Brachytherapy for Non-Melanoma Skin Cancer

04/21/2014: MTAC REVIEW

Evidence Conclusion: The published study on EBT for the treatment of NMSC that was identified by the literature search was a small case series with no control or comparison group (evidence table 1). A total of 122 patients with 171 NMSC lesions (from July 2009 to April 2012) received EBT to a dose of 40 Gy in eight fractions, delivered twice weekly. Patients were assessed for acute and late toxicities, cosmesis, and local control. In 2010 Bhatnagar and Loper retrospectively reported on the short-term (median 4.1 months) results of 37 patients (44 lesions); and in 2013, Bhatnagar published the outcomes of 42 patients (46 lesions) with one or more-year follow-up data. The author reported that all lesions resolved with treatment, with no recurrences. The early side effects of the therapy were rash dermatitis (83% of the lesions) and pruritus (18%). Late adverse events included grade 1 hypopigmentation in 10% of the lesions, rash dermatitis (6.5%), as well as alopecia, and dry desquamation that occurred at lower rates (2.2%) each. One-year cosmetic evaluation was performed for 42 of the 46 lesions; 39 (92.9%) were graded as excellent, and 3/42 (7.1%) were good. Two-year outcome data for 22 lesions in 21 patients (Bhatnagar 2012) showed that cosmesis was excellent for 20 evaluable lesions, and good for 1.
Based on these results the authors concluded that EBT provides a convenient nonsurgical option for NMSC patients. The study was a case series with its limitations and potential biases. EBT was not compared any other surgical procedure or radiation therapy; it had a short follow-up duration, and the authors did not discuss how patients were selected for the procedure, and whether there were any dropouts.
Bhatnagar A, the principal investigator of the study received a research grant from the industry sponsoring the study. Conclusion: There is insufficient published evidence to determine the safety and efficacy of EBT for the treatment of NMSC. There is an ongoing clinical trial “Electronic Brachytherapy for the Treatment of NMSC” (NLM Identifier NCT01016899) with the objective of recording the recurrence in patients treated for nonmelanoma (basal cell and squamous cell carcinomas) skin cancer using the Xoft Axxent Electronic Brachytherapy System. The trial will also evaluate the cosmetic outcomes and skin toxicities related to the treatment.
Articles: The literature search for EBT for the treatment of NMSC identified only one study on the use of electronic brachytherapy for the treatment of NMSC. The initial results were reported in 2010 (Bhatnagar A, and Loper A, 2010) and 1-year results were published in 2013 (Bhatnagar A 2013). Bhatnagar A. Nonmelanoma skin cancer treated with electronic brachytherapy: results at 1 year. Brachytherapy. 2013; 12(2):134-140. See **Evidence Table.** Bhatnagar A, Loper A. The initial experience of electronic brachytherapy for the treatment of non-melanoma skin cancer. Radiat Oncol. 2010; 5:87. doi: 10.1186/1748-717X-5-87 See **Evidence Table.**

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/21/2016: MTAC REVIEW
Electronic Brachytherapy (EBT) for the treatment of non-melanoma skin cancer (NMSC)
Evidence Conclusion: There is insufficient published evidence to determine whether the safety and efficacy outcomes of electronic brachytherapy for NMSC are as good or superior to the outcomes of alternative treatment options. There are no published randomized or non-randomized controlled trials that compared EBT to an alternative therapy for the treatment of NMSC. The available published evidence consists of case series that used different systems for the delivery of HDR. The largest series (Bhatnagar 2010 & 2013) that used one of the three commercially available devices (the Axxent system, Xoft Inc. Sunnyvale, CA) was reviewed by MTAC earlier in 2014, and did not provide sufficient evidence on the long-term efficacy or safety of the procedure.
The more recent case series identified by the search were small retrospective series with no comparison groups, and do not provide additional evidence to support the use of EBT for NMSC. In a recently published article, Linos and colleagues (2015), expressed their concern regarding the increase in the use of EBT for skin cancer. The authors analyzed Medicare claims data and found that EBT use for skin cancer is increasing rapidly in the Medicare population. They indicated this may be attributable to marketing by the manufacturers, and that there is insufficient long-term data on the efficacy and safety of the therapy to cover the period during which recurrence and radiation sequelae would be expected (Linos, 2015).
Articles: The updated literature search for the use of electronic brachytherapy in the treatment of NMSC did not identify any controlled trial that compared the therapy with an alternative mode of treatment. The search only identified a number of small retrospective case series and a systematic review of the observational studies reporting on the outcomes of low-dose or high-dose brachytherapy used for the treatment of NMSC of the eyelid (Frakulli 2015).

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Per NCCN Guidelines Version 1.2017 Basal Cell Skin Cancer. P. 11
“There is insufficient long-term efficacy and safety data to support the routine use of electronic surface brachytherapy.”

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Superficial Radiation Therapy for Treatment of Nonmelanoma Skin Cancer. Lansdale, PA: Hayes, Inc.; 3/2018

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/06/2014	05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC],	08/04/2020

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

	08/07/2023[MPC], 04/02/2024[MPC]	

[MPC] Medical Policy Committee

Revision History	Description of Change
04/05/2016	Added MTAC review
04/25/2017	Added NCCN Guideline
04/17/2018	Added Hayes Guideline
08/04/2020	Removed deactivated CPT code 0182Tand CPT code 77401

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Electroretinography

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Electroretinography"*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this test provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Liutkevičienė et al., 2012:
During electroretinography (ERG), a total retinal response to light stimulus is recorded. ERG is comprised by a and b-waves which are generated by the outer segments of photoreceptors and Muller cells respectively. B-wave represents activities in the inner retinal layers. Several stimulations and registration techniques help record potentials of various retinal structures: early receptor potential, ERP; standard electroretinogram of full field by ISCEV (International Society for Clinical Electrophysiology of Vision); photopic negative response, PhNR; pattern (alternating contrast) ERG, pERG; multifocal ERG (mfERG).

Dettoraki et al., 2016:
Multifocal electroretinography (mfERG)
Multifocal electroretinography (mfERG) is an objective evaluation of visual function. It is noninvasive and assesses retinal diseases. During mfERG, several areas of the retina are stimulated but each response is recorded independently. mfERG measures the electrophysiological activity of the retina. Under the influence of light, retinal responses are recorded, permitting diagnosis of retinal abnormality.

Back to Top

The stimulation of the retina is done by hexagonal elements alternating between black and white. Similar to full-field ERG, a corneal electrode records electrical response of the retina which consists of waveforms. The waveforms include three responses: an initial negative response (N1), a positive response (P1) and a second negative response (N2). These responses represent the function of the external layer of the retina (photoreceptors and bipolar cells). The location of the stimulus and anatomical areas correspond to the fovea, parafovea, perifovea, and periphery. mfERG can show the amplitudes of the signal.

Many factors can alter the waveforms. These include unstable electrode contact, poor fixation, continuous blinking, and errors in refraction.

mfERG detects abnormalities of the macula, peri-macular area and the mid peripheral zone of the retina which are not always seen on fundoscopy, such as chloroquine (CQ) or hydroxychloroquine (HCQ) toxicity, siderosis, anorexia nervosa, tilted disk syndrome and keratoconus. mfERG can assess drug- induced retinal toxicity. In addition, mfERG can detect central lesion in all macular diseases (age-related macular degeneration, central serous chorioretinopathy, vitelliform maculopathy, macular hole, juvenile retinoschisis and other diseases). Further, mfERG can estimate the degree of central lesion in early stages of Stargardt's maculopathy and toxic maculopathy. The combination of mfERG and visual evoked potentials (VEPs) is beneficial in the differential diagnosis of retinal and optic nerve diseases.

Another type of mfERG is wide-field (WF)-mfERG that targets peripheral areas of the retina. The testing field of WF-mfERG is 90 degree versus 45 degree for conventional mfERG. WF-mfERG is useful in detecting abnormality of retina in retinitis pigmentosa, retinal vein occlusion, birdshot chorioretinitis and vigabatrin toxicity.

Retinal toxicity
Although not frequent, drug-induced ocular toxicity must be detected early to avoid permanent vision loss. There are several medications that can cause ocular toxicity. The most frequent affecting the retina include chloroquine (CQ) and hydroxychloroquine (HCQ), vigabatrin (VGB), deferoxamine, ethambutol, interferon-α, tamoxifen, digoxin, sildenafil, canthaxanthin, amiodarone and nefazodone. Evaluation of retinal toxicity is founded on medical history and ophthalmic examination. However, other investigations including mfERG, optical coherence tomography (OCT), fundus autofluorescence (FAF), perimetry, and fundus angiography are also valuable. The sensitivity and specificity of these tests are not clear. Symptoms of CQ or HCQ retinopathy include blurred vision, photophobia, scotomas, and difficulty reading. The fundus is described as "bull's eye maculopathy".

Whatham 2013:
Full-field ERG stimulates the central and peripheral visual fields with flashlight. Pupils are dilated and response to the stimulation is assessed under dark-adapted and light-adapted conditions. The International Society for Clinical Electrophysiology of Vision (ISCEV) recommends a minimum of 20 minutes dark adaptation to produce a dark adapted (scotopic) state of sensitivity and a minimum of 10 minutes adaptation to a background luminance of 30 cd/m2 to produce a light-adapted (photopic) state of visual sensitivity. Full-filled ERG detects a range of retinal dysfunction, such as rod-cone dystrophy. Full- field ERGs are normal in focal retinal diseases including age-related macular degeneration and Stargardt's disease.

https://eyewiki.org/Electroretinogram:
The pattern ERG (PERG) uses the same stimuli, pattern-reversal stimuli, that is used in visual evoked potential (VEP). PERG records retinal ganglion cell activity and may detect optic neuropathies.
One difference between full-field ERG and mfERG is that in full-field ERG, the recording is a massed potential from the whole retina. Multifocal ERGs can map small scotomas in the central 40+ degrees of visual field (Creel, 2019). Full-field ERGs are used to record the global health of the retina, such as in retinitis pigmentosa (Creel, 2019).

Medical Technology Assessment Committee (MTAC)

Electroretinography (ERG)
7/13/2020: MTAC REVIEW
Evidence Conclusion:
HCQ-induced retinopathy: A systematic review and meta-analysis of studies with high risk of bias shows that mfERG has a high sensitivity and variable specificity. In addition, accuracy of mfERG improves with older age, increased HCQ dose, and longer duration of treatment. mfERG may detect retinal toxicity earlier than other tests.

Back to Top

Metallic foreign bodies: There is insufficient evidence to assess ERG and retinal toxicity from metallic foreign bodies. The literature is comprised of case reports and case series. However, the trend from available evidence shows that ERG detected abnormalities in patients with intraocular metallic foreign bodies prior to surgery with improvement after removal of the foreign bodies.
Retinitis pigmentosa: Several studies show decreased amplitude of ERG and delayed implicit time in patients with retinitis pigmentosa. This suggests that ERG detects abnormalities in this population. Clinical validity was not reported and comparison with electro-oculogram or visual evoked potential (VEP) was rare. However, there is correlation between mfERG and corresponding mfVEP. Further, ERG may be useful in allowing long-term follow-up of disease progression in retinitis pigmentosa. mfERG may add to the diagnostic information of several patients with retinitis pigmentosa. ERG may distinguish between HCQ-induced retinal toxicity and retinitis pigmentosa. The evidence is comprised of case series and case reports with small sample sizes.
Cone-Rod dystrophy: Studies assessing clinical validity were not identified. The evidence is comprised of case reports or case series or retrospective study showing that ERG may detect cone-rode dystrophy and be useful to monitor disease progression.
Leber's congenital amaurosis, congenital stationary night blindness, achromatopsia: The evidence is insufficient to assess the accuracy of ERG in these diseases.

Articles: See Evidence Table

The use of Electroretinography (ERG) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary- experimental, investigational or unproven:

CPT® Codes	Description
92273	Electroretinography (ERG), with interpretation and report; full field (ie, ffERG, flash ERG, Ganzfeld ERG)
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)
0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
09/01/2020	09/01/2020 MPC, 09/07/2021 MPC, 09/06/2022MPC , 09/05/2023MPC , 03/12/2024MPC	09/01/2020

MPC Medical Policy Committee

Revision History	Description
09/01/2020	MPC approved to endorse a non-coverage policy for electroretinography. Requires 60-day notice, effective date 02/01/2021.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Enteral Formula

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Enteral Nutrition (L38955)
Local Coverage Articles	Enteral Nutrition (A58833)

For Non-Medicare Members

The criteria are for formulas only. The pumps and associated equipment are considered durable medical equipment and are covered as part of the durable medical equipment benefit.

Elemental formulas are composed of amino acids, fats, sugars, vitamins, and minerals and lack whole or partial protein. An example of an elemental formula is Vivonex. Most formulas are not elemental as they contain complete proteins and complex carbohydrates, examples of which are Ensure or ProSobee.

To qualify for enteral nutritional formula, elemental formula (either replacement or supplemental) or non-elemental formula, the member must meet **ONE of the following**, either I, II,III or IV:

I. To qualify for Nutritional Replacement Therapy, using an *elemental* formula, members must meet **ONE of the following:**
   A. Members must have at least **ONE of the following** diagnoses:
      1. Crohn's Disease
      2. Inflammatory Bowel Disease
      3. Short Bowel Syndrome
      4. Eosinophilic gastrointestinal associated disorders
   B. The member must also meet **ALL of the following**:
      1. Formula is intended for home use
      2. The member is managed by a Gastroenterologist
      3. The member has been evaluated and will be followed by a Registered Dietitian
      4. Elemental total nutritional replacement represents 80 - 100% of diet or 80% or greater of the daily dietary requirements
      5. Alternative approaches, other than use of an elemental formula, have not resulted in adequate nutrition and control of symptoms.
      6. Member must meet **ALL of the following:**
         a. Able to tolerate oral supplementation
         b. If unable to tolerate oral supplementation, member must meet **ALL of the following**:
            - The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.
            - The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.

Back to Top

Date Sent: 4/29/24

II. To qualify for Nutritional Supplementation Therapy using an *elemental* formula, members must meet **All of the following:**
   A. Members must have at least **ONE of the following** diagnoses:
      1. Crohn's Disease
      2. Inflammatory Bowel Disease
      3. Short Bowel Syndrome
      4. Cystic Fibrosis involving the intestine
      5. Eosinophilic gastrointestinal associated disorders
   B. Members must also meet **ALL of the following**:
      1. Intended for home use
      2. Growth failure/retardation or cachexia has been documented
      3. The member is managed by a Gastroenterologist
      4. The member has been evaluated and will be followed by a Registered Dietitian
      5. Other therapies, such as medication, have not resulted in adequate nutrition/weight gain
   C. Member must meet **ONE of the following:**
      1. Able to tolerate oral supplementation
      2. If unable to tolerate oral supplementation, member must meet **ALL of the following**:
         a. The member or caregiver must demonstrate the ability to place a nasogastric tube or manage a surgically placed feeding tube.
         b. The member or caregiver must also be able to demonstrate the ability to regulate flow either via gravity drip or pump.

III. Oral nutrition or supplements using *non-elemental* formula may be considered medically necessary when used for the treatment of inborn errors of metabolism. Member must meet **ALL of the following**:
   A. Must have **ONE of the following** diagnosis:
      1. Phenylketonuria [PKU]
      2. Maple syrup urine disease (MSUD)
      3. Homocystinuria,
      4. Histidinemia
      5. Tyrosinemia
      6. Glycogen Storage Type II Syndrome (GSD II or Pompe disease)
   B. Formula is intended for home use (not for use in the hospital or nursing facility)

IV. *Non-elemental formula* is covered for members who require tube feeding under the following conditions:
   a) Non-function or disease of the structures that normally permit food to reach the small bowel. The condition could either be anatomic (obstruction due to head and neck cancer, reconstructive surgery, etc.) or a motility disorder (e.g., severe dysphagia following a stroke, congenital defects, etc.) **AND**
   b) Requires tube feeding to maintain weight and strength commensurate with the patient's overall health status **AND**
   c) The patient's condition is anticipated to be long term in duration, typically at least 3 months (90 days).

*Elemental formula can be delivered by tube only if indications in I or II above are met

The following are not covered:
- Intra-peritoneal nutrition is considered experimental and investigational.

*Diagnosis Codes that are covered for Eosinophilic Gastrointestinal Associated Diseases
ICD-10
K20.0 Eosinophilic esophagitis
K52.81 Eosinophilic gastritis or gastroenteritis
K52.82 Eosinophilic colitis

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist (PCP, GI specialist)
- Last 6 months of radiology notes if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations..

Background

Until 1996, the only Kaiser Permanente plans that had coverage for enteral therapy were the Medicare plans. In 1996 an appeals case caused Kaiser Permanente to reevaluate the potential inclusion of enteral therapy for all groups. The reevaluation, which included a special work group and the Benefits Committee, concluded that the use of elemental enteral therapy for ineffective GI absorption that represented a major portion of the consumer's calorie intake, should be covered up to the level of replacement of regular cost of food (80% of charges).

This coverage was to be added in 1997 to all plans under dietary formula where enteral nutrition therapy benefit is not in place. Since only subsets of specific consumers are eligible for this coverage, criteria were developed for consistent review of requests.

In 1998, Kaiser Permanente received a request to consider coverage for Glycogen Storage Type II Syndrome supplemental formula. After review of the case and literature, the decision was made to add the disease to the criteria for coverage.

In July 1998 Kaiser Permanente received an update of the Healthy Options criteria for coverage of enteral feedings. In October 2005 the MMA program updated the coverage criteria that are applicable to Healthy Options. Kaiser Permanente criteria were adjusted to reflect the new changes.

Evidence and Source Documents

03/1998

Articles: Definitions: Inflammatory Bowel Disease includes Crohn's Disease of small intestine or colon, Ulcerative Colitis, and overlap syndromes (Non-Specific IBD, Segmental Colitis) An Elemental Diet contains oligo-peptides as the major protein source. Vivonex (lower fat- 2.5%) and Vital HN (higher fat- 8%) are typical elemental diets. Non-elemental diets contain intact proteins from a defined source (such as milk protein, meat or egg)

Growth Retardation/ Failure requires: A pediatric patient (defined as age<18 years, and epiphyses not fused on radiography) and a height per age <5th percentile, or a decrease in growth velocity of >= 2cm/year, or bone age> 2 SD below chronologic age Nutritional Replacement Therapy requires >90% (and preferable 100%) of the caloric intake be provided by the elemental formula Nutritional Supplementation Therapy requires that >50% of the caloric intake is provided by the elemental formula. The use of elemental enteral nutrition in inflammatory bowel disease has progressed from strictly nutritional to therapeutic. Although the mechanism is not fully understood, disease activity and intestinal permeability decrease in patients "fed" with elemental diets, as compared to regular diet or TPN. The therapeutic role is best documented in the management of Crohn's Disease [especially of the small intestine]. The role of this therapy in Ulcerative Pancolitis, Ulcerative Colitis limited to the left colon, nonspecific IBD, and Segmental Colitis is not supported by these data. Nutritional Therapy (whether Replacement or Supplement) is used only in conjunction with other drug therapy (including 5-ASA compounds, corticosteroids, immunosuppressives and antibiotics) not in lieu of these other therapies. The consideration of surgery as primary therapy must be considered in patients with significant strictures complicating nutrition.

References:

Griffiths et al "Meta-analysis of Enteral Nutrition as a Primary Treatment of Active Crohn's Disease" Gastro 108, 1995

Meta-analysis of enteral nutrition vs. steroids as primary therapy; findings were that steroids were more effective. Also compared composition of diets and found no clear data [not significant power] supporting elemental over polymeric.

Teahon et al "Alterations in Nutritional Status and Disease Activity during Treatment of Crohn's Disease with Elemental Diet" Scand J Gastro 30, 1995

Replacement of diet with Vivonex or similar for 5-week period, 1850-3700 kcal/d. Required significant malnutrition at entry into study. Improvement in inflammatory activity preceded nutritional improvement in most cases.

Fernandez-Banares et al "How Effective is Enteral Nutrition in Inducing Clinical Remission in Active Crohn's Disease? A meta-analysis of the Randomized Clinical Trials" JPEN 19, 1995

Applicable Codes

Back to Top

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Elemental formula

HCPC Codes	Description
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Formula for inborn errors of metabolism

HCPC Codes	Description
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Non-elemental formula

HCPC Codes	Description
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

Other specialized formulas

Not routinely covered; the medical record must document why the specific formula is medically necessary

***Not covered by Medicare**

HCPC Codes	Description
B4102*	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103*	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit *(i.e., diabetic, renal, post-surgical, ketogenic)*
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit

Back to Top

Date Sent: 4/29/24

	*almost always taken with another formula unless eating orally and requiring one specific nutrient

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
7/11/1984	1/5/2010 MDCRPC, 11/2/2010 MDCRPC, 9/6/2011MDCRPC, 7/3/2012MDCRPC, 5/07/2013MDCRPC,2/04/2014 MPC, 12/02/2014 MPC, 10/06/2015MPC, 08/02/2016MPC, 06/06/2017MPC, 04/03/2018MPC, 04/02/2019MPC, 04/07/2020MPC, 04/06/2021MPC, 04/05/2022MPC, 04/04/2023MPC, 01/09/2024MPC	11/13/2023

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
8/31/2016	Added LCD for Enteral Therapy
12/06/2016	Added Intraperitoneal Nutrition (IPN) to the non-covered list
05/31/2018	Removed the Microsoft link
03/02/2021	MPC approved to amend the current criteria to include indications for non-elemental formula for patients receiving nutrition via tube feeding. Requires 60-day notice, effective date 08/01/2021.
08/13/2021	Added clarifying timeframe to define long term in IV.c. as typically at least 3 months (90 days).
7/28/2023	Updated Medicare policy article link (A58833)
11/13/2023	Updated Medicare LCD link Enteral Nutrition (L38955) and policy article link (A58833).

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
EOS imaging system in children and adolescents with scoliosis

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "EOS imaging system in children and adolescents with scoliosis"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Scoliosis

Scoliosis is a deformity of the spine that affects 2 to 4% of adolescents (Reamy & Slakey, 2001; Roach, 1999; Smith, Sciubba, & Samdani, 2008) and can result in cardiopulmonary compromise. It is defined as a lateral curvature of the spine more than 10 degrees with vertebral rotation (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008). Males and females are affected equally but evolution of the curve is more frequent in females than males (Miller, 1999). It can be classified as neuromuscular, congenital, or idiopathic which is the most common form of scoliosis (Reamy & Slakey, 2001; Smith, Sciubba, & Samdani, 2008). Idiopathic scoliosis can be categorized as infantile (0 to 3 years), juvenile (4 to 9 years), and adolescent (≥ 10 years); the most common form of idiopathic scoliosis is adolescent idiopathic sclerosis (Reamy & Slakey, 2001; Roach, 1999; Smith et al., 2008).

Scoliosis requires frequent radiographic examination to assess the curve, identify underlying etiology, and help in treatment decision (Yvert et al., 2015). Standard imaging technologies including x-ray film, computed radiography (CR) and digital radiography (DR) have been used for diagnosis and monitoring. Nevertheless, there is growing concern on radiation-based harm on the long-term among children who undergo repeated x-rays (Bone & Hsieh,

Back to Top

2000; Doody et al., 2000). New imaging system, EOS, has been the center of attention with the promise of reducing radiation dose and ensuring higher quality image.

EOS imaging system (From https://www.eos-imaging.com/us/professionals/eos/eos and Wade et al., 2013; McKenna et al., 2012)
EOS is an X-ray imaging that utilizes slot-scanning technology and is manufactured by EOS imaging (formerly Biospace Med, Paris, France) (Wade et al., 2013). It is a bi-planar technology that is based on two perpendicular fan beams of X-rays and proprietary detectors that travel vertically while scanning the patient. EOS can take posteroanterior (PA) and lateral images concurrently. EOS generates three-dimension images and assessment of individual vertebral rotation can be done. It generates, not only, 2D images similar to conventional imaging techniques, but also produces 3D images that are reconstructed through sterEOS software using the posteroanterior and lateral images, and a 3D statistical spine model. It also permits the rotation of a scoliotic curve with accuracy. EOS system provides low dose stereo-radiographic images. Micro dose option for pediatric follow up exams provides lesser radiation exposure. It is believed that the quality of image is high and therefore improves diagnostics.

EOS is indicated in conditions where frequent x-rays can cause harm due to radiation effect. These diseases include scoliosis (Gummerson & Millner, 2010), the main indication, sagittal deformities (kyphosis), and lower limbs deformities.

EOS is performed while the patient is in an upright, weight-bearing (standing, seated or squatting) position, and can take the entire body or a segment. The physician may choose the adequate position for the exam on the EOS radiolucent chair. The patient stays inside the EOS booth, and then an x-ray of the whole body is taken in less than 20 seconds for an adult and less than 15 seconds for a child. It is believed that EOS eliminates the need for multiple images.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

EOS imaging system in children and adolescents with scoliosis

Evidence Conclusion:

EOS accuracy

There is a lack of studies comparing the accuracy of EOS to that of standard imaging techniques.

Reproducibility & reliability of EOS 3D spine reconstruction

Rehm et al., 2017

A retrospective study (Rehm et al., 2017) evaluated the inter reader reproducibility and reliability of EOS imaging full spine reconstruction in patients with adolescent idiopathic scoliosis (AIS).
Seventy-three consecutive patients (31 men, 42 women) with moderate AIS (mean Cobb angle was 18.2° (range, 9.8°-49.9°)) had their whole spine examined with EOS imaging (AP and lateral). Mean age was 17 years (range 9-58 years). Two readers performed 3D reconstructions of the spine with sterEOS software.
Findings:

- Radiation exposure: Mean of total absorbed dose was 593.4 µGy ± 212.3
- Mean scan-time: Mean scan-time was 9.5 seconds ±1.7
- Reconstruction time: varied significantly between the readers (14.6 min vs 15.2mn P<0.0001)
- Inter-reader reproducibility and reliability of every single vertebra rotation from T1-L5: was good to very good for frontal and lateral rotation measurement but limited for axial rotation.
- Interclass correlation (ICC) was > 0.80 for all vertebral rotations but for axial rotation it was between 0.51 to 0.88. ICC was ≥0.85 for kyphosis, lordosis, pelvic incidence, sacral slope, pelvic tilt.

Main limitations: Results were limited to patients with moderate scoliosis (mean Cobb angle was 18.2° (range, 9.8°-49.9°)); the study design was retrospective with inherent bias of observational study.
Conclusion: 3D reconstruction of the spine with EOS imaging was reproducible and reliable. Inter-reader reproducibility and reliability of every single vertebra rotation was good but limited for the axial rotation.

Vidal et al., 2013

A reproducibility study (Vidal, Ilharreborde, Azoulay, Sebag, & Mazda, 2013) assessed the reliability of radiographic measurement in adolescent idiopathic scoliosis using EOS system. Seventy-five patients were recruited. Mean age was 12 years, patients had Lenke type 1 or 2 AIS; patients were divided in three groups: AIS group, operated AIS, and control. The authors reported great intra and interobserver reliability in sagittal curvatures, pelvic variables and global sagittal balance. Correlation coefficient was at least 0.85 for each

Back to Top

examiner and among the examiners. The main limitation was the lack of comparison with conventional radiographs.

Ilharreborde et al., 2016 (EOS micro dose protocol for the radiological follow-up of adolescent idiopathic scoliosis) A prospective study evaluated the reliability of EOS x-ray micro dose protocol. The authors included 32 patients who were followed for AIS. All patients underwent EOS x-ray with micro dose protocol and 3D reconstructions were performed. Intrarater and interrater reproducibility were assessed. The authors reported that intraoperator repeatability was better than inter-operator reproducibility for all clinical measurements. Interclass correlation (ICC) was >0.91 for all parameters.

Effectiveness – Radiation dose, image quality, patient health outcomes

EOS vs x-ray film or computed radiography

Wade et al., 2013

A systematic review (Wade et al., 2013) assessed the clinical effectiveness of EOS imaging system in children with scoliosis and other orthopedic conditions. A total of three observational studies were included. Inclusion criteria encompassed studies that compared EOS with X-ray film, computed radiography or digital radiography in patients with any orthopedic condition. Studies that reported any outcome were also included. Primary outcome was patient health outcomes; and secondary outcomes were radiation dose and quality of image. The risk of bias of individual studies was overall high.

Study characteristics included: sample size varied from 49 to 140 patients; patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis or for follow-up; mean age was 14.7 – 14.8 years (SD 4.8); comparison was done between EOS/earlier version with x-ray film in two studies and with computed radiograph (CR) in one study.

Outcomes:

Patient health outcomes: were not reported
Image quality: comparable or better with EOS; no significance was reported
Radiation dose: was lower with EOS for all comparators (please refer to table below)

Radiation dose results	Mean ESD (mGy); EOS vs film; (Kalifa et al., 1998)	Mean ESD (mGy) second study; EOS vs film	Mean ESD (mGy); EOS vs CR; (Deschenes et al., 2010)
Spine PA	EOS 0.07, film 0.92	EOS 0.23, film 1.2	
Spine lateral	EOS 0.13, film 1.96	EOS 0.37, film 2.3	
Spine AP	EOS 0.08, film 0.93		
Pelvis	EOS 0.06, film 1.13		
Centre of back			EOS 0.18, CR 1.04
Proximal lateral point			EOS 0.27, CR 2.38
Outer side of proximal breast			EOS 0.11, CR 0.83
Proximal anterosuperior iliac spine			EOS 0.16, CR 1.47
Proximal iliac crest			EOS 0.30, CR 2.47
Distal iliac crest			EOS 0.11, CR 0.73
Nape of neck			EOS 0.20, CR 0.59

CR, Computed Radiography; ESD, Entrance Surface Dose;

Conclusion: there was limited data on the clinical effectiveness of EOS. EOS imaging appeared to be comparable or better than x-ray film or computed radiography in children with scoliosis in term of image quality. In addition, radiation dose appeared to be lower for EOS than x-ray or computed radiography. Also, there was no suggestion that the use of EOS enhanced management of scoliosis (from the nature and quality of the image). The long-term benefits from low dose of radiation were also unknown.

Quality assessment: the overall risk of bias was high; due to study design, risk of bias, and precision issues, the quality of evidence from the systematic review was considered low. Eight criteria of AMSTAR were met.

McKenna et al., 2012

This systematic review (McKenna et al., 2012) included the same studies already analyzed in the above systematic review (Wade et al., 2013). Therefore, the conclusion is the same.

Dietrich et al., 2013

Back to Top

A study (Dietrich, Pfirrmann, Schwab, Pankalla, & Buck, 2013) aimed at comparing the radiation dose, workflow, patient comfort of EOS x-ray system and digital radiography. Data of forty-seven consecutive AP and lateral spine radiographs of standard digital radiography were compared to 134 AP and lateral spine radiographs using EOS x-ray system. Outcomes are presented in the following table:

	DR (Digital Radiograph)	EOS x-ray	P-value
DAP (Dose Area Product)	392.2±231.7 cGy*cm2	158.4±103.8 cGy*cm2	**P<0.001**
Mean examination time	449 ±122 s	248 ±77 s	**P<0.001**
Patients' comfort (noise during examination)	1.4	1.8	**P<0.01**

Table show results for spine radiographs

Limitations: Limitation included: dose area product (DAP) measurement is not the most accurate technique for measuring radiation dose; bias due to baseline confounding, bias in selection of participants into study and measurement bias were not clear; bias due to departures from intended interventions was low; missing data bias and bias in selection of the reported result were low.
Conclusion: Compared to digital radiograph, EOS x-ray system reduces radiation dose and increases noise during examination.

Yvert et al., 2015

A prospective study (see evidence table 1) reported that EOS x-ray may have better or similar image quality than digital radiography with a dynamic flat detector. In addition, no significant difference was reported between the two systems in term of radiation dose.

Hirsch et al., 2016

A prospective study (Hirsch, Ilharreborde, & Mazda, 2016) of 50 patients compared the irradiation dose and reducibility of the cobb angle on bending EOS x-ray and standard x-ray.
Irradiation dose: was five times lower with EOS bending imaging than standard bending x-ray.
Reducibility of Cobb angle: No significant difference was reported.
Patients in this study underwent preoperative assessment for AIS; this included standing AP and lateral EOS x-rays of the spine, standard side-bending x-rays in the supine position, and standing bending x-rays in the EOS booth.
Limitations across studies included study design, sample size, selected outcomes, high risk of bias; literature lacks evidence for clinical outcomes.

Conclusion:

- **Accuracy**
  - There is lack of studies on the test accuracy
- **Reproducibility & reliability of 3D spine reconstruction:**
  - Three observational (one retrospective, two prospective studies) studies were reviewed
  - The studies focused on reliability of spine reconstruction in patients with adolescent idiopathic scoliosis (AIS) using EOS system
  - High inter-reader reproducibility and reliability was reported for all clinical measurements including sagittal curvatures, pelvic variables and global sagittal balance
  - The main limitations resided in the study design and the small sample size
- **Effectiveness – radiation dose, image quality, patient health outcomes**
  - One systematic review and three observational studies were reviewed
  - Radiation dose and image quality were evaluated
  - Comparison was made between EOS x-ray and computed radiography or x-ray film
  - Patients were children and adolescents undergoing follow-up for scoliosis or required spine radiographs for the diagnosis of scoliosis
  - Radiation dose was lower with EOS x-ray than the comparators
  - Image quality was comparable or better with EOS
  - Patient health outcomes: lack of data preclude conclusion on patient health outcomes
  - Data on the association of dose reduction and cancer occurrence were insufficient
  - There was no suggestion that the use of EOS enhances management of scoliosis
- **Evidence**: Overall, evidence is low

Back to Top

- Compared to conventional techniques, EOS system has better or similar image quality and reduces radiation dose. However, the impact of this benefits is not clear.

The use of EOS imaging system in children and adolescents with scoliosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC	08/07/2018

MPC Medical Policy Committee

Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Epidural Steroid Injections

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Epidural Steroid Injections for Pain Management (L39242)
Local Coverage Article (LCA)	Billing and Coding: Epidural Steroid Injections for Pain Management (A58995)

For Non-Medicare Members

MPC approved to adopt the proposed revisions to the existing ESI criteria to include acknowledge the importance of conservative therapy. Changes include the following:

Epidural Steroid Injections (Interlaminar, Caudal, or Transforaminal)

Initial Epidural Steroid Injections (ESI)

Initial Epidural Steroid Injections (ESI) are proven and medically necessary when **ALL of the following** criteria are met:

- One of the five indications below:
  - **Suspected Lumbar Radiculopathy defined as:**
    - Lower extremity pain is > or equal to back pain present in nerve root distribution (e.g., L5, S1, etc.) **PLUS, ONE or MORE**:
      - Positive supine straight leg raising test - radicular leg pain reproduced when the leg is extended >30°(e.g., if patient reported pain down the posterior thigh and lateral calf, expectation is a positive SLR test would reproduce that pain and not cause nonspecific pain like calf tightness or low back pain) OR
      - Motor weakness or sensory loss in a radicular distribution (must be in a specific radicular distribution) OR
      - EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR
      - Patient's history or advanced imaging consistent with symptoms described
  - **Suspected Cervical Radiculopathy/Radicular pain defined as**:
    - Pain in a *nerve root* distribution (e.g., C6, C7) OR
    - Motor weakness or persistent sensory loss in a radicular distribution (must be in a specific radicular distribution) OR
    - EMG/NCS confirms acute radiculopathy consistent with the patient's symptoms OR
    - Patient's history or advanced imaging consistent with symptoms described
  - **Suspected Thoracic Radiculopathy/Radicular Pain defined as:**

Back to Top

  - Band of numbness OR
  - Pain or sensitivity in the thoracic dermatomal distribution OR
  - Patient's history or advanced imaging consistent with symptoms described

- **Lumbar Radicular Pain (at any level) defined as:**
  - Moderate to severe pain in nerve root distribution (e.g., L5, S1, etc.) **AND**
  - Patient's available history and prior imaging is consistent with radicular pain as the primary etiology

- **Neurogenic claudication** defined as:
  - Bilateral or unilateral leg pain upon standing and walking that is temporarily relieved by forward flexion or sitting or lying down OR
  - The pain of lumbar stenosis is caused by relative ischemia of the lumbar nerve roots when in an upright position

- Treatment of presumed radiculopathy when there has been failure of at least a *4-week trial* of appropriate conservative management **with BOTH of the following:**
  - Physical Therapy* or home exercise* **AND**
  - Medications (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) oral or topical or acetaminophen) unless contraindicated

  **If conservative therapy is not appropriate, the medical record must clearly document why such approach is not reasonable.*

- MRI or CT with or without Myelography within the past 24-months demonstrates **ONE of the following:**
  - MRI or CT can be waived for the indication of simple lumbar radicular pain without loss of neurologic function (numbness or weakness) of less than six months duration
  - For an indication of *spinal stenosis*: Imaging consistent with moderate to severe lumbar spinal stenosis at the level to be treated for patients with a clinical diagnosis of neurogenic claudication
  - For an indication of *radiculopathy*: Imaging consistent with compression or displacement of the corresponding nerve root **OR**, if imaging does not show compression an EMG consistent with acute nerve impingement

  AND
- None of the contraindications below without documentation of a medically justifiable reason for proceeding **

Repeat Epidural Steroid Injections (ESI)

Repeat Epidural Steroid Injections (ESI) are proven and medically necessary when **the following** criteria are met.

- Pain has returned or deterioration in function has occurred **AND**
- If initial steroid injection was done empirically (without CT or MRI) and patient did not respond adequately, advanced imaging must be done prior to repeat injections **AND**
- Prior injection resulted in less than 50% improvement in pain for two or more weeks and the ESI approach is being changed (intralaminar to transforaminal or vice versa) or a different level is being injected (evidence of nerve root compression by CT, MRI, or EMG is required) **OR**
- Patients condition has declined after patients' initial injection resulted in at least 50% improvement in pain for two or more weeks and **at least ONE of the following:**
  - Increase in the level of function/physical activity (e.g., return to work)
  - Reduction in the use of pain medication and/or additional medical services

  NOTE: Additional epidural injections are ***not*** considered medically necessary if these criteria are not met.

Epidural Steroid Injection (ESI) Limitations

- Maximum of four (4) ESI sessions along the spinal column per year.

  Definitions:
  - A year: the 12-month period starting from the date of service of the first approved injection
- Maximum of two (2) transforaminal ESI injections in one date of service

****Epidural Steroid Injection (ESI) exclusions/contraindications**

Back to Top

- Anticoagulated
- Axial back pain (isolated to neck, mid-back, or low back pain)
- Back pain in the setting of acute spinal fractures
- Bleeding disorders that are not reversed
- Systemic bacterial or fungal Infection
- Currently on antibiotics/antifungals for an infection
- Currently on high dose steroids
- Demyelinating disease that is causing radicular symptoms
- Local malignancy
- Other CNS processes which predispose to transverse myelitis (case-by-case)
- Uncontrolled Diabetes

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (including PT notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Epidural steroid injections can serve as both a diagnostic and a therapeutic tool for patients with symptoms related to a disc herniation in the spine. Overall, the volume of evidence for the use of therapeutic epidural injections in the treatment of acute and chronic back pain is large. Clinical studies have shown that epidural steroid injections have provided short-term improvement and may be considered in the treatment of selected patients with radicular pain as part of an active therapy program. There is however insufficient evidence to demonstrate that epidural steroid injections are effective in the treatment of back pain in the absence of radicular symptoms.

References

Washington State Department of Labor & Industries Spinal Injections Coverage Decision. Retrieved 01/26/2023 from https://lni.wa.gov/patient-care/treating-patients/treatment-guidelines-and-resources/_docs/SpinalInjectionsCoverageDecision.pdf

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPCS Codes	Description
62320	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62321	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance

Back to Top

62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
62324	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance
62325	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (ie, fluoroscopy or CT)
62326	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); without imaging guidance
62327	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (ie, fluoroscopy or CT)
64479	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, single level
64480	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, each additional level (List separately in addition to code for primary procedure)
64483	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, single level
64484	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
03/07/2023	03/07/2023[MPC],	07/12/2023

[MPC] Medical Policy Committee

Revision History	Description
03/07/2023	MPC approved to adopt clinical criteria for Epidural Injections. Requires 60-day notice, effective date 08/01/2022.
06/06/2023	MPC approved to adopt the proposed revisions to the existing ESI criteria to include acknowledge the importance of conservative therapy. 60-day notice required, effective date 11/01/2023
07/12/2023	Updated effective date from 8/1/2023 to 8/14/2023 for the 3/7/2023 approved criteria updates.

Back to Top

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Epidural Lysis of Adhesions for Chronic Low-Back Pain

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"*Epidural Lysis of Adhesions for Chronic Low-Back Pain*"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Estimates for the prevalence of back pain in a lifetime range from 54% to 80%. Chronic persistent back pain is seen in up to 60% of patients five years after the initial episode. Back pain is associated with substantial economic and social costs (Boswell et al., 2005).

Epidural lysis of adhesions (also known as epidural adhesiolysis) is a procedure developed by Dr. Gabor Racz in 1989 to treat chronic low back pain in patients who have failed to respond to conservative treatments. The goals of the procedure are to break down fibrous adhesions in the epidural space and apply medication (i.e. local anesthetics and corticosteroids). Fibrous epidural lesions can develop after surgical laminectomy, or can occur secondary to annular tear, hematoma or infection. The adhesions prevent free movement of structures in the intervertebral foramen and the bony vertebral canal and prevent direct application of medications to structures believed to be the source of pain. The role of fibrous epidural adhesions in causing chronic spinal pain, however, remains controversial (Belozer & Wang, 2004; Manchikanti et al., 2004).

The basic procedure for epidural lysis of adhesions is as follows: A 16-gauge RK needle enters the epidural space and contrast material is injected. Next, an epidurogram is performed to visualize spread of contrast medium

Back to Top

Date Sent: 4/29/24

and identify filling defects. If the filing defect corresponds to the area of pain, a specially designed spring-guided reinforced catheter (Racz catheter) is threaded into the filling defect. Lysis of adhesions is carried out by intermittent injections of normal or hypertonic saline through the catheter. After adhesiolysis, local anesthetic and corticosteroids are injected. The original procedure, as described by Racz, requires the catheter to stay in place for 3-days, with additional injections of local anesthetic and steroid occurring on days 2 and 3. The procedure was modified to a 1-day protocol by Manchikanti and colleagues (Heavner et al., 1999).

Patients often undergo multiple adhesiolysis treatments. The American Society of Interventional Pain Physicians (ASIPP) suggests that with a 3-day protocol, patients should be limited to 2 interventions per year and with a 1-day protocol, patients should be limited to 4 interventions per year. Spinal endoscopic adhesiolysis procedures should be limited to a maximum of 2 per year, provided that the patient experienced at least a 50% reduction in pain for at least 2 months (Boswell et al., 2005).

Epidural adhesiolysis can be conducted with a spinal endoscope (called a myeloscope). This allows a 3-dimesional view of the contents of the epidural space. Proponents believe that spinal endoscopy improves the ability to perform appropriate adhesiolysis and provide targeted administration of medications (Belozer & Wang, 2004).

Possible side effects of epidural lysis of adhesions include dural puncture, spinal cord compression, infection and administration of high volumes of fluids which would potentially result in excessive epidural hydrostatic pressures (Boswell et al., 2005). In addition, the FDA has received multiple reports of catheter shearing or unraveling, as recently as April 2005. In most of these cases, sheared catheter pieces were left inside the patient (FDA website).

The Racz epidural catheter received premarket approval from the FDA in 1996.

Medical Technology Assessment Committee (MTAC)

Epidural Lysis of Adhesions

04/03/2006: MTAC REVIEW

Evidence Conclusion: One RCT evaluated the 3-day procedure for epidural lysis of adhesions. Conclusions cannot be drawn about effectiveness of this treatment from the study because there was no control group that did not receive the treatment. The study compared three alternate ways of performing the procedure. In addition, conclusions cannot be drawn about the relative effectiveness of different ways of performing the procedure since a between-group statistical analysis was not reported. Study validity was limited by a high drop-out rate and no intention to treat analysis, and lack of details about randomization and blinding procedures. Two RCTs evaluated the 1-day procedure for epidural lysis of adhesions. Both were conducted by Manchikanti and colleagues, the group that developed the shortened procedure. One of these was on percutaneous adhesiolysis (Manchikanti et al., 2004) and the other was on spinal endoscopic adhesiolysis (Manchikanti et al., 2005). The studies had similar methodology, and similar findings. Manchikanti et al., 2004 found significantly lower pain in each of two groups receiving epidural adhesiolysis (one received normal saline and the other, hypertonic saline) compared to a no treatment control group at 3, 6 and 12 months. Manchikanti et al., 2005 found significantly lower pain in a group receiving spinal endoscopic adhesiolysis compared to a no treatment control group at 3, 6 and 12 months. In both studies, the authors reported multiple outcomes without specifying primary outcomes or adjusting their p-value for multiple comparisons. Actual p-values were low enough that most of the differences would still have been statistically significant if the p-value had been adjusted. The clinical significance of outcomes using the VAS scale is not clear, but a substantially higher proportion of patients experienced ³50% pain reliefs. A limitation of the two studies was that patients could choose to be unblinded at 3 months, which could bias responses at 6 and 12 months. 25% of patients in the control group in the Manchikanti et al., 2004 study and 33% of all patients in the Manchikanti et al., 2005 study chose to be unblinded at 3 months.

Articles: Three randomized controlled trials were identified and critically appraised. One was on the original 3-day procedure and two were on the 1-day procedure. In addition, one non-randomized controlled trial and several case series were identified. The non-randomized controlled trial was not evaluated further because there were two later RCTs by the same research group on the 1-day procedure. The RCTs were: Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty: Prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. Reg Anesthesia Pain Med 1999; 24: 202-207. See Evidence Table. Manchikanti L, Rivera JJ, Pampati V. et al. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: A randomized double-blind trial. Pain Physician 2004; 7: 177-186. See Evidence Table. Manchikanti L, Boswell MV, Rivera JJ et al. A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain. BMC Anesthesiology 2005; 5:10. See Evidence Table.

Back to Top

Date Sent: 4/29/24

The use of Epidural Lysis of Adhesions in the evaluation of chronic low-back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
62263	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
62264	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/27/2006	04/20/2006 MDCRPC, 03/19/2007 MDCRPC, 12/17/2007 MDCRPC, 09/08/2008 MDCRPC, 07/13/2009 MDCRPC, 06/01/2010 MDCRPC, 04/05/2011 MDCRPC, 02/07/2012 MDCRPC, 12/04/2012 MDCRPC,10/01/2013 MPC , 08/05/2014 MPC, 06/02/2015MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC , 10/06/2020MPC, 10/05/2021MPC , 10/04/2022MPC , 10/03/2023MPC	09/08/2015

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
External Trigeminal Nerve Stimulation (eTNS) for ADHD

Criteria

For Medicare Members

Source)	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, **"External Trigeminal Nerve Stimulation (eTNS) for ADHD"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use the Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care (B-820-T) MCG* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Attention-deficit/hyperactivity disorder (ADHD) is the most common behavioral disorder in childhood. It is defined in the DSM-5 as a "P*ersistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development and negatively impacts directly on social and academic/occupational activities"*. The reported prevalence of ADHD in children varies from 2 to 18 percent depending upon the diagnostic criteria and the population

Back to Top

studied. The etiology of the disorder is not fully known, but according to the experts, a combination of genetic, neurological, and environmental factors contributes to its pathogenesis and heterogeneous phenotypes (Felt 2014, Polanczyk 2015, Belanger 2018).

There are three sub-types of ADHD: 1. Predominantly inattentive type (including poor concentration, difficulty completing tasks, ease of distraction, and disorganization); 2. Predominantly hyperactive -impulsive type (e.g. restlessness, persistent fidgeting, impatience, excessive talking, difficulty waiting for turn); and 3. The combined type. Diagnosing a child with ADHD can be challenging due to the lack of specific tests, biomarkers, or symptoms in addition to the common presence of other comorbidities that may affect symptom presentation, increase the severity of the disorder and/ or lead to greater functional impairment. The DSM-5 requires the presence of a sufficient number of core symptoms and functional impairment to diagnose an individual with ADHD. This requires extensive evaluation by a health care professional and involves obtaining information from multiple sources primarily from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care; comprehensive evaluation of the child's symptoms which should include the assessment for other conditions that might coexist with ADHD such as emotional or behavioral disorders (e.g., anxiety, depressive oppositional defiant, and conduct disorders), developmental (e.g. learning and language disorders), and physical conditions (e.g. tics, and sleep apnea) (AAP Guidelines 2011, Felt 2014, Akutagava-Martin 2016, Bélanger 2018).

Treatment of ADHD varies depending on the age of the patient and the presence of comorbidities. It needs to be individualized and is often multimodal requiring the use of both behavioral and pharmacological therapies. The American Academy of Pediatrics guideline recommends behavioral therapy as a first line treatment of preschool aged children (4-5 years of age); FDA- approved medications for ADHD and/or parent- and/or teacher administered behavior therapy as a first line treatment for elementary school-aged children (6–11 years of age); and FDA-approved medications as the first line treatment for adolescents (12-18 years of age). Psychostimulants, are most effective for the treatment of core ADHD symptoms, have generally acceptable adverse effect profiles and may be considered for children aged 6 years and older. Effective behavioral therapies include parent training, classroom management, and peer interventions. Other nonpharmacological interventions such as social, organizational skills, and cognitive training; diet; and exercise should be considered for children with ADHD and other psychiatric and developmental comorbidities (Felt 2014. Feldman 2018).

It is reported that around 70% of patients with ADHD using stimulant medications respond to therapy. In some cases, however, the response may me suboptimal and requires the use of more than one drug. This, in addition to the stigma of using stimulants, its side effects, intolerance, and lack compliance among some children, have led to the investigation of and/or development of alternative non-pharmacological therapies for the potential treatment of ADHD. Among these approaches are EEG-based neurofeedback, computer-based working memory training, and neuromodulation therapy (Grigolon 2019).

Neuromodulation therapy is an evolving therapy that has been, and/or being investigated for the potential treatment of different chronic conditions including pain, spinal cord injuries, epilepsy, movement disorders, and others. It is defined as the "alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body". Existing and emerging neuromodulation treatments range from non-invasive techniques such as transcranial magnetic stimulation (TMS) to techniques involving the surgical implantation of devices to alter activity in discrete areas of the nervous system. Among these therapies are deep brain stimulation, hypoglossal nerve stimulation, spinal cord stimulation, vagus nerve stimulation, occipital nerve stimulation and trigeminal nerve stimulation (TNS) (International Neuromodulation Society website).

TNS is a non-invasive neuromodulation technique that has been recently developed for neurological and psychiatric disorders based on the hypothesis that electrical stimulation of the supraorbital branch of the trigeminal nerve modulates cortical and subcortical areas related to neuropsychiatric disorders. The trigeminal nerve carries sensory information from the skin, muscles, and skull to extensive important structures in the brain, including the nucleus solitarius, the locus coeruleus, the vagus nerve and the cerebral cortex. The nerve also sends signals to the anterior cingulate cortex, which is believed to be involved in mood, attention and decision-making (Grigolon 2019, NeuroSigma website, International Neuromodulation Society website).

In April 19, 2019, the FDA granted marketing approval, through a de novo premarket review pathway*, of the Monarch eTNS System (NeuroSigma) to be used as a non-drug option for the treatment of attention deficit hyperactivity disorder (ADHD) in children 7 to12 years of age who are not currently taking prescription ADHD medication (FDA website accessed May 9, 2019).

Back to Top

The Monarch eTNS System™ (NeuroSigma, Inc., Los Angeles CA) is a small device, the size of a cell phone, powered by a 9-volt battery. It is connected through a thin wire to a small electrode patch that adheres to a patient's forehead during sleep. The system delivers mild electrical stimulation to the branches of the trigeminal nerve, which sends therapeutic signals to the parts of the brain assumed to be involved with concentration and impulse control. The child wears the patch for an average of eight hours at night and removes it in the morning. The electrical stimulation feels like a tingling sensation on the skin, and the device should be used in the home under the supervision of a caregiver during periods of sleep. The exact mechanism of eTNS is not yet known, but according to some investigators, neuroimaging studies showed that eTNS increases activity in the brain regions that are believed to be important in regulating attention, emotion and behavior. It is reported that the response to eTNS may take up to 4 weeks to become evident, and patients should consult with their health care professional after four weeks of use to assess treatment effects (FDA website).

According to the FDA, "the Monarch eTNS System should not be used in children under seven years of age, in patients with an active implantable pacemaker, with active implantable neurostimulators, or in patients with body-worn devices such as insulin pumps. The eTNS System should also not be used in the presence of radio frequency energy such as magnetic resonance imaging (MRI) as it has not been tested in an MRI machine, or cell phones, because the phone's low levels of electromagnetic energy may interrupt the therapy. The most common side effects observed with eTNS use are drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache and fatigue. No serious adverse events were associated with use of the device" (FDA website).

Medical Technology Assessment Committee (MTAC)

External Trigeminal Nerve Stimulation (eTNS) for ADHD

07/08/2019: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine the comparative safety and effectiveness eTNS to stimulants and /or behavioral therapies currently used for the treatment of ADHD in children.

- There is low-moderate quality evidence from one relatively small sham-controlled randomized pilot trial that eTNS has more than a placebo short-term effect in improving the severity and frequency of ADHD symptoms examined by ADHD-RS and CGI-I in around 50% of selected children 8-12 years of age during 4 weeks of therapy.

- There is insufficient evidence to determine the sustainability of the observed effect of eTNS after discontinuation of the treatment.

- There is insufficient evidence to determine the long-term safety and efficacy of TNS in the treatment of children with ADHD.

- There is insufficient evidence to determine the optimal duration of TNS therapy i.e. whether it should be used only for 4 weeks, long-term, or periodically applied to the child.

- eTNS therapy is not without side effects; it was associated with an increase in appetite, weight gain, fatigue, headache, drowsiness and other adverse events. The authors noted that the adverse effects were not clinically significant leading to discontinuation of the treatment.

- Long-term RCTs comparing the effectiveness of eTNS to other therapies is needed to determine the equivalence or superiority of TNS to standard therapies, optimal duration of treatment, durability of the observed effect, and whether TNS would have a potential impact on child's brain development.

Articles: The literature search only identified the published pivotal randomized, sham-controlled pilot study on trigeminal nerve stimulation for ADHD (McGough, 2019) and an earlier small observational feasibility study of trigeminal nerve stimulation in youths ADHD (McGough, 2015). Both studies were conducted by the same group of principal investigators who had financial ties with the industry.

Back to Top

McGough JJ, Sturm A, Cowen J, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry*. 2019 Apr; 58(4): 403-411.

McGough JJ, Loo SK, Sturm A, et al. An eight-week, open-trial, pilot feasibility study of trigeminal nerve stimulation in youth with attention-deficit/hyperactivity disorder. *Brain Stimul*. 2015 Mar-Apr; 8(2):299-304. See Evidence Table

The use of External Trigeminal Nerve Stimulation (eTNS) for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® /HCPC Codes	Description
E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
Dx Codes	**Description**
F90.0-F90.9	Attention-deficit hyperactivity disorder

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/06/2019	08/06/2019[MPC], 08/04/2020 [MPC], 08/03/2021 [MPC], 08/02/2022[MPC], 08/07/2023[MPC], 02/13/2024[MPC]	08/03/2021

[MPC] Medical Policy Committee

Revision History	Description
08/06/2019	MPC approved to adopt non-coverage policy
08/03/2021	Added HCPC code K1016 and Dx codes F90.0-F90.9. MPC approved to adopt MCG Care Guideline B-820-T Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care for medical necessity reviews. Requires 60-day notice, effective date January 1, 2022.
04/17/2024	Replaced termed code K1016 with new code E0733 effective 1/1/2024

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria**, "Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders"** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Dysphagia is a clinical term that refers to difficulty in swallowing. It may be caused by various pathologies including neuromuscular disorders and diseases such as multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson disease, and myasthenia gravis. Other etiologies for dysphagia include stroke, traumatic brain injury, head and neck tumors, ageing, generalized weakness, and other non-neurogenic causes. Dysphagia may have a major impact on the quality of life of patients and can lead to malnutrition, dehydration, or aspiration pneumonia (Park 2016).

Dysphagia may occur at any phase of the swallowing process; in the oral phase when impaired lingual movements may lead abnormal bolus formation and manipulation; in the pharyngeal phase due weakening of the pharyngeal constrictors that are crucial for the transfer of the oral bolus from the mouth to the esophagus,

Back to Top

decreased hyoid bone movement, and delayed laryngeal movements leading to pharyngeal residues and aspiration; or in the esophageal stage due to impaired upper esophageal sphincter movements.

Swallowing difficulty in ALS patients may result from weakness and/or spasticity of the muscles of deglutition, including the muscles of mastication, the tongue, lips, pharynx and larynx. In addition, weakness of the respiratory and ventilatory muscles impairs the airway protection by reducing the expiratory pressure needed to produce effective cough. In MS, the swallow coordination can be disrupted by demyelination of the corticobulbar tracts, cerebellar and/or brainstem involvement and the weakness or paresis of the muscles important for the swallow function. Research showed that disruption of the neuromuscular sequencing of pharyngeal and laryngeal events during swallow occurred in up to 90% of individuals with MS. In addition, similar to ALS, the reduced strength of the expiratory muscles not provide sufficient pressure for cough production and airway clearance. The pathophysiology of oropharyngeal dysphasia in Parkinson's disease is not clearly understood but is postulated to be due to dysfunction of the brain stem, degeneration of the substantia nigra, as well as disturbance of nondopaminergic neural networks (Van hooren 2014, Park 2016, Byeon 2016, Plowman 2016, Silverman 2017).

Management of dysphagia can be broadly divided into two approaches: 1. The remedial approach with the goal of improving swallowing function through different exercises; and 2. The compensatory approach that aims at safer swallowing e.g. by controlling the material and viscosity of the food, and the use of specific postural techniques and maneuvers during the food intake. The compensatory approaches, however, have a temporary effect and cannot induce recovery of the damaged swallow network. Investigators have thus focused on the remedial approaches that aim at restoration of function. Different new therapeutic modalities for managing swallowing in neurologic disorders have been developed and introduced to practice in the recent years, such as neuromuscular electrical stimulation, deep brain stimulation, respiratory muscle training, and others (Byeon 2016, Park 2016).

Recently expiratory muscle strength training (EMST) has emerged as a potential remedial therapy for swallowing disorders. It is an exercise program that focuses on increasing the force-generating capacity of the expiratory muscles during breathing with the aim of improving the maximum expiratory pressure, voluntary coughing effectiveness, as well as improving displacement of the hyoid during swallowing. Researchers explained that during the swallowing process suprahyoid muscle contraction in the pharynx pulls the hyoid bone in the anterior superior direction, and that sufficient movement of the hyoid bone in this direction is associated with airway protection and safe swallowing such as opening of the upper esophageal sphincter during swallowing. Neurogenic disorders may result in weakness of the suprahyoid muscles (anterior belly of the digastric, mylohyoid, and geniohyoid muscles) that are important for coughing and breathing out forcefully and swallowing. Weakness of these muscles leads to insufficient movement of the hyoid bone and in turn reduces the cough capacity and airway clearance. Activation of the suprahyoid muscles during EMST is thus believed to be effective in improving swallowing. It was initially investigated in the early 2000s by a team of researchers in Florida as a swallowing rehabilitation intervention in patients with Parkinson's disease (Pitts 2012, Laciuga 2014, Eom 2017, Moon 2017, Park 2016, Pearson 2017, Silverman 2017).

Expiratory muscle training is performed by hand-held resistive or pressure threshold devices. The resistance-based devices rely on adjusting the diameter of the airflow vent holes in the device. Reducing the dimeter of the vent holes imposes resistance requiring increases respiratory muscle force. These devices have no threshold for the user to overcome and can be ineffective for strength training if used with inadequate airflow. Pressure-threshold devices on the other hand, rely on the pressure exerted during expiration. The device has a pressure threshold relief valve that opens only when a sufficient expiratory pressure is generated by the user during a forceful expiration into the device.

EMST150 device (Aspire Products, LLC; Gainesville, Florida) is a pressure-threshold handheld calibrated device that includes a one-way, spring-loaded valve with an adjustable external dial. The valve blocks the flow of air until enough pressure is produced. Once the targeted pressure is produced, the valve opens, and air begins to flow through the device. The latter allows adjusting the pressure amount in a range between 0 and 150 cm H_2O. The pressure-threshold load is based on the patient's maximum expiratory pressure (MEP) obtained through a pressure manometer. During training the pressure threshold device is adjusted incrementally to progressively increase the resistance (progressive overload). The expiratory force must be sufficient to open the spring-loaded valve and allow the air flow. The pressure released valve requires a consistent flow of air to remain open. If the expiratory force is inadequate, the valve will not open and no air will flow through the device. These mechanics may serve as a biofeedback during the use of the device. The "dose" of EMST is typically defined in terms of the number of repetitions per set, with 5 sets completed each day, for 5 days per week with the device resistance set at 75% of the patient's MEP and progressed each week (Pitts 2009, Troche 2010, Brooks 2017).

Back to Top

When training ceases or the body undergoes a long period of detraining (inactivity) following a period of physical training, it loses some or all the positive gains achieved during training. This suggests that training should take place continually to maintain the benefits of an exercise program, particularly in individuals with neurodegenerative disease (https://emst150.com/faq/)

EMST is a form of therapy and is not subject to FDA regulations. The technology has not been previously reviewed by MTAC it is being reviewed based on a request form the Clinical Review Unit for decision support.

Medical Technology Assessment Committee (MTAC)

Date: 07/09/2018 MTAC REVIEW

Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders

Evidence Conclusion:

The published studies that investigated the benefit of expiratory muscle strength training in patients with dysphagia due to neurogenic disease are limited in quantity and quality. The majority examined pre-post effect of EMST among patients with swallowing disorders secondary to Parkinson's disease (PD) and were conducted by the team of investigator who developed the EMST150 device. The published RCTs that used EMST in patients with PD or other neurologic disorders compared the therapy to sham treatment and not to any other remedial or compensatory approaches to determine whether it has equivalent or superior effect to the traditional therapies used for the management of dysphagia. The trials were too small with attrition bias and examined the effect of the therapy only for the duration of expiratory training (4-5 weeks), which does not allow examining the durability of effect after discontinuation of the therapy. In addition, the published trials generally included patients in the early stages of the disease/disorder or those with mild to moderate dysphagia and may not be generalized to more severe or advanced cases who may not benefit from or tolerate the treatment.

Effects of EMST on dysphagia secondary to Parkinson's disease

Troche et al's, 2010 RCT (Evidence table 1) compared EMST versus sham treatment in 68 participants with mild to moderate dysphagia secondary to Parkinson's disease. The primary outcome was improvement in swallowing safety using penetration-aspiration score (PAS). Secondary outcomes included swallow physiology as assessed by hyoid movement and UES opening, as well as swallow quality of life and respiratory measure (maximum expiratory pressure [MEP]).

After 4 weeks of active or sham EMST training, patients in the active therapy group showed statistically significant improvement in in the PAS compared to baseline values, while those undergoing sham therapy group did not show a significant improvement. The authors calculated a NNT of 5 to gain on additional improvement and a NNT of 2 for a net benefit improvement with the use of EMST. The results also showed that EMST group had significant improvements in the upper esophageal sphincter (UES) opening, UES widest, and UES closure, but with no significant improvement in hypoid elevation duration. Both the active and sham therapy groups showed some improvement in the swallow quality of life. The adherence to therapy and adverse events were not discussed.

The study was randomized and controlled. However, it was a short-term study that compared EMST to a sham treatment and not to an alternative active therapy. In addition, the authors compared pre-post outcomes within each group and not between groups. The trial included patients with mild to moderate impairment in swallowing due to PD and its results may not be generalized to severe swallowing impairment in patients with PD, or to swallowing dysfunction due to other diseases or disorders.

A very small follow-up study (Troche, 2014) explored changes in MEP and PAS three months after the end of EMST training among 10 participants selected from the original trial and showed no statistically significant deterioration in MEP or PAS three months post completion of the EMST regimen. The authors reported that the detraining effects on swallow safety was less clear and concluded that the results of this study indicate that there is a need for the development of maintenance programs to sustain function following intensive periods of training. It is worth noting that the device used in the trial EMST150 was initially developed by the principal investigators of the trial.

In a study published by a single author (Byeon, 2017), 33 patients with dysphagia caused by Parkinson's disease were randomly assigned to receive EMST using EMST150 device (n=18) or EMST plus postural techniques (n=15). The postural techniques included chin tucking, head rotation, head tilting, bending head back and lying down straight for 30 minutes per session. The therapy was given 5 days a week for 4 weeks. The primary outcome was swallowing recovery measured by video fluoroscopic studies (VFS). The results of the trial showed a decrease in mean VSF scale score in both groups after treatment, but the decrease in the combined intervention group was significantly greater than in the EMST-only group. the study was a small RCT, with short follow-up duration, and conducted mainly among men, all of which would limit generalization of the results.

Back to Top

Effects of EMST on dysphagia secondary to stroke

There were three smalls RCTs, (Park et al, 2019 [n=27] Moon et al, 2017 [n=18] and Eom et al, 2017 [N=40]) published to date, that investigated the effect of a 4-week EMST on suprahyoid muscle activity and airway aspiration in patients with oropharyngeal dysphagia secondary to acute/subacute stroke. The trials were conducted by the same team of principal investigators in university hospitals in Korea, which makes it difficult to rule out a potential overlap between the participants. All three trials had similar protocol, intervention, outcome measures, and results. To avoid introducing bias by duplication the results for the overlapping participants, the largest and most recent trial (Eom et al, 2017) was selected for critical appraisal.

Eom and colleagues' trial (2017) (Evidence table 2) randomized 33 patients >65 years of age with dysphagia due to stroke to undergo active EMST therapy using EMST150 device or to a sham therapy using a nonfunctional EMST system with no loading device. The two groups underwent training for 4 weeks (5 sets of 5 breaths 5 days a week for 4 weeks). All participants were assessed by fluoroscopic swallowing study (VFSS) before and after the intervention. The primary outcome was improvement in swallowing assessed by video fluoroscopic scale (VDS) and safety measured by in laryngeal penetration score (PAS). Only 26 (78.8%) of the participants completed the study.

The overall results of the study showed that the 2 groups improved in both the oral and pharyngeal phases of the VDS and the PAS after the 4 weeks of therapy compared to baseline. The improvements observed were significantly better in the active treatment group.

The study was randomized, controlled, and had objective outcomes. However, it was a very small trial, conducted among patients with subacute stroke and the improvement, as observed in the placebo group, may be due to the natural neurological recovery of the condition and not due to the intervention. In addition, the study period was only four months and insufficient to determine the long-term durability of the observed effects.

Effects of EMST on dysphagia secondary to multiple sclerosis

Silverman and colleagues' (2017) sham controlled RCT (Evidence table 3) examined the effect of EMST on the swallowing function and swallow-related quality of life in 42 patients with MS. 36 completed the maximum pressure expiratory (MEP) test and were randomized, and n=32 completed 5-week study. Sixteen patients underwent EMST using the EMST150 device and twenty patients underwent a sham therapy using the EMST150 device without an internal pressure threshold spring. All participants were instructed to complete 5 sets of five repetitions (total of 25 times in approximately 20 minutes /day) 5 days a week for 5 weeks. The primary outcomes were the change in MEP, penetration aspiration score (PAS), and improvement swallow quality-of-life (SWAL-QOL). MEP was obtained weekly to monitor and adjust the device, and video fluoroscopy was used to record swallow function and measure PAS.

The overall results showed improvement in MEP in the two study groups with no significant difference between them. The improvement in the sham group and lack of statistical significance between the 2 groups suggests that simple expiratory breathing alone without the positive pressure load can improve the MEP in patients with MS. The results also show that PAS improved in 40% in the EMST and 14% in the sham group. There was no significant difference between the 2 groups in the total swallow score.

The study was randomized, controlled, blinded, and had objective outcomes. However, it was a very small trial, with no power analysis, unclear method of randomization and allocation concealment, only 76% of the enrolled participants completed the trial, and there was no ITT analysis. In addition, the study period was only five weeks, does not allow examining the long-term durability of observed benefit, and the authors had financial ties with the industry.

Conclusion:

- There is no published evidence to date to determine that EMST is superior or equivalent to other remedial or compensatory approaches used to manage swallowing disorders in patients with neurogenic disease or disorders.
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes, compared to no treatment in selected patients with mild to moderate dysphagia secondary to Parkinson's disease,
- There is low-quality evidence showing that EMST may improve short-term swallowing outcomes in patients with dysphagia secondary to acute/subacute stroke, compared to no active treatment. The benefits observed in the sham therapy groups may suggest that the EMST has a placebo effect, or that dysphagia may improve as a natural recovery of the condition and not due to the intervention.
- The benefits observed in the sham therapy groups in neurogenic conditions other than stroke may also indicate a placebo effect of the EMST, or that expiratory breathing alone without the positive pressure load can improve the MEP.

Back to Top

- There is insufficient evidence to determine whether the short-term benefits observed with EMST therapy compared to sham treatment would last after treatment cessation.
- Adverse outcomes were not reported in any of the trials.

The use of Expiratory Muscle Training Therapy (EMST150) for Patients with Dysphagia due to Neurologic Diseases or Disorders doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018 MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC	08/07/2018

MPC Medical Policy Committee

Revision History	Description
08/07/2018	Added MTAC review from 7/9/18 and created document

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Extracorporeal Photopheresis

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Extracorporeal Photopheresis (110.4)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Extracorporeal Photopheresis for Acute and Chronic Graft vs. Host
Medical necessity review no longer required for this service.

Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)
Must meet **ALL of the following**:

A. The extracorporeal device must be FDA approved;
B. The patient has cutaneous t-cell lymphoma that has not responded to other forms of treatment;
C. The use is for palliative treatment of associated skin manifestations.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Extracorporeal photopheresis (ECP) is a treatment modality for graft-versus-host disease (GVHD) and cutaneous t-cell lymphoma (CTCL). CTCL refers to several clonal t-cell malignancies that primarily manifest as skin conditions. GVHD is a complication of allogenic stem cell transplantation.

Extracorporeal photopheresis (ECP) is one of the treatment options for refractory acute and chronic GVHD. ECP involves removing the patient's peripheral blood and separating it into leukocyte-depleted blood and leukocyte-enriched plasma. The leukocyte-depleted blood is returned to the patient. The leukocyte-enriched plasma is exposed to ultraviolet light in the presence of an extracorporeally administered photosensitizing agent, 8-methoxypsoralen (8-MOP). The cells are then re-infused into the patient and die in one-week period. During that week, they are capable of stimulating an anti-idiotypic t suppressor response. The exact mechanism of action of ECP is not known. The Therakos Photopheresis System is FDA approved as a class III medical device specifically for photopheresis (Greinix et al., 2000; Woltz et al., 2006).

Back to Top

Date Sent: 4/29/24

There are no agreed-upon standards for the optimal frequency and duration for ECP treatment in patients with chronic GVHD, and there is wide variability in practice. Patients may be treated two or three days a week every two to three weeks for 3 to 30 months (Woltz et al., 2006).

Extracorporeal photopheresis (ECP) is also a treatment option for CTCL. ECP involves removing a portion of the patient's blood and separating into red and white blood cells by centrifugation. The red cells are returned to the patient. The white cells are mixed with a photosensitizing agent, 8-methoxypsoralen or methoxsalen (Uvadex, Therakos), and irradiated with ultraviolet light (UVA light, 320-400 nm). When activated, the photosensitizing agent binds with the cellular DNA of the white cells and accelerates their death. The altered cells are then re-infused into the patient. The intention is that these cells will stimulate an immune response against the damaged pathogenic t cell clones. In the pivotal study upon which FDA approval was based, a case series with 37 patients by Edelson and colleagues, a greater treatment effect was seen in patients with erythrodermic CTCL (later-stage disease) compared to those with plagues or tumors. This distinction has been difficult to confirm in later case series because studies generally include patients at different stages of clinical disease and do not report findings separately by disease stage. The effectiveness of ECP for treating CTCL, particularly Sezary Syndrome, continues to be debated in the literature. Some of the controversies are whether prior treatment with systemic corticosteroids and systemic chemotherapy reduces the effectiveness of ECP and which sub-groups of patients are most likely to benefit from ECP treatment. To date, there have not been any randomized controlled trials comparing ECP to other treatments for CTCL (Apisarnthanarax et al., 2002; Russell-Jones, 2000; FDA Web site; Therakos Web site).

The FDA has approved the photopheresis device UVAR and the photosensitizing Uvadex (both by Therakos) for the palliative treatment of skin manifestations of cutaneous t-cell lymphoma that has not responded to other forms of treatment. ECP is covered by Medicare for the same indication.

Evidence and Source Documents

Extracorporeal Photopheresis for Acute and Chronic Graft vs. Host Disease
Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

Medical Technology Assessment Committee (MTAC)

Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease

BACKGROUND

Graft-versus-host disease (GVHD) is a complication of allogenic stem cell transplantation (SCT). There are two forms of GVHD, acute and chronic. Acute GVHD occurs within the first 100 days of transplantation. In acute GVHD, the T-lymphocytes from the donor recognize tissues or cells in the recipient as foreign and produce a multi-organ (i.e. skin, liver, intestines) autoimmune-like syndrome. The T-lymphocytes use information from genetic markers known as human leukocyte antigens (HLA) to detect differences. Even when donors are matched for HLA markers, GVHD can occur because minor differences in these markers could still exist. Efforts to prevent acute GVHD include using closely matched donors, umbilical cord blood and/or post transplant immunosuppression with drugs including cyclosporine and methotrexate. Acute GVHD is commonly treated with corticosteroids which produce sustained responses in 50-80% of patients depending on the initial severity of disease. Second-line therapy includes different combinations of immunosuppressive agents. Newer treatments include infusion of mesenchymal stem cells (MSC), down-regulation of antigen-presenting cells (APC) and suicide gene transduced T cells (Bacigalupo, 2007). Chronic GVHD can occur after the first 100 days post-transplant, either in patients who experienced acute GVHD or a de novo onset. It is the main cause of late morbidity and mortality after allogenic SCT. Chronic GVHD generally involves donor T cells expanding and attacking the host's immunologic system; its pathophysiology is poorly understood compared to acute GVHD (Woltz et al., 2006; PerezSimon et al., 2006). Standard first-line treatment for chronic GVHD includes prednisone alone or in combination with a calcineurin inhibitor such as cyclosporin or tacrolimus. A recent review article (Perez-Simon et al., 2006) states that there is no generally accepted salvage treatment for patients with chronic GVHD who do not respond to prednisone. Treatments that have been used for refractory chronic GVHD include mycophenolate mofetil, anti-interleukin-2a receptor antagonists, sirolimus, pentostatin, CD20 antagonists, tumor necrosis factor-a antagonists and extracorporeal photopheresis. Other, newer treatments include anti-CD25 immunotoxin and inhibition of nuclear factor-dB. The authors of the review article recommend that chronic GVHD patients enter clinical trials for salvage treatment if at all possible. Extracorporeal photopheresis (ECP) is one of the treatment options for refractory acute and chronic GVHD. ECP involves removing the patient's peripheral blood and separating it into leukocyte-depleted blood and leukocyte-enriched plasma. The leukocyte-depleted blood is returned to the patient. The leukocyte-enriched plasma is exposed to ultraviolet light in the presence of an extracorporeally administered photosensitizing agent, 8-methoxypsoralen (8-MOP). The cells are then re-infused into the patient and die in one-week period. During that week, they are capable of stimulating an antiidiotypic T

Back to Top

suppressor response. The exact mechanism of action of ECP is not known. The Therakos Photopheresis System is FDA approved as a class III medical device specifically for photopheresis (Greinix et al., 2000; Woltz et al., 2006). There is no generally agreed-upon standards for the optimal frequency and duration for ECP treatment in patients with chronic GVHD, and there is wide variability in practice. Patients may be treated two or three days a week every two to three weeks for 3 to 30 months (Woltz et al., 2006). ECP for acute and chronic graft versus host disease was first reviewed by MTAC in 2002. At that time, the empirical evidence consisted of small case series, with sample sizes varying from 3 to 23. The item failed MTAC evaluation criteria, and the Health Plan Medical Directors decision was to review requests on a case-by-case basis. A new review is being requested due to the length of time since the previous review, and recent changes made to Medicare criteria. Medicare now covers ECP for patients with chronic GVHD whose disease is refractory to standard immunosuppressive drug treatment.

06/12/2002: MTAC REVIEW
Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease
Evidence Conclusion: There is not enough evidence to permit conclusions on the effectiveness of extracorporeal photopheresis for treating acute or chronic graft-versus-host disease.
Articles: The search yielded 16 articles. There were no randomized controlled trials. Seven of the articles were reviews or editorials, two were case reports and seven were small case series (varying in size from n=3 to n=23). Due to the low grade of evidence and the small size of the studies, no evidence tables were created.

The use of extracorporeal photopheresis in the treatment of acute and chronic graft versus host disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/20/2007: MTAC REVIEW
Extracorporeal Photopheresis in the Treatment of Acute and Chronic Graft Versus Host Disease
Evidence Conclusion: The published studies that evaluated actigraphy for the assessment of insomnia were conducted on selected groups of patients and used different actigraph models, software, and scoring algorithms. Most studies were conducted in sleep laboratories where recording conditions are standardized, and the artifacts controlled. These controls would be lost when the actigraphy devices are used in the home environment, where it is intended for use. Also, the algorithms that were validated for a specific model, mode of operation, or in a selected population may by not be equally accurate when used with a different brand of device, different gender or age group. The studies reviewed compared actigraphy to PSG, but the authors did not indicate whether the investigators interpreting the results of one test were blinded to the results of the other. The overall results of the studies reviewed, indicate that compared to polysomnography, actigraphy had a high sensitivity (92-98%) but very low specificity (28-48%) in detecting insomnia. It was also found to overestimate the total sleep time and sleep efficiency. Actigraphy tends to overestimate sleep in people with insomnia when they are lying quietly as quiet wakefulness could be miscoded as sleep. Insomnia patients can remain inactive for a period of time attempting to fall asleep on the other hand actigraphy may underestimate the amount of sleep and overestimate the duration awake among those who are asleep but are restless or have large amounts of movements during sleep. The use of actigraphy for the assessment of periodic leg movements in sleep was evaluated in only a few small studies with methodological limitations. It was compared with polysomnography with bilateral anterior tibialis electromyelography (BATEMG). However, EMG and leg actigraphy are not interchangeable, and each measures a different event. One records electrical activity of a certain muscle and the other records leg acceleration. Leg activity may be due to movement artifacts produced by obstructive sleep apnea. Kemlink et al (2007) did not exclude patients with suspicious sleep apnea and did not adjust for it in the analysis. In conclusion there is insufficient evidence to determine that actigraphy would replace PSG or add to its value in the diagnosis and management of patients with sleep disorders.
Articles: No randomized or non-randomized controlled trials were identified. The empirical evidence continues to consist of case series. The largest case series on ECP for acute GVHD (n=59) and for chronic GVHD (n=71) identified in the search were critically appraised. In addition, a case series on ECP in pediatric patients with either acute or chronic GVHD (n=77) was critically appraised. There were additional smaller case series. The studies reviewed include: Greinix HT, Knobler RM, Worel N et al. The effect of intensified extracorporeal photochemotherapy on long-term survival in patients with severe acute graft versus host disease. Stem Cell Transplant 2006; 91: 405-408. See Evidence Table. Couriel DR, Hosing C, Saliba R et al. Extracorporeal photochemotherapy for the treatment of steroid resistant chronic GVHD. Blood 2006; 107: 3074-3080. See Evidence Table. Messina C, Locatelli F, Lanino e et al. Extracorporeal photochemotherapy for pediatric patients with graft versus host disease after hematopoietic stem cell transplantation. Br J Hematol 2003; 122 118-127. See Evidence Table.

The use of extracorporeal photopheresis in the treatment of acute and chronic graft versus host disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Back to Top

Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

BACKGROUND

Cutaneous T-cell lymphoma (CTCL) refers to several clonal T-cell malignancies that primarily manifest as skin conditions. The classical subsets of CTCL include mycosis fungoides (MF), the most common form, and Sezary Syndrome (SS). MF usually presents as chronic eczematous or psoriasiform patches or plaques whereas SS is characterized by erythroderma and leukemia. SS is sometimes viewed as an advanced form of MF. According to the CTCL disease staging system (stage IA-IVB), patients with Sevary Syndrome have stage IV disease. (Apisarnthanarax et al., 2002; Duvic et al., 2003; RussellJones et al., 2000). Therapeutic options differ according to clinical disease stage. Early patch-plaque MF (Stage 1 and IIA) is generally a benign and chronic condition and can be treated with conservative therapies such as topical corticosteroids, retinoids and mechlorethamine (nitrogen mustard). Early stage disease can also be treated with ultraviolet B (UVB) phototherapy or psoralen plus ultraviolet A photochemotherapy (PUVA). Some of the treatments used in early stage disease, such as PUVA or oral bexarotene, are also used for later stage disease but may be less effective. Historically, the most common treatment for late-stage disease (Stage IIB-IVB) is chemotherapy. No single-agent or multi-agent regimen has been shown to be clearly superior to the others. Disadvantages of systemic chemotherapeutic agents are that they have immunosuppressive effects which can lead to opportunistic infections, sepsis or death (Apisarnthanarax et al., 2002). Extracorporeal photopheresis (ECP) is another treatment option for CTCL. ECP involves removing a portion of the patient's blood and separating into red and white blood cells by centrifugation. The red cells are returned to the patient. The white cells are mixed with a photosensitizing agent, 8-methoxypsoralen or methoxsalen (Uvadex, Therakos), and irradiated with ultraviolet light (UVA light, 320-400 nm). When activated, the photosensitizing agent binds with the cellular DNA of the white cells and accelerates their death. The altered cells are then reinfused into the patient. The intention is that these cells will stimulate an immune response against the damaged pathogenic T cell clones. In the pivotal study upon which FDA approval was based, a case series with 37 patients by Edelson and colleagues, a greater treatment effect was seen in patients with erythrodermic CTCL (later-stage disease) compared to those with plagues or tumors. This distinction has been difficult to confirm in later case series because studies generally include patients at different stages of clinical disease and do not report findings separately by disease stage. The effectiveness of ECP for treating CTCL, particularly the following information was used in the development of this document and is provided as background only. Sezary Syndrome continues to be debated in the literature. Some of the controversies are whether prior treatment with systemic corticosteroids and systemic chemotherapy reduces the effectiveness of ECP and which sub-groups of patients are most likely to benefit from ECP treatment. To date, there have not been any randomized controlled trials comparing ECP to other treatments for CTCL (Apisarnthanarax et al., 2002; Russell-Jones, 2000; FDA website; Therakos website). The FDA has approved the photopheresis device UVAR and the photosensitizing Uvadex (both by Therakos) for the palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other forms of treatment. ECP is covered by Medicare for the same indication. Extracorporeal photopheresis for CTCL has not been reviewed previously by MTAC. ECP for the treatment of graft versus host disease was reviewed by MTAC in June, 2002.

06/05/2006: MTAC REVIEW

Extracorporeal Photopheresis for Cutaneous T-Cell Lymphoma (CTCL)

Evidence Conclusion: There are no randomized controlled trials evaluating the efficacy of extracorporeal photopheresis for treating patients with CTCL. The published literature consists of small, predominantly retrospective case series. The ECP treatment protocol was similar in the case series that were reviewed, generally consisting of treatment every 4 weeks with a tapering off by lengthening treatment intervals in patients who achieved a response. Data from case series suggests that ECP might be helpful for treating skin manifestations of CTCL, the FDA approved indication. However, there are no data on the efficacy of ECP for skin conditions compared to an alternative treatment or no treatment. In the single prospective study, 27/37 patients had a positive response to treatment, defined as at least a 25% reduction in the skin score. 24/29 patients with erythroderma had a positive response after a mean follow-up of 42 weeks (Edelson et al., 1987). A study published 5 years later on the 29 patients with erythroderma (Heald et al., 1992) found that most of the patients had at least some improvement in skin manifestations of CTCL and 6 had a complete remission. It is not possible to draw conclusions about survival after ECP treatment due to the lack of comparative data from RCTs. Predicted median survival using life-table analysis in the Heald/Edelson study was 60 months from time of diagnosis of the erythrodermic state. One of the case series (Fraser-Andrews et al. 1998) included a non-randomized comparison group of patients who did not receive ECP treatment. They did not find a statistically significant difference in median length of survival from time of SS diagnosis in the two groups (39 months in ECP-treated patients vs. 26.5 months in non-ECP treated patients, p=0.12). Other than a lack of randomization, limitations of the Fraser-Andrews study was the wide variety of other treatments patients received before, during and after ECP treatment, or instead of ECP treatment. It is difficult to attribute a response to the ECP treatment itself. The limited data on use of ECP for CTCL identified few adverse effects.

Back to Top

Articles: No randomized controlled trials were identified. The empirical studies were all case series, each with a sample size of less than 50. Desirable features of case series were prospective design, larger sample size, clear eligibility criteria, longer follow-up and survival included as an outcome. Three studies included survival as an outcome in addition to treatment response, had sample sizes n>25 and had reasonably long-term follow-up; however, only one of them was prospective. These three studies were critically appraised. The prospective study reporting on patient survival was the original Edelson (1987) study, with follow-up data reported by Heald and colleagues in 1992. Excluded studies include a prospective study that included only 14 patients and a small (n=20) study that included survival as an outcome but was retrospective and did not specify eligibility criteria. *Studies reviewed include:* Heald P, Rook A, Perez M et al. Treatment of erythrodermic cutaneous T-cell lymphoma with extracorporeal photochemotherapy. J Am Acad Dermatol 1992; 27: 427-433. (Follow-up of Edelson R et al. NEJM 1987; 316: 297-303). See Evidence Table. Gottlieb SL, Wolfe JT, Fox FE et al. Treatment of cutaneous t-cell lymphoma with extracorporeal photopheresis monotherapy and in combination with recombinant interferon alfa: A 10-year experience at a single institution. J Am Acad Dermatol 1996; 35: 946-957. See Evidence Table. Fraser-Andrews E, Seed, P, Whittaker S. et al. Extracorporeal photopheresis in Sezary syndrome. Arch Dermatol 1998; 134: 1001-1005. See Evidence Table.

The use of extracorporeal photopheresis in the palliative treatment of cutaneous T-cell lymphoma lesions does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
36522	Photopheresis, extracorporeal

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/12/2002	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 12/03/2013[MPC] ,10/07/2014[MPC], 08/04/2015[MPC], 11/01/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 03/12/2024[MPC]	08/20/2007

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Facet Joint Injections/Medial Branch Block

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Facet Joint Interventions for Pain Management (L38803)
Local Coverage Article (LCA)	Billing and Coding: Facet Joint Interventions for Pain Management (A58405)

For Non-Medicare Members

Effective until August 15, 2023

No review required.

Effective August 15, 2023

Kaiser Permanente has elected to use coverage guidance from Noridian Local Coverage Determination (LCD) L38803 Facet Joint Interventions for Pain Management for Diagnostic Facet Joint Procedures, therapeutic facet joint procedures.

For covered criteria:

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (including PT notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Facet joint injections are used to treat specific etiologies of back pain, generally in the absence of radicular symptoms. Some indications for diagnostic facet joint injections include strong suspicion for the pain of facet joint etiology (focal tenderness over the facet joint, pain in response to hyperextension, rotational movement, or bending laterally, leg pain not extending below the knee), chronic low back pain, neck pain not relieved with conservative management, or low back pain with normal imaging. Given the natural history of these symptoms, it is recommended that conservative treatments are trialed for at least 3 months prior to consideration of facet injections.

Back to Top

Medial branch block injections are also used for evaluating candidacy for possible facet neuropathy. They involve injection of anesthetic near to the medial branch nerves near the facet joint. These are typically used in preparation and for diagnostic purposes prior to a facet neurotomy.

Applicable Codes

References

Centers for Medicare & Medicaid Services. (2022, February). *Facet Joint Interventions for Pain Management. (L38803).* https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38803&ver=6&keyword=medial%20branch%20block&keywordType=starts&areaId=s56&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPCS Codes	Description
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level (List separately in addition to code for primary procedure)
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level (List separately in addition to code for primary procedure)
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)

Considered Not Medically Necessary - experimental, investigational or unproven:

CPT® or HCPCS Codes	Description
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0214T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; second level (List separately in addition to code for primary procedure)
0215T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; third and any additional level(s) (List separately in addition to code for primary procedure)
0217T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; second level (List separately in addition to code for primary procedure)
0218T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; third and any additional level(s) (List separately in addition to code for primary procedure)

Back to Top

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
03/07/2023	03/07/2023[MPC],	7/12/2023

[MPC] Medical Policy Committee

Revision History	Description
03/07/2023	MPC approved to adopt Medicare criteria for non-Medicare members. Requires 60-day notice, effective date 08/01/2023.
7/12/2023	Updated effective date to 8/14/2023

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Fecal Microbial Transplant for Treatment of C. Difficile Infection

- Fecal GI Infusion
- Fecal Capsule (G3 OpenBiome)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Medical Policy Clinical Review Criteria, ***Fecal GI Infusion for the Treatment of C. Difficile Infection,*** for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Effective Until August 1st, 2024

Service	Criteria
Fecal GI Infusion	Fecal GI infusion is covered when **ALL of the following** are met: 1) Clostridium difficile infection confirmed by a positive stool test for *C.* difficile toxin 2) Has had at least two recurrences following adequate antibiotic therapy This would be defined as a symptomatic toxin-positive failure after at least one prolonged tapering course of vancomycin (generally over a 4-6-week period).
FMT capsule, G3 OpenBiome	If the above criteria are met, oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection is covered.

Effective August 1st, 2024

Service	Criteria
Fecal GI Infusion	Review no longer required—Policy Retired
FMT capsule, G3 OpenBiome	Review no longer required—Policy Retired

Back to Top

Date Sent: 4/29/24

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Clostridium difficile (C difficile) is the leading cause of antibiotic associated diarrhea and its rates continue to rise. During the past several years, the incidence of C difficile infection (CDI) has increased to an epidemic level; it has become more severe, more refractory to standard treatment, and more likely to relapse. According to the CDC, the number of hospitalized patients with any CDI discharge diagnoses more than doubled from approximately 139,000 to 336,600, and the number with a primary CDI diagnosis more than tripled, from 33,000 to 111,000 from 2000 to 2009. This rise in incidence and severity of the disease is possibly associated with the emergence of the hypervirulent strain (NAPI/ribotype 027). CDI is responsible for a spectrum of infections including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which may lead to sepsis and even death. It often occurs in patients in health-care settings where antibiotics are prescribed, and symptomatic patients are concentrated. The most common risk factor for CDI is the use of broad-spectrum antibiotics or the concomitant use of multiple and prolonged antimicrobials. Other risk factors include advanced age (65 years or older), recent organ transplantation, gastrointestinal surgery, inflammatory bowel disease, immunosuppressive drugs, presence of multiple co-morbidities, and others. Mature colonic bacterial microbiota (community of micro-organisms) in a healthy adult is generally resistant to C difficile colonization. Any factor altering the balance of intestinal microbiota leads to a selective advantage and colonization by C difficile colonization after exposure to the bacteria
The standard treatment for C difficile associated disease includes discontinuation of offending/inducing antibiotic and treatment with metronidazole or vancomycin. Most patients initially respond to this therapy, but 15-30% experience a symptomatic recurrence after discontinuation of the treatment. The risk of recurrence rises to 40% after a first recurrence and to more than 60% after two or more recurrences. The increased incidence and severity of CDI, and the high recurrence rate with conventional treatments have led researchers to explore alternative strategies and therapies with varying degrees of success. These include the use of additional courses of metronidazole and vancomycin, pulsed/tapered antibiotics, the use of new drugs as nitazoxanide and fidaxomicin, immune therapy such as IV immunoglobulin, active immunization, toxin binding, and alternative approaches as the use of probiotics (such as lactobacillus species, which is a low-virulent microorganism that could compete with C difficile for nutrients and sites of mucosal adherence), and fecal transplantation to recreate the colonic environment (Brandt 2012, Guo 2012, Kassam 2011, 2013).

Fecal transplantation (FT), also known as fecal microbiota transplantation (FMT), fecal bacteriotherapy, fecotherapy, fecal microbiota reconstitution, or human probiotics infusion, refers to the process of instilling a liquid suspension of stool from a healthy donor into the gastrointestinal (GI) tract of another person, theoretically to promote normalization of flora and restore the intestinal microbiota. It is of particular utility in recurrent or refractory C difficile infection. The exact mechanism of FMT in treating CDI is not clear but may involve the re-colonization of microbiota with missing components to generate colonization resistance or direct antagonistic activity of the normal microbiota to C difficile. There is also the possibility that the transplantation of donated flora results in an immunological response facilitating the eradication of C difficile. The re-establishment of the normal composition of the intestinal flora by the use of human fecal microbiota was first used by Ben Eiseman in 1958 for the treatment of four patients with pseudomembranous colitis. Lately, FMT has received more attention with the publication of promising results of case series. It is however, not widely accepted as a therapeutic tool due to lack of published trials with long-term outcomes and concerns regarding its safety and acceptability (Guo 2012, Matilla 2012).

There is no clear definition of CDI, its recurrence, relapse or re-infection, and there is no standardized protocol for FMT as regards the choice of donor (family member or volunteer donor), screening of donors, quantity and preparation of stools collected, form of infusion, and measurement of outcomes. There is also no consensus on the most appropriate form of delivery for the fecal microbiota. Until 1989 retention enema was the most common route for FMT; subsequently it was infused via nasogastric tube, colonoscopy and more recently self-administered enemas. The colonoscopic approach seems to be the most common and favored approach as it allows the examination of the disease extent and inoculation of the entire colon and ileum. Regardless of the delivery method, the steps of the procedure are similar and include evaluating the patient eligibility, patient consent, identification and screening of donors, preparation of the sample, and infusion of the suspension prepared. Donor stool is most often used within 8 hours of passage, but frozen samples have been thawed and used 1-8 weeks after passage. Stool is commonly suspended in saline; however, water, milk, and yogurt have also been used as diluents. The suspension is filtered through gauze pads or strainer, and then aspirated into syringes for use. The

Back to Top

volume of stool suspension used for FMT varied between studies from less than 200 ml to 500 ml or more. Patients undergoing FMT typically remain on their CDI antimicrobials until 2-3 days prior to the procedure. Bowel preparation is performed regardless of the route. If infused via nasogastric tube, the suspension is applied after fitting the tube in place. After the infusion the tube is rinsed with saline solution and removed. If applied via colonoscopy, the colonoscope is inserted and advanced to the terminal ileum, and then working backwards the stool suspension is administered, most in the terminal ileum and ascending colon. The aftercare requires regular clinical checkups and testing the stools for C difficile. The risk of the procedure includes risks associated with application as perforation and hemorrhage, as well as the risk of microbial translocation and sepsis. FMT is relatively contraindicated in patients with severe comorbid conditions or those taking immunosuppressants, though such patients have been successfully treated with the fecal transplant (Brandt 2011, Gough 2011, Postigo 2012, Rohlke 2012, Kleger 2013, Aroniadis 2013).

Fecal transplantation is not regulated by FDA, to date, as fecal matter is organic. According to the FDA the complex nature of FMT products presents specific scientific and regulatory challenges. The Center for Biologics Evaluation and Research (CBER), together with the National Institute of Allergy and Infectious Disease (NIAID) are holding a public workshop in May 2013, to facilitate clinical development of FMT.

Medical Technology Assessment Committee (MTAC)

Fecal GI infusion for the Treatment of C. Difficile infection

04/15/2013: MTAC REVIEW

Evidence Conclusion: There is some evidence from one small RCT that fecal transplantation has a significantly higher success rate than vancomycin in treating patients with recurrent C difficile infection. Meta-analyses of case series with no control groups also show a high cure rate of recurrent CDI with FMT. There is insufficient evidence to determine whether FMT is effective for the treatment of patients with the more virulent strain ribotype 027 C difficile. There is insufficient evidence to determine the most effective and safe modality for delivering the FMT. There is insufficient evidence to determine the long-term efficacy and safety of FMT.

Articles: The literature search for studies on fecal transplantation for the treatment of *C difficile* infection revealed one recent RCT (van Nood 2013), and four systematic reviews (Gough 2011, Guo 2012, Kassam 2013 and Sofi 2013). The latter two pooled the results of the published studies in meta-analyses. Sofi and colleague's analyses combined the results of case series and case reports, while Kassam and colleagues excluded the small case series (<10 subjects) and case reports in an attempt to minimize bias. The search also identified a review comparing nasogastric versus colonoscopic FMT (Postigo 2012), and a protocol for a Cochrane review, which is still being prepared. van Nood 2013 RCT, and the Kassam and colleagues' meta-analysis that had a more valid methodology were selected for critical appraisal: van Nood E, Vrieze A, Nieuwdorp M, et al. Duodenal infusion of donor feces for recurrent Clostridium difficile, *N Engl J Med.* 2013; 368:407-415. See Evidence Tables. Kassam Z, Lee CH, Yuan Y et al. Fecal Microbiota Transplantation for Clostridium difficile Infection: Systematic Review and Meta-Analysis. *Am J Gastroenterol* 2013; Mar 19. doi:10.1038/ajg.2013.59 See Evidence Tables.

The use fecal GI infusion for the treatment of C. difficile infection meets the *Kaiser Permanente Medical Technology Assessment Criteria*.

Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection

BACKGROUND

Clostridium difficile (*C difficile*) infection (CDI) is one of the most prevalent hospital acquired infections in the United States and is the leading cause of antibiotic associated diarrhea. The incidence of *C*DI has increased to an epidemic level; it has become more severe, more refractory to standard treatment, and more likely to relapse. According to the CDC, CDI was estimated to have caused almost half a million infections in the United States in 2011, and 29,000 deaths within 30 days of the initial diagnosis. It is believed that the rise in incidence and severity of the disease may be related to the emergence of the hypervirulent strain of the organism (NAP1/BI/027) that is particularly associated with higher rates of treatment failure and recurrence (Youngster 2014, Hirsch 2015, CDC webpage accessed November 2015). CDI is responsible for a spectrum of infections including uncomplicated diarrhea, pseudomembranous colitis, and toxic megacolon, which may lead to sepsis and even death. It often occurs in patients in health-care settings where antibiotics are prescribed, and symptomatic patients are concentrated. The most common risk factor for CDI is the use of broad-spectrum antibiotics or the concomitant use of multiple and prolonged antimicrobials. Other risk factors include advanced age (65 years or older), recent organ transplantation, gastrointestinal surgery, inflammatory bowel disease, immunosuppressive drugs, presence of multiple co-morbidities, and others. Mature colonic bacterial microbiota (community of micro-organisms) in a healthy adult is generally resistant to colonization and overgrowth of pathogenic bacteria. Any factor altering the balance of intestinal microbiota allows pathogens such as *C difficile* to proliferate and dominate the gut ecosystem

(Matilla 2012, Rohlke 2012, Sofi 2012, Brandt 2012, Kassam 2013, Hirsch 2015). The standard management of CDI includes discontinuation of offending/inducing antibiotic and treatment with metronidazole or vancomycin. Most patients initially respond to this therapy, but 15-30% experience symptomatic recurrence after discontinuation of the treatment. It is reported that antibiotics targeting CDI may eradicate the active infection, but do not restore the long-lasting dysbiosis of the microbiota, which is the major risk factor for relapse. This risk rises to 40% after a first recurrence and to more than 60% after two or more recurrences. The increased incidence and severity of CDI, and the high recurrence rate with conventional treatments have led researchers to explore alternative strategies and therapies with varying degrees of success. These include the use of additional courses of metronidazole and vancomycin, pulsed/tapered antibiotics, the use of new drugs as nitazoxanide and fidaxomicin, immune therapy such as IV immunoglobulin, active immunization, toxin binding, and alternative approaches such as use of probiotics as lactobacillus species, which is a low-virulent microorganism that could compete with *C difficile* for nutrients and sites of mucosal adherence, and fecal microbiota transplantation (Brandt 2012, Guo 2012, Kassam 2013, Hirsch 2015). Fecal microbiota transplantation (FMT), also known as fecal transplantation (FT), fecal bacteriotherapy, fecotherapy, fecal microbiota reconstitution, or human probiotics infusion, refers to the process of transplantation of stools from a healthy individual into the gastrointestinal (GI) tract of the affected patient, theoretically to promote normalization of flora and restore the intestinal microbiota. It may be particularly useful in recurrent or refractory *C difficile* infection. The exact mechanism of FMT in treating CDI is not clear but may involve the re-colonization of microbiota with missing components to generate colonization resistance or direct antagonistic activity of the normal microbiota to *C difficile.* There is also the possibility that the transplantation of donated flora results in an immunological response facilitating the eradication *of C difficile.* The re-establishment of the normal composition of the intestinal flora by the use of human fecal microbiota was first used by Ben Eiseman in 1958 for the treatment of four patients with pseudomembranous colitis. Lately, FMT has received more attention with the publication of promising results of a small RCT and a number of case series (Guo 2012, Matilla 2012, van Nood 2013). There is no standardized protocol for FMT as regards the choice of donor (family member or volunteer donor), screening of donors, quantity and preparation of stools collected, form of infusion, and measurement of outcomes. There is also no consensus on the most appropriate form of delivery for the fecal microbiota. Traditionally FMT has been performed by transplanting a liquid suspension of feces from a related healthy donor into the gastrointestinal tract of the affected patient through nasogastric tube, endoscopy, enema, or colonoscopy. The traditional methods are time-consuming, may be technically challenging, unaesthetic, and not accepted by many patients (Brandt 2011, Gough 2011, Postigo 2012, Rohlke 2012, Kleger 2013, Aroniadis 2013). More recently, orally administered capsules containing cryopreserved fecal material have been described. The capsules are generally prepared using fecal material harvested from unrelated healthy donors fulfilling strict criteria including screening negative for HIV, hepatitis A, B, and C as well as Treponema pallidum. Fecal matter is collected under sterile conditions, combined with saline, processed, sieved, centrifuged, and mixed again with saline along with glycerol, to protect the biological material from becoming damaged when frozen. The fecal material is then dispensed into double or triple capsules and stored at -80°C (-112°F). The capsules should be kept frozen until the time of administration and ingested as quickly as possible after extraction from the freezer. Capsules may be kept at room temperature for up to 90 minutes for patient comfort and ease of swallowing. Another described method is the immediate freezing and storing of the fecal suspension or slurry in 5- or 10-ml syringes at -80°C then thawing and triple encapsulating it prior to its use. Capsules should never be refrozen and should be disposed of if not used within 90 minutes. OpenBiome (Boston, MA) a stool bank that created a fecal transplant pill (G3) recommends the intake 30 capsules, swallowed consecutively in a single session for the treatment of CDI (OpenBiome website, Youngster 2014, Hirsch 2015). FMT capsule G3 (OpenBiome) are size 00 (approximately the size of a large multivitamin) and are provided with two placebo test capsules. The patient is asked to ingest one test capsule prior to the start of treatment, under direct observation of the physician, to ensure the patient's ability to swallow. Any clinical concerns suggesting an aspiration risk is an absolute contraindication to capsule administration. Other contraindications include severe complicated CDI, dysphagia, history of gastroparesis, allergy to any of the ingredients, adverse events attributable to a previous FMT, and any condition that the treatment my pose a health risk (OpenBiome website). According to OpenBiome, FMT Capsule G3 may be used as a treatment for *C. difficile* infection not responsive to standard therapies in accordance with the FDA's guidance on the use of fecal microbiota for transplantation, and in clinical trials under an Investigational New Drug (IND) application.

12/21/2015: MTAC REVIEW

Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory *clostridium difficile* infection

Evidence Conclusion: There is a lack of published studies on the use of oral cryopreserved FMT capsules for patients with relapsing or refractory CDI. Currently the literature on oral FMT capsules for patients with relapsing *C difficile* infection (CDI) consists of two small case series and one case report. Youngster and colleagues (2014) (evidence table 1), evaluated the safety and rate of resolution of diarrhea following the administration of cryopreserved FMT capsules in 20 patients (11-89 years of age) with refractory *C. difficile* infection. The oral

Back to Top

capsulized FMT was prepared from stool samples gathered from healthy adult volunteers who had been comprehensively screened for infectious diseases and avoided eating common allergens for several days before donating. Each patient ingested 15 FMT capsules consecutively each day for two successive days. If their symptoms did not improve within 72 hours, they were offered a second course of treatment with fecal material from the same donor. They were followed-up for 6 months and the primary outcomes were safety and clinical resolution of diarrhea with no relapse at 8 weeks. The results of the study show that after the first 2 days of treatment, 14 of the 20 patients (70%) experienced clinical resolution of diarrhea, defined as less than 3 bowels movements /24 hours, and remained symptom free for 8 weeks. After a second course of treatment, four of the remaining patients became symptom free, resulting in an overall 90% rate of symptom resolution. No serious adverse events were reported. The study was a small observational study with no control or comparison group and relied on patient report on clinical outcomes. Patients with symptomatic improvement were not retested for *C difficile.* The authors indicated that it was a pilot feasibility study that only provides preliminary data on the safety and effectiveness of this the oral capsulized FMT. Hirsch et al, 2015 (Evidence table 2), conducted a chart review of 19 patients treated with orally administered FMT capsules for recurrent CDI. FMT was prepared from stools donated by healthy volunteers unrelated to the recipients. Before receiving the FMT, the patients were required to discontinue any CDI antimicrobial treatment for 24 hours and were given a proton pump inhibitor on the evening and morning prior to the therapy. After a light breakfast, they received 6-22 capsules of FMT under supervision in an outpatient setting and were instructed to sit upright and not eat for an hour after ingesting the capsules. Patients were encouraged to drink 4 oz. of fermented milk product twice daily and to consume pro-biotic nutrients for at least 3 days after the FMT. They were followed-up by phone interviews within 2 days, 3 weeks, and after 90 days to assess the response to the therapy and adverse events. Those with recurrent CDI were retreated with antimicrobial therapy and subsequently offered repeat FMT (approximately 6 weeks after the initial FMT) and followed up for an additional 90 days. The primary outcome was resolution of CDI associated diarrhea without relapse assessed at 90 days after the last FMT. 13 of the 19 patients treated (68%) responded to a single course, and four responded to the second course of therapy with a total response rate of 89%. No serious adverse events were reported. The study was a small retrospective case series with no control or comparison group and relied on patient and family report on clinical outcomes. In addition, the follow-up duration was insufficient to determine the long-term safety and effectiveness of the orally ingested FMT capsules. It is also worth noting that the authors have financial ties to Symbiotic Health Inc. Conclusion: There is insufficient evidence to determine that orally ingested FMT capsules prepared from stools provided by volunteer donors is safe and effective for the treatment of patients with CDI. There is insufficient evidence to determine that orally ingested FMT capsules prepared from stools provided by volunteer donors is safe and effective for the treatment of patients with CDI with the more virulent strain *C difficile* (NAP1/BI/027). There is insufficient evidence to determine the long-term efficacy and safety of orally ingested FMT capsules. Case series may only generate hypothesis and large RCTs with long-term follow up are studies are needed to support the observed findings and determine the optimal donor, optimal dose of FMT, long-term safety, and long-term efficacy of cryopreserved oral capsulized FMT.

Articles: The literature search revealed two small cases series (one prospective and one retrospective) and a case report on the use of oral cryopreserved FMT capsules for patients with relapsing CDI. There are no published meta-analyses or randomized controlled trials, to date, that compared the use of the oral FMT capsules to standard therapy or to other traditional methods of delivering FMT for the treatment of refractory or relapsing CDI.

The following two case series were critically appraised. Youngster I, Russell G, Pindar C, et al. Oral, capsulized, frozen fecal microbiota transplantation for relapsing Clostridium difficile infection. *JAMA*. 2014 Nov 5; 312(17):1772-1778. See Evidence Table 1. Hirsch BE, Saraiya N, Poeth K, et al. Effectiveness of fecal-derived microbiota transfer using orally administered capsules for recurrent Clostridium difficile infection. *BMC Infect Dis*. 2015 Apr 17; 15:191 See Evidence Table 2.

The use of Oral, capsulized, frozen fecal microbiota transplantation (FMT capsule, G3 OpenBiome) for the treatment of recurrent or refractory clostridium difficile infection does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

Back to Top

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/13/2013	05/13/2013 MDCRPC, 01/07/2014 MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC 05/02/2017MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC, 02/01/2022MPC, 02/07/2023MPC , 03/12/2024MPC	03/12/2024

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
01/06/2016	MTAC review was discussed at MPC and approved to adopt criteria for FMT capsule, G3 OpenBiome
05/02/2017	Revised criteria language so it is specific on how to manage care after two recurrences
05/02/2017	Adopted Kaiser Permanente policy for Medicare members
03/12/2024	MPC approved to retire clinical criteria as it meets parameters, effective August 1st, 2024. 60-day notice required.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Fertility Services

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

Referrals to Reproductive Endocrinology and Infertility (REI) specialists and associated services are not covered as a base benefit and are only eligible for coverage when the member has a sterility and infertility (SI) rider or other evidence of coverage in their contract. **When a Sterility/Infertility (SI) rider is present, initial consultation with an REI specialist is covered without additional criteria review. However, tests and procedures are subject to clinical criteria (as elaborated below).**

Please note that individual riders/contracts may vary in benefit design either excluding or waiving criteria for some services. These may include, but are not limited to, fertility-promoting medications, medications for erectile dysfunction, artificial insemination, in vitro fertilization, long-term cryopreservation, surrogacy services and tubal reanastomosis. The member's rider/contract should be reviewed before making a final coverage determination and supersedes clinical review criteria.

Reproductive services are also subject to lifetime coverage limits which vary by rider/contract and service category.

Exclusions

Unless otherwise stated in the members rider/contract, the following services are not covered

- Reproductive services after voluntary sterilization of a male or female partner (e.g., tubal ligation, vasectomy), including tubal reanastomosis, vas reanastomosis, sperm extraction, artificial insemination and in vitro fertilization
- Long-term cryopreservation (i.e., apart from real-time efforts to conceive)
- Costs related to donor genetic material used for artificial insemination or invitro fertilization
- Services for the purpose of surrogacy
- Routine use of pre-implantation genetic testing (with IVF); medical necessity criteria for pre-implantation genetic testing can be found in a separate clinical criteria - see PGD criteria here

The following services are subject to clinical review criteria unless the services have been specifically excluded or the criteria has been waived in the member's rider/contract.

Back to Top

Date Sent: 4/29/24

Definition of Infertility	The definition of infertility is used to determine eligibility for infertility workup (e.g., diagnostic laboratory or imaging studies) apart from other reproductive services enumerated below. Based on Kaiser Permanente policy, a member is considered infertile if they are unable to conceive or produce conception: • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under 35 years of age or 6 months for members 35 years of age and older • Inability to achieve conception after 6 cycles of artificial insemination (of which at least 3 cycles must be medically supervised) for members under 35 years of age or 3 cycles of medically supervised artificial insemination for members 35 years of age and older • A member is not considered "infertile" if they have had a voluntary sterilization (e.g., tubal ligation, vasectomy) *S*ome members may be eligible for reproductive services without meeting the definition of infertility. Please refer to specific criteria listed below.*
Pharmaceutical Therapy to Promote Fertility	• Both oral and injectable medications to promote ovulation for the purpose of fertility require evidence of coverage (SI rider or contract language) and are covered under the pharmacy benefit subject to any applicable prior auth requirements. • Medications for erectile dysfunction are not covered under this policy but may or may not be covered under the pharmacy benefit subject to any applicable prior auth requirements.
Artificial insemination (AI)	AI including intravaginal, intracervical, and intrauterine insemination techniques and associated medications, laboratory, imaging, and procedure codes may be covered for the purpose of conception. This includes hysterosalpingogram that would confirm tubal patency necessary for the success of such techniques. Members are eligible for coverage when they have a SI rider that does not specifically exclude these services, have not exceeded their lifetime maximum and meet **ONE OR MORE** of the following criteria: • Natal female member without a male partner (applies to single members and same-sex female couples) • Natal female member's male partner is unable to participate in natural insemination due to a physical condition. Erectile dysfunction responsive to medical therapy is excluded even when such medication is not a covered benefit. • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under 35 years of age or 6 months for members 35 years of age and older • Documentation of an infectious disease that would make unprotected heterosexual intercourse unsafe according to the medical opinion of the member's treating clinician • Documentation of a heritable genetic trait in the male partner (such as an autosomal dominant trait in the male or co-occurrence of an autosomal recessive trait in both partners)

Back to Top

Date Sent: 4/29/24

	would jeopardize the future health of naturally inseminated offspring according to the medical opinion of the member's treating clinician and the member intends to use donor genetic material that does not pose the same risk
In Vitro Fertilization (IVF)	IVF techniques including egg retrieval, fertilization, short-term storage, implantation and associated medications, laboratory, imaging, and procedure codes are eligible for coverage when the member has an SI rider that does not specifically exclude these services, has not exceeded their lifetime maximum and meets **ONE OR MORE** of the following criteria: • Inability to achieve conception after frequent unprotected heterosexual intercourse lasting 12 months for members under 35 years of age or 6 months for members 35 years of age and older • Presence of previously diagnosed male-factor infertility that is reasonably expected to prevent conception (with heterosexual intercourse or artificial insemination). Mild to moderately reduced sperm count and/or motility are not included. • Inability to achieve conception after 6 cycles of artificial insemination (of which at least 3 cycles must be medically supervised) for members under 35 years of age or 3 cycles of medically supervised artificial insemination for members 35 years of age and older • Presence of previously diagnosed female factor infertility that is reasonably expected to prevent conception with heterosexual intercourse or artificial insemination (e.g., fallopian tubes are not patent) • Member has coverage and meets criteria for Preimplantation Genetic Testing
Surgical Procedures of the Fallopian Tube(s) to Promote Fertility	Surgical therapy of the fallopian tube(s) to promote fertility may be covered when the patient has an SI rider or evidence of coverage in their contract and meets **ALL** of the following criteria: • Member meets the definition of infertility above • Imaging (HSG) confirms scarring of the fallopian tube(s) or the patient has undergone prior surgery of the fallopian tube(s) not for the purpose of voluntary sterilization (e.g. ectopic tubal pregnancy) • The member intends to become pregnant once tubal patency is re-established • The member has not had a voluntary tubal ligation for the purpose of sterilization

If requesting these services, please send the following documentation to support medical necessity:

• Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Back to Top

Infertility is a common problem. According to the Centers for Disease Control and Prevention (CDC), about 10 percent of U.S. women ages 15 through 44 years have difficulty getting pregnant or staying pregnant.[1]

Both women and men can have problems that cause infertility. About one-third of infertility cases can be connected to the woman. Another third of the cases of infertility can be connected to the man. In the remainder of instances, a cause can't be found.

Applicable Codes

Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
Diagnostic services to Evaluate Potential Infertility	
54500	Biopsy of testis, needle (separate procedure)
54505	Biopsy of testis, incisional (separate procedure)
54800	Biopsy of epididymis, needle
55200	Vasotomy, cannulization with or without incision of vas, unilateral or bilateral (separate procedure)
55300	Vasotomy for vasograms, seminal vesiculograms, or epididymograms, unilateral or bilateral
55550	Laparoscopy, surgical, with ligation of spermatic veins for varicocele
58340	Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS) or hysterosalpingography
58345	Transcervical introduction of fallopian tube catheter for diagnosis and/or re-establishing patency (any method), with or without hysterosalpingography
58350	Chromotubation of oviduct, including materials
58540	Hysteroplasty, repair of uterine anomaly (Strassman type)
58560	Hysteroscopy, surgical; with division or resection of intrauterine septum (any method)
58700	Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)
58740	Lysis of adhesions (salpingolysis, ovariolysis)
58752	Tubouterine implantation
58770	Salpingostomy (salpingoneostomy)
58920	Wedge resection or bisection of ovary, unilateral or bilateral
74740	Hysterosalpingography, radiological supervision and interpretation
76831	Saline infusion sonohysterography (SIS), including color flow Doppler, when performed
89300	Semen analysis; presence and/or motility of sperm including Huhner test (post coital)
89310	Semen analysis; motility and count (not including Huhner test)
89320	Semen analysis; volume, count, motility, and differential
89321	Semen analysis; sperm presence and motility of sperm, if performed
89322	Semen analysis; volume, count, motility, and differential using strict morphologic criteria (eg, Kruger)
89325	Sperm antibodies
89329	Sperm evaluation; hamster penetration test
89330	Sperm evaluation; cervical mucus penetration test, with or without spinnbarkeit test
89331	Sperm evaluation, for retrograde ejaculation, urine (sperm concentration, motility, and morphology, as indicated)
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner
Q0115	Postcoital direct, qualitative examinations of vaginal or cervical mucous
S3655	Antisperm antibodies test (immunobead)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Back to Top

CPT® or HCPC Codes	Description
Intrauterine Insemination (ICI/IUI)	
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
89260	Sperm isolation; simple prep (eg, sperm wash and swim-up) for insemination or diagnosis with semen analysis
89261	Sperm isolation; complex prep (eg, Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
89268	Insemination of oocytes
S4035	Stimulated intrauterine insemination (IUI), case rate
Advanced Reproductive/Fertilization Services (IVF)	
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation
89250	Culture of oocyte(s)/embryo(s), less than 4 days;
89251	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89257	Sperm identification from aspiration (other than seminal fluid)
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89264	Sperm identification from testis tissue, fresh or cryopreserved
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89335	Cryopreservation, reproductive tissue, testicular
89337	Cryopreservation, mature oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356	Thawing of cryopreserved; oocytes, each aliquot
S4011	In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate
S4020	In vitro fertilization procedure cancelled before aspiration, case rate
S4021	In vitro fertilization procedure cancelled after aspiration, case rate
S4027	Storage of previously frozen embryos
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit
S4037	Cryopreserved embryo transfer, case rate
S4040	Monitoring and storage of cryopreserved embryos, per 30 days
Zygote Intra-Fallopian Transfer (ZIFT)	
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
S4014	Complete cycle, zygote intrafallopian transfer (ZIFT), case rate
Gamete Intra-Fallopian Transfer (GIFT)	
S4013	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
Intracytoplasmic Sperm Injection (ICSI); or Ovum Microsurgery	
55870	Electroejaculation
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, microtechnique; greater than 10 oocytes
Sterilization Reversal Services	

Back to Top

Date Sent: 4/29/24

55400	Vasovasostomy, vasovasorrhaphy
58750	Tubotubal anastomosis
58760	Fimbrioplasty
58672	Laparoscopy, surgical; with fimbrioplasty
58673	Laparoscopy, surgical; with salpingostomy (salpingoneostomy)

Considered Not Covered:
Unless otherwise stated in the members rider/contract, the following services are generally not covered

CPT® or HCPC Codes	Description
89342	Storage (per year); embryo(s)
89343	Storage (per year); sperm/semen
89344	Storage (per year); reproductive tissue, testicular/ovarian
89346	Storage (per year); oocyte(s)
S4023	Donor egg cycle, incomplete, case rate
S4025	Donor services for in vitro fertilization (sperm or embryo), case rate
S4026	Procurement of donor sperm from sperm bank

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Date	Date Last Revised
1/25/2019	02/05/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 04/02/2024[MPC]	08/22/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt coverage for KP I&F and SBG plans
06/04/2019	Added SEIU has no requirements regarding: age, duration of time, or gender per SEIU contract
05/05/2020	Information regarding the SI-AO rider for SIEU cryopreservation (Effective 8/1/2020) was added
01/04/2022	Added definition of infertility from KP policy document. Listed groups that are no longer requiring a diagnosis of infertility for members to access benefit as of 01/01/2022.
12/16/2022	Updated criteria to include indication for, *"A member is not considered "infertile" if they have had a voluntary sterilization."*
06/06/2023	MPC approved to adopt the proposed changes to Fertility Services criteria definition of infertility with additional indications for AI and IVF. Renamed title of criteria to "Fertility Services" (formerly Infertility Services). Requires 60-day notice, effective 11/1/2023.
8/22/2023	Updated applicable codes

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Hip Surgery Procedures for Femoroacetabular Impingement Syndrome

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Hip Surgery Procedures for Femoroacetabular Impingement Syndrome***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Hip surgery for labral tear repair (29916)	Labral repair (29916) does not require review. When a diagnosis of labral tear has been confirmed with imaging, FAI procedures (29914 and/or 29915) may be covered as part of the repair.
Hip surgery procedures for Femoroacetabular impingement Syndrome (FAI) (29914, 29915)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to osteoarthritis. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over coverage

Back to Top

Date Sent: 4/29/24

of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration. Surgery to correct FAI includes arthroscopy, open dislocation of the hip, and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

Medical Technology Assessment Committee (MTAC)

Femoroacetabular Impingement Syndrome

06/17/2013: MTAC REVIEW

Evidence Conclusion: There is no new evidence that would change or add to the recommendations of the HTA review as regards the conservative or surgical treatment of femoroacetabular impingement. The results of these non-randomized observational studies as well as other published retrospective series with or without a comparison group should be interpreted with caution. Due to the nature of the study design, they are subject to selection bias, observation bias, confounding and other limitations, and only provide the lowest grade of evidence.
Articles: Larson CM, Giveans R, Stone RM, et al. Arthroscopic debridement versus refixation of the acetabular labrum associated with femoroacetabular impingement. Mean 3.5 –year follow-up. *Am J Sports Med*. 2012; 40:1015-1021. Larson and colleagues (2012) reported on outcomes of two cohorts of patients with femoroacetabular impingement who were treated with either arthroscopic debridement or refixation of the acetabular labrum in one center, but at different time periods. The mean follow-up ranged between 24 and 72 months with a mean of 42 months. The results indicate that the labral fixation was associated with better Harris Hip Scores (HHS), Short Form-12 (SF-12) and visual analog scale (VAS) for pain outcomes compared to arthroscopic focal debridement. Zingg PO, Ulbrich EJ, Buehler TC, et al. Surgical hip dislocation versus hi arthroscopy for femoroacetabular impingement. Clinical and morphological short-term results. *Arch Orthop Trauma Surg*.2013; 133:69-79. Zingg and colleagues (2013) compared surgical hip dislocation versus hip arthroscopy in 38 patients presenting with clinically FAI that was morphologically verified with plain radiographs and MRI. In 28 of the 38 participants the selection of the procedure was based on the patient's decision, and only 10 agreed to be randomly allocated to either procedure. There were statistically significant differences in the morphological pathology (in terms of acetabular coverage angle, and head-neck offset ratio) between the two groups at baseline. The primary outcome of the study was the alpha angle on a cross-table view. The results of the study showed that patients in the hip arthroscopy group had faster recovery and better short-term outcomes compared to those treated with surgical hip dislocation. However, the hip arthroscopy showed some overcorrection of the cam deformity and limited frequency of labrum refixations, which the authors indicate that they may lead to negative impact on long-term outcomes.

The use of FIS does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Per the Washington State Health Care Authority Health Technology Clinical Committee (HTCC) coverage determination following Femoroacetabular Impingement Syndrome re-review (adopted 1/17/2020):

Hip surgery for femoroacetabular impingement syndrome is not a covered benefit.

Applicable Codes

Considered not medically necessary:

CPT® Codes	Description
27299	Unlisted procedure, pelvis or hip joint
29914	Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date	Date Reviewed	Date Last

Back to Top

Created		Revised
08/06/2013	02/04/2013[MPC], 12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	01/09/2024

[MPC] Medical Policy Committee

Revision History	Description
06/06/2017	Adopted KP policy for Medicare members
04/07/2020	Removed generic service code 27299 and added more specific codes 29914, 29915 and 29916
04/29/2020	Added CPT codes 27299 and 29862 and ICD-10 codes M25.851, M25.852 and M25.859
04/26/2021	Removed CPT code 29862 and ICD-10 codes M25.851, M25.852 and M25.859
11/06/2021	Removed CPT code 29916
04/05/2022	Added the Washington Health Care Authority HTCC decision from January 2020.
01/09/2024	MPC approved to revise the FAI policy to allow for FAI procedures to be authorized when a separate procedure for labral repair is indicated. 60-day notice is not required.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Foot Care

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Routine Foot care services still require review and need to meet medical necessity as outlined in the LCD. The following ***retired*** LCD's are to be used to determine medical necessity for routine foot care reviews: LCD for Routine Foot Care (L24356) These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. LCD for Symptomatic, Pathological Nail and its Treatment (L24366). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. Wound and Ulcer Care (L38904)
Local Coverage Article	None

For Non-Medicare Members

I. For the purpose of the Clinical Review Criteria foot care* is defined as:

Back to Top

A. Cutting or removal of corns or calluses;
B. Trimming, cutting, clipping, or debriding of nails;
C. Other hygienic and preventative maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot;
D. Asymptomatic foot care is not typically a covered service unless certain complications are present. It is not provided more frequently than every 60 days. The criteria below identify when foot care is covered. They are divided into sections of foot care for the asymptomatic and symptomatic foot.

II. Kaiser Permanente covers foot care services as medically necessary when **EITHER** of the following criteria is met:
   A. The foot care services that are associated with systemic conditions that are significant enough to result in severe circulatory insufficiency and/or areas of severe desensitization in the lower extremities, including, but not limited to, **ANY** of the following:
      - Marked diabetic neuropathy documented on physical exam*
      - Peripheral vascular disease*
      - Marked peripheral neuropathy documented on physical exam*
      - Non-traumatic partial amputation of a foot

*For neuropathies chart must record the physical findings of severe loss of sensation such that non-professional services might pose a danger to the patient. For peripheral vascular disease, the diagnosis and severity must have been confirmed by a vascular surgery evaluation.

   B. In the absence of a systemic condition, treatment of mycotic nails may be covered.
      - The treatment of mycotic nails for an ***ambulatory*** patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.
      - The treatment of mycotic nails for a ***non-ambulatory*** patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

III. Exclusions
   A. General diagnoses such as arteriosclerotic heart disease, circulatory problems, vascular disease, and venous insufficiency are not sufficient to permit coverage of routine foot care. Likewise, incapacitating injuries or illness such as rheumatoid arthritis, CVA, fractured hip and blindness which make trimming the nails difficult, ***are not*** diagnoses for which routine foot care is payable.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Asymptomatic foot care or routine foot care is usually not covered for members in the absence of localized illness, injury or symptoms involving the foot. Most Kaiser Permanente coverage contracts exclude routine foot care coverage. Kaiser Permanente developed criteria consistent with the Medicare those published by Medicare.

Foot care includes:
- Cutting or removal of corns or calluses
- Trimming, cutting, clipping, or debriding of nails
- Other hygienic and preventative maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

Back to Top

- Debridement of nails is a procedure that is needed to remove excessive material (reduce thickness and length) from a dystrophic nail but not a non-dystrophic nail. In contrast, trimming of nails is a procedure that may be directed at either type of nail.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
11055	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); single lesion
11056	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); 2 to 4 lesions
11057	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); more than 4 lesions
11719	Trimming of nondystrophic nails, any number
11720	Debridement of nail(s) by any method(s); 1 to 5
11721	Debridement of nail(s) by any method(s); 6 or more
G0127	Trimming of dystrophic nails, any number
G0247	Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include the local care of superficial wounds (i.e., superficial to muscle and fascia) and at least the following, if present: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails
S0390	Routine foot care; removal and/or trimming of corns, calluses and/or nails and preventive maintenance in specific medical conditions (e.g., diabetes), per visit

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/27/1997	08/03/2010[MDCRPC], 06/07/2011[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 03/12/2024[MPC]	02/02/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	Editorial changes were made to criteria
9/1/2015	Changed LCD hyperlink
09/08/2015	Revised LCD L36107 & L34199
06/07/2016	Revised criteria to simplify guidelines
08/06/2019	Criteria revision regarding need for confirmation and documentation from the appropriate vascular surgeon specialist. An amendment was made to II. A. 4. to read “non-traumatic partial amputation of a foot.”
02/02/2021	MPC approved to update criteria for routine foot care services and exclusions.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Galectin-3 Blood Assay Test

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Galectin-3 Blood Assay Test" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies for congestive heart failure (CHF).

The use of Galactin-3 for all other indications does not meet medical necessity because its clinical utility has not been established.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Heart failure (HF) is one of the most frequent and challenging medical disorders. It is a complex progressive disease with high morbidity and mortality. The prognosis of patients with HF is poor despite the advances made in the diagnosis, medical management, and device therapies. It is thus important to diagnose HF early and to identify the patients at higher risk of poor outcomes (Lok 2013, Browners 2014).

Accurate risk stratification of HF patients may help in the decision making for managing the disease; including individualizing the therapeutic approach and the proper use of invasive and costly therapies. However, risk prediction in acute, chronic, and new onset HF remains a challenge. Clinical parameters, such as advanced age, higher New York Heart Association (NYHA) functional class, reduced left ventricular ejection fraction (LVEF), lower body mass index, renal dysfunction, and anemia, have all been associated with poor outcomes in HF, but are not significant predictors of mortality. In recent years efforts were made to find biomarkers that might help in the risk stratification, and prognostication of acute and chronic heart failure. Brain natriuretic peptide (BNP) and its N-terminal part (NT-proBNP) have become well-established markers used in the diagnosis and management of HF patients. Both are released in response to myocyte stretch and provide useful information for HF diagnosis,

Back to Top

prognosis, and response to therapy. However, natriuretic peptides only indicate ventricular loading conditions and may not reveal other important mechanisms for HF. Other novel biomarkers from different physio pathological pathways such soluble ST2, growth differentiation factor-15, highly sensitive troponins, and Galectin-3, have recently emerged and are being evaluated for their potential use in adding value to the risk stratification of HF patients. For a biomarker to be useful to a clinician, it should be available, accurate, and reliable. It also should add incremental value to the clinical variables or other established markers, provide prognostic information, have an impact on patient management, and be responsive to interventions (Carrasco-Sanchez 2014, Coburn 2014, Filipe 2014, Gruson 2014, Pouleur 2014, Schmitter 4014, Srivatsan 2014).

Galectin-3 (Gal-3) is a member of a family of proteins comprising soluble β-galactoside-binding lectins that have regulatory roles in fibrogenesis, inflammation, tissue repair, and cell proliferation. It is mainly known for its role as a mediator of tumor growth, progression, and metastases. Gal-3 is also associated with increased age, diabetes, nephropathy, and fibrotic conditions such as liver fibrosis, renal fibrosis, idiopathic lung fibrosis, and chronic pancreatitis. Recently, it has been suggested that Gal-3 may play a role in the pathophysiology of HF through promotion of inflammation, myocardial fibrosis and myocardial remodeling, which are key processes for the development and progression of HF. It was thus suggested that an increased Gal-3 level in the circulation may reflect active and excessive myocardial fibrogenesis in patients with HF and can thus be used as a marker for poor prognosis related to excessive and potential irreversible myocardial fibrosis (Lok 2010, Gullestad 2013, Carrasco-Sanchez 2013, Suarez 2014).

GAL-3 is measured in the circulation by manual or automated assays. The enzyme linked immunosorbent assay manual assay (ELISA) is the most frequently used method in the published studies. Manual assays are, however, laborious and take considerable time for sampling, handling, incubation, and washing steps. More recently, several automated assays with faster delivery of the results, have been developed and are commercially available. A number of manual and automated assays have received FDA approval for measuring circulating Gal-3. Others are still seeking approval. The ARCHITECT Galectin-3 assay, BGM Galectin -3TM are among those approved by the FDA to be used in conjunction with clinical evaluation as an aid in assessing the prognosis of patients diagnosed with chronic heart failure.

Galectin-3 testing in HF patients has not been previously reviewed by MTAC. It is being reviewed for its use as a prognostic marker in patients with heart failure based on requests from contracted providers for its coverage.

Medical Technology Assessment Committee (MTAC)

Galectin-3 Blood Assay Test

02/09/2015: MTAC REVIEW

Evidence Conclusion: 1. Prognostic value of galectin-3 in patients with acute or chronic heart failure: The published studies on the prognostic value of Gal-3 in patients with HF are mainly secondary studies analyzing data from existing databases for RCTs examining the effect of drug therapy or other interventions on outcomes of patients with HF. In these studies, blood samples were obtained once at baseline and the plasma was stored for years at temperatures below 70o-80oC. Baseline plasma Gal-3 levels were then correlated with the incidence of CVD, HF, rehospitalization, and mortality during follow-up. The results were not validated in external cohorts and could be related to specific characteristics of the patients studied, or other unmeasured cofounders. There are several other issues with these kinds of analyses that would limit generalization of their results. Retrospective analyses may only suggest correlation and not causality; blood samples were obtained only once in the majority of studies, with no serial measurements of Gal-3 and thus cannot determine whether it varies by time and the effects of this variation if any, the plasma samples were frozen, and it is unknown if Gal-3 would degrade over the years. In addition, a number of these studies used arbitrary cutoff levels for Gal-3 to categorize patients into subgroups in order to test for interactions and associations. It was also questioned whether the detection of Gal-3 in the circulation accurately reflects activity in the tissues. The ideal study for evaluating the prognostic value of a novel biomarker would be a prospective study with long-term follow-up that examines the additive or incremental value of the new biomarker on top of existing established prognostic markers or clinical variables. The results should then be externally validated in other patient populations. In general, the analyses of the published studies suggest that the plasma concentration of Gal-3 is high in patients with HF. There is insufficient evidence however, to determine that the high plasma level of Gal-3 in these patients is an independent prognostic marker for poorer outcomes. The results of the published analyses are conflicting; some suggest that after adjusting for many clinical variables including NT-proBNP, elevated Gal-3 levels may be associated with higher rates of all-cause mortality, CV events and /or rehospitalization in patients with heart failure. Other analyses, on the other hand, show that after adjusting for similar or additional clinical variables including NT-proBNP, Gal-3 is not a significant independent prognostic marker for any of the outcomes studied (Table 3 shows the differences in the variables adjusted for). There were variations between the studies in their inclusion criteria, patient characteristics, cause,

Back to Top

type, severity, duration, and therapies used for managing the heart failure. There were also differences in population sizes, duration of follow-up, number of covariables used in the multivariate analyses, and the cutoff for Gal-3, which was mainly arbitrarily selected. Studies that showed a significant association between Gal-3 and outcomes tended to be smaller studies that adjusted for less clinical variables in their analyses. The two largest studies HF-ACTION (Felker et al, l 2012) and CORONA (Gullestad et al, 2014) showed that Gal-3 was significantly associated with the risk of primary outcomes studies in the univariate analyses performed, but the association observed was no longer significant when series of multivariable models including NT-proBNP were performed. Chen and colleagues (2015) performed a meta-analysis of 11 studies with 8,419 participants (Evidence table 1) to assess the association between Gal-3 and adverse outcomes in HF patients. The pooled results of the analysis suggest that increased serum Gal-3 was associated with higher all-cause mortality or CV mortality after adjusting for other established factors. These results, however, have to be interpreted with caution due to several limitations. The meta-analysis pooled the results of studies including patients with acute or chronic, and with systolic or diastolic heart failure, and conducted among different patient populations. Two of the 11 studies included in the analysis were performed by the same principal authors among the same group of patients. There was significant heterogeneity between the studies as well as significant publication bias. The population sizes varied between the included studies from 240 to 1,440 patients, and the follow-up duration ranged between 1 and 8.7 years. There were also differences between the studies in the cutoff values for Gal-3 and the variables adjusted for in calculating the hazard ratios (table 3). Meijers et al's (2014) pooled analysis (Evidence table 2) of three clinical trials showed that patients with elevated Gal-3 (>17.8 ng/mL) were more likely to be re-hospitalized for HR at 30, 60, 90, and 120 days after discharge. Gal-3 was found to be an independent predictor for re-hospitalization after adjusting for age, gender, NYHA class, renal function, LVEF, and BNP. Addition of Gal-3 to the clinical risk model comprising these variables significantly improved the net risk classification of patients for postdischarge rehospitalization and fatal events at each time point. The pooled analysis had its limitations and its results should be interpreted with caution.

2. Incremental value of galectin-3: The most commonly used way to evaluate the ability of a prognostic HF biomarker in predicting an event is to assess the area under the Receiver Operator Curve (AUC) which is a balance of sensitivity and specificity of the test or tool, and to compare it with a gold standard (C-statistics). However, a small but statically significant difference between the AUC for the gold standard and biomarker studied, may be clinically irrelevant, and there is no generally agreed upon clinically improvement in the C-statistics (Januzzi 2014). Area under Receiver Operator Curve (AUC) for Gal-3, NT-proBNP, and combinations

Author/ Study	N of patients	Outcome	AUC						
			Clinical model	Ref. † model	Gal-3	NT-proBNP Or BNP	Clinical or Reference model +Gal-3	Clinical model +BNP	Gal-3 +BNP
Zhang et al, 2015	1,440	All-cause death		0.82	0.71	0.79	0.83		0.81
		CV death		0.83			0.83		
Ahmad et al 2014/ HF-ACTION	813	Pump failure	0.82		0.76	0.83	0.83	0.87	
		SCD	0.68		0.66	0.67	0.71	0.73	
De Boer et al, 2010/COACH	592	Death or HF hospitalization			0.67	0.65 (BNP)			0.69
Lok, et al, 2010/ DEAL-HF* 2013	232	All-cause mortality			0.612	0.611			
	209				0.68	0.63			0.69
Van Kimmenade 2006**	599	Mortality			0.74	0.67			

†Reference model included sex, age, DM, ischemic HD, SBP, NYHA functional class, LVEF, ARB/ACE I, B-blocker, hemoglobin, sodium, and NT-proBNP.

*Patients with high baseline levels of both markers were observed to have approximately 1.5-2-fold higher mortality rate compared to those in other categories.

** The combination of an elevated galectin-3 with NT-proBNP was a better predictor of mortality than either of the 2 markers alone.

Back to Top

oCutoff values for Gal-3 were: 22.4 for in-hospital death in Zhang et al's study (sensitivity =0.69 and specificity =0.62), 13.9 ng/mL in HF-ACTION, and 18.05 ng/mL in DEAL-HF
oCutoff values for NT-proBNP were: 2,472 pg/mL in Zhang et al's study, and 852 pg/mL in HF-ACTION.
Accuracy of Gal-3 in the diagnosis of HF was studied in a small study with N= 35 patients with HF and 43 controls (Sheng et al, 2014) showing the following results:

	Sensitivity %	Specificity %	Accuracy %	PPV %	NPV %	AUC
Gal-3	94.3	65.1	78.2	68.8	93.3	0.891
NT-proBNP	77.1	90.7	84.6	87.1	83.0	0.896

At a cutoff of 17.8 ng/mL for Gal-3 and 100 pg/mL for NT-proBNP

90.7 84.6 87.1
83.0 0.896

3. Clinical utility of Galectin-3: The literature search did not identify any randomized controlled trial that examined the use of Gal-3 as a target in HF therapy, or that evaluated its impact on selecting a management strategy for patients with HF. Published studies on the disruption of galectin-3 gene to block myofibroblast activation are experimental, with the hypothesis that direct inhibition of Gal-3 may be possible by N-acetyle-seryl-aspartyl-lysyl-proline (Ac-SDKP), a naturally occurring tetrapeptide that prevents and reverses inflammation and collagen deposition in heart after hypertension or myocardial infarction (Hrynchyshyn 2013). Studies on anti-galectin-3 therapy for heart failure are ongoing. The effect of measuring the concentration of circulating Gal-3 on patient management was indirectly examined in post hoc analyses of data obtained from RCTs evaluating different therapies for HF; rosuvastatin in the CORONA study and valsartan in the Val-HeFT.
The CORONA study (Kjekshus et al, 2007) aimed at examining the beneficial effects of rosuvastatin among patients with chronic, symptomatic, systolic, ischemic heart failure. The trial randomized 5,011 patients over the age of 60 years, with chronic ischemic heart failure to receive 10 mg of rosuvastatin or placebo per day. The primary composite outcome was death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke. Secondary outcomes included death from any cause, any coronary event, death from cardiovascular causes, and the number of hospitalizations. After a median follow-up of 32.8 months the results of the trial showed that rosuvastatin did not reduce the primary outcome or the number of deaths from any cause in these older patients with systolic heart failure but reduced the number of cardiovascular hospitalizations. In a post hoc analysis of CORONA study, Gullestad and colleagues (2012) investigated whether plasma Gal-3 can identify patients with chronic HF for whom statins are effective. Of the 5,011 patients enrolled in the CORONA study, 1,462 (29%) patients had baseline plasma specimens available for measuring Gal-3. These were obtained from nonfasting blood samples obtained at baseline and stored at -80oC. There were significant baseline differences between this subset of patients and the entire CORONA participants. For this secondary analysis, the investigators categorized patients into two groups based on the median Gal-3 baseline level (19.0 ng/mL) and found that after a median follow-up of 32.8 months, patients with Gal-3 below the median level who were assigned to rosuvastatin had significantly lower primary event rate, lower total mortality, and lower rates for the composite outcome of all-cause mortality and HF hospitalization, compared to placebo. No benefits were observed for patients with Gal-3 above the median level. The authors noted that the combination of Gal-3 and NT-proBNP (at cutoff of 102.7 pmol/L) identified patients with a large benefit from rosuvastatin treatment. Val-HeFT trial (Cohn et al, 2001) was a randomized placebo-controlled trial that enrolled 5,010 patients >18 years of age with symptomatic HF to evaluate the efficacy of valsartan. Blood was sampled, and the separated plasma was stored at -70oC. The primary outcomes of Val-HeFT were all-cause mortality and the first morbid event (defined as death, sudden death with resuscitation, hospitalization for HF, or the administration of intravenous inotropic drug or vasodilator for four or more hours without hospitalization). The results of the trial showed that after a median follow-up duration of 23 months, valsartan had no effect on mortality, but reduced the first morbid event by13% and hospitalization for HF by 28%. These 3 endpoints were analyzed in the Galectin-3 substudy by Anand and colleagues (2013). This post hoc analysis of Val-HeFT trial examined whether circulating Gal-3 levels can predict the response to valsartan. Baseline samples for measuring Gal-3 were available for 1,650 patients (~30% of the participants). The overall results of this secondary analysis indicate that the use of valsartan was not associated with a beneficial effect on any outcome in this subgroup of patients with available baseline Gal-3 measurements. The authors then arbitrarily categorized patients into two groups based on the median level of Gal-3 (16.2 ng/mL) and found that valsartan treatment was associated with a significant decrease in hospitalization only among patients with Gal-3 below the median level and not for those with levels above the median. This is a posthoc analysis with several limitations and does not directly examine the impact of measuring Gal-3 levels on patient management, and/or treatment outcomes. The results of these post hoc analyses should be interpreted with caution due to several limitations. The studies did not directly examine the impact of

Back to Top

measuring Gal-3 levels on patient management, and/or treatment outcomes. They were secondary analyses that included less than one third of the population in each of the two trials, there were some significant baseline differences between the patients with Gal-3 measurements and the entire participants in each of the studies, Gal-3 was measured from specimens obtained at baseline and stored for years, and the results of the trials did not show any significant effect of either drug used (rosuvastatin or valsartan) on the primary outcomes studied. *Conclusions:* There is insufficient evidence from longitudinal studies with long-term follow-up and serial measurements of Gal-3 to determine that elevated circulating Gal-3 levels are independent prognostic markers for poor outcomes in patients with HF. There is insufficient evidence to determine that Gal-3 adds clinically significant incremental value to established markers and clinical variables. There is insufficient evidence to determine that circulating Gal-3 has an impact on management decisions made for patients with HF.
Articles: The literature search revealed over 200 articles on Galectin-3 and heart failure. The great majority were unrelated to the current review. There were several published studies on the prognostic value of Gal-3 in patients with heart failure. These were mainly secondary analyses of data or subsets of data collected for patients enrolled in large cohort studies or randomized controlled trials that investigated different other therapies or interventions. The search also identified a pooled analysis of the results of 3 trials (Meijers 2014), and a more recent meta-analysis (Chen et al, 2015) that pooled the results of 11 studies. The literature search did not identify any RCT that directly studied the impact of using the plasma levels Gal-3 on the management of patients with HF. The two meta-analyses were selected for critical appraisal (Evidence tables 1 & 2). The characteristics of the studies included in the larger meta-analysis as well as selected studies published in the last 5 years and not included in the meta-analyses were reviewed and summarized in Evidence Table 3. Chen A, Hou W, Zhang Y et al. Prognostic value of serum galectin-3 in patients with heart failure: a meta-analysis. Int J Cardiol 2015; 182:168-170. See Evidence Table 1. Meijers WC, Januzzi JL, de Filippi C, et al. Elevated plasma galectin-3 is associated with near-term rehospitalization in heart failure: a pooled analysis of 3 clinical trials. Am Heart J. 2014 Jun;167(6):853-60.e4.See Evidence Table 2.

The use of Galectin-3 Blood Assay Test does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
82777	Galectin-3

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
03/03/2015	03/03/2015[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	08/04/2015

[MPC] Medical Policy Committee

Revision History	Description
08/04/2015	Addendum: Insufficient Evidence for all other indications Addendum: Congestive Heart Failure (CHF) as an indication

Back to Top

KAISER PERMANENTE®

Clinical Review Criteria

Gender Affirming Surgeries

Kaiser Foundation Health Plan of Washington

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Gender Dysphoria and Gender Reassignment Surgery (140.9). CMS has deferred to the local MAC for decision coverage (Noridian for Washington State. Currently Noridian has no policy as of 04/05/2022)
Local Coverage Determinations (LCD)	None
Local Coverage Article	MM9981 - Gender Dysphoria and Gender Reassignment Surgery
Kaiser Permanente Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Gender Affirming Surgeries***" for medical necessity determinations. Use the Non-Medicare criteria below.

Self-Funded Groups:

Coverage may vary for members of self-funded groups and may provide additional exclusions – see member's specific contract or contact member services for specific exceptions and limitations.

Self-Funded Group	Policy
For Microsoft employees	See the member's contract for specific coverage details
For Sound Health and Wellness	See ***Non-Medicare policy*** below for coverage details, **with the exception of the following exclusions**: • Facial contouring and other facial reconstructive surgeries; and • Procedures including but not limited to hairline advancement and transplantation; and • Body hair removal (*except face/neck and preop genital hair removal*); and • Voice modification including speech therapy; and • Collagen injections • Liposuction • Abdominoplasty; and • Other cosmetic procedures are not covered services under the plan *Per the Summary of Material Modifications dated March 31, 2023*
For Washington State Teamsters Trust	See the member's contract for specific coverage details
For King County employees	See the member's contract for specific coverage details. Coverage

Back to Top

	criteria are based on the Standards of Care published by the World Professional Association for Transgender Health.

Effective until November 1, 2023

For Non-Medicare Members:

Members must be enrolled in the Kaiser Permanente of Washington Gender Health Case Management Program to qualify for the gender health services benefit.

All referrals must be submitted by the Gender Health Case Management team.

I. Requirements for hair removal to treat gender dysphoria
Kaiser Permanente of Washington will cover hair removal for members with documented gender dysphoria according to the criteria below. Member can have either electrolysis or laser hair removal or both. The member must work with the Kaiser Permanente of Washington Gender Health Case Manager to determine the best provider for the service and arrange for either insurance billing or member reimbursement for services.

Procedures:

Facial Hair Removal*
- 16+ with parental consent or 18+ years old
- Currently on antiandrogens (spironolactone, leuprolide) unless contraindicated OR testosterone <100 OR hx of orchiectomy

Body Hair Removal*
- 16+ with parental consent or 18+ years old
- Treatment with antiandrogens for 2-3 years unless contraindicated AND testosterone <100 OR hx of orchiectomy

**Hair removal for non-binary patients reviewed on a case-by-case basis.*

Preoperative hair removal for genital reconstructive surgery – as indicated based on surgical plan, see element V below.

Note: Patients who have not had gender reassignment surgery (gonadectomy or vaginoplasty) should continue hormone/anti-androgen therapy unless contraindicated during and after hair removal to prevent recurrence.

II. Requirements for Mastectomy (i.e., initial mastectomy, with nipple sparing or tattooing) for members assigned female at birth or non-binary members. Member must meet **ALL of the following**:
- A. Age 18 years or older (Note: age requirement will not be applied to mastectomy for members assigned female at birth or non-binary members if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)
- B. Single letter of referral from a qualified mental health professional*; *and*
- C. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; *and*
- D. Capacity to make a fully informed decision and to consent for treatment; *and*
- E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.
- F. Twelve months of living in a gender role that is congruent with their gender identity (real life experience).

❖ Note that a trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy for members.

If the referring medical provider or mental health provider requests surgical intervention prior to the patient's completion of 12 months of living in desired gender, the surgeon, the primary care provider, and the qualified mental health professional must submit evidence of medical necessity and clear rationale for the proposed surgical intervention to be done early. The three providers must submit written documentation to the plan that includes:
- a. A comprehensive, coordinated treatment plan with evidence that all treatment plan criteria for surgery and treatment goals have been met; and
- b. Clear rationale for the variation from the 12-month period of living in desired gender; and

Back to Top

c. Patient understands the treatment plan, risks and benefits of surgery prior to completing the 12-month period; and
d. The plan will determine authorization and consent to care based on medical necessity from the documentation outlined in A-F above.

III. Requirements for breast augmentation for members assigned male at birth:
A. Single letter of referral from a qualified mental health professional; and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; and
C. Capacity to make a fully informed decision and to consent for treatment; and
D. Age 18 years or older (Note: age requirement will not be applied to augmentation for members assigned male at birth if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
F. Twelve months of living in a gender role that is congruent with their gender identity (real life experience) and
G. Twelve months of continuous hormone therapy as appropriate to the member's gender goals.

If the referring medical provider or mental health provider requests surgical intervention prior to the patient's completion of 12 months of hormone therapy and/or living in desired gender, the surgeon, the primary care provider, and the qualified mental health professional must submit evidence of medical necessity and clear rationale for the proposed surgical intervention to be done early. The three providers must submit written documentation to the plan that includes:

a. A comprehensive, coordinated treatment plan with evidence that all treatment plan criteria for surgery and treatment goals have been met; and
b. Clear rationale for the variation from either the 12-month period of hormone therapy and/or living for 12 months in desired gender; and
c. Patient understands the treatment plan, risks and benefits of surgery prior to completing the 12-month period; and
d. The plan will determine authorization and consent to care based on medical necessity from the documentation outlined in A-G above.

The criteria above apply for only initial augmentation mammaplasty for members assigned male at birth, any additional breast augmentation after an initial mammaplasty is considered a cosmetic procedure, and therefore, a contract exclusion.

IV. Requirements for gonadectomy (hysterectomy and oophorectomy for members assigned female at birth and orchiectomy in members assigned male at birth):
A. Two referral letters from qualified mental health professionals*, one in a purely evaluative role. (At least one letter should be an extensive report. Two separate letters or one letter with two signatures is acceptable. One referral letter can be from a Kaiser Permanente of Washington Gender Health Case Manager and the other needs to be from a qualified mental health professional*); and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age of majority (18 years or older); *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones – chart notes must describe the contraindications in detail)

V. Requirements for genital reconstructive surgery (including, but not limited to: vaginectomy, vulvectomy, colpocleisis, colpectomy, metoidioplasty, vaginoplasty, perineoplasty, colovaginoplasty, penectomy, clitoroplasty, labioplasty, phalloplasty, scrotoplasty, urethroplasty, testicular prosthesis (expanders and implants), penile prosthesis. hair removal in the pubic surgical area for members assigned male at birth, hair removal on the

 Back to Top

forearm prior to phalloplasty for members assigned female at birth, Mons Resection)

A. Two referral letters from qualified mental health professionals*, one in a purely evaluative role (At least one letter should be an extensive report. Two separate letters or one letter with two signatures is acceptable. One referral letter can be from a Kaiser Permanente of Washington Gender Health Case Manager and the other needs to be from a qualified mental health professional*); and
B. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria; and
C. Capacity to make a fully informed decision and to consent for treatment; and
D. Age 18 years and older; and
E. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); and
G. Twelve months of living in a gender role that is congruent with their gender identity (real life experience)

VI. Eligibility for: layrngochrondroplasty for members assigned male at birth is based on meeting **ALL of the following** criteria:

A. Member is at least 18 years old
B. Member has been diagnosed with persistent, well documented gender dysphoria.
C. Member has the capacity to make fully informed decisions and to consent to treatment.
D. If significant medical or mental health concerns are present, they are reasonably well controlled.
E. Member has a current referral letter for laryngochrondroplasty surgery or other gender reassignment surgery from a qualified mental health professional who has independently assessed the patient. This assessment must be current within the past 12 months. For providers working within a multidisciplinary specialty team, the assessment and recommendation can be documented in the patient's chart. The referral is expected to cover the following recommended content:
   a. The client's general identifying characteristics.
   b. Results of the client's psychosocial assessment, including any diagnoses.
   c. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date.
   d. An explanation that the criteria for surgery have been met and a brief description of the clinical rationale for supporting the patient's request for surgery.
   e. A statement about the fact that the patient has the capacity to provide informed consent.
   f. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.
F. Member has had a mental health evaluation and a medical evaluation and has been deemed to have no medical or psychological contraindications for surgery.

VII. Requirements for gender affirming voice modification surgery

A. Pitch lowering surgery (eg Type III thyroplasty) is considered medically necessary if the voice fails to deepen below speaking F0 150Hz after 1.5 years of consistent masculinization hormone therapy

OR

B. Pitch elevation surgery is considered medically necessary when speaking $F_0 < 150$ Hz

AND

C. ALL of the following are met**:**
   a. Age 18 years of age or older
   b. Persistent, well-documented gender dysphoria per DSM 5 Gender Dysphoria
   c. Capacity to make a fully informed decision and to consent for treatment
   d. Single letter of referral from a qualified mental health professional in support of the requested procedure(s)*
   e. Established with a Speech Language Pathologist (SLP) with experience working with Transgender patients for voice therapy and has engaged with voice therapy techniques with consistent follow-up, documented as attendance at ≥ 75% of sessions for at least 6 months
   f. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz (feminizing) or speaking F0 below 150Hz (masculinizing)
   g. Member agrees to follow-up post-operatively with their surgeon and voice therapist/SLP on a regular

 Back to Top

cadence (1 week, 1 month, 3 months, 6 months, 1 year, 2 years, etc.)

h. Patient has none of the following contraindications:
   1. No active laryngeal pathology, except for muscle tension
   2. No medical diagnoses that would impair wound healing
   3. No medical diagnoses that would seriously impair breathing or swallowing
   4. No planned upcoming surgeries within 2 months after pitch modification surgery
   5. If significant medical or mental health concerns are present, they must be reasonably well controlled. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.

VIII. Requirements for gender affirming facial surgery– member must meet **ALL** of the following:

A. Member is at least 18 years old
B. Member has been diagnosed with persistent, well documented gender dysphoria
C. Member has the capacity to make fully informed decisions and to consent to treatment
D. If significant medical or mental health concerns are present, they are reasonably well controlled
E. Member is undergoing or has undergone other treatments to transition gender
F. Member has a current referral letter for gender-affirming procedure(s) from a qualified mental health professional who has independently assessed the patient within the past 12 months. For providers working within a multidisciplinary specialty team, the assessment and recommendation can be documented in the patient's chart. The referral letter is expected to cover the following content:
   a. The client's general identifying characteristics.
   b. Results of the client's psychosocial assessment, including any diagnoses.
   c. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date.
   d. A statement about the fact that the patient has the capacity to provide informed consent.
   e. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

With regard to requested gender affirming facial surgery– must meet **ALL** of the following:

A. For each requested procedure, documentation from an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery) that the member experiences dysphoria specifically associated with that facial element is required (e.g., documentation of dysphoria related to a stereotypically masculine nose for a requested rhinoplasty); **AND**
B. The goal of each procedure is to alter or reshape the facial feature to an appearance that is within the range of normal for the member's identified gender, as determined by an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery)

Procedures for gender affirming facial surgery may include (but are not limited to): mandible contouring, brow lift, and forehead reduction, among others. See below for a list of common procedures* which may or may not be covered for a particular patient.

Procedures intended solely to reduce the appearance of aging that will not result in significant improvement of the condition being treated are considered not medically necessary.

*Procedures considered for gender affirming facial surgery when medical necessity criteria in the applicable policy statement listed above are met – this list represents common procedures; others will be reviewed on a case-by-case basis:

Typically covered:

- Brow lift
- Hairline advancement
- Lip lift
- Mandible contouring
- Forehead reduction and contouring

Back to Top

Sometimes covered:

- Rhinoplasty

Typically not covered:

- Blepharoplasty
- Lip augmentation
- Cheek implants
- Facelift

IX. The following procedures are **not covered** as a part of this benefit:

- Abdominoplasty
- Calf implants
- Collagen injections
- Cryopreservation of fertilized embryos
- Drugs for hair loss or growth
- Facials
- Hair implant
- Liposuction
- Mastopexy
- Neck tightening
- Pectoral implants
- Removal of redundant skin
- Reversal of prior genital surgery or reversal of surgery to revise secondary sex characteristics
- Sperm preservation in advance of hormone treatment or gender surgery
- Ultrasonic Assisted Lymphatic Massage
- All other cosmetic procedures that do not meet medical necessity

* Characteristics of a Qualified Mental Health Professional:

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria;
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; and
5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

Effective November 1, 2023

For Non-Medicare Members:

Members must be enrolled in the Kaiser Permanente of Washington Gender Health Case Management Program to qualify for the gender health services benefit. **To be considered in network all *initial* referrals for gender affirming services including surgical consults (excluding GAHT and/or blockers) must be submitted by the Gender Health Case Management team *(Not applicable for options patients utilizing out of network benefit. Out of network provider to place referral and request authorization from the health plan).***

I. Requirements for hair removal to treat gender dysphoria

Kaiser Permanente of Washington will cover hair removal for members with documented gender dysphoria according to the criteria below with a goal of hair removal to align with identified gender. Member can have either electrolysis or laser hair removal or both. The member must work with the Kaiser Permanente of Washington Gender Health Case Manager to ensure prior authorization is obtained for the service and arrange for either insurance billing or member reimbursement for services.

Procedures:

Facial Hair Removal*

Back to Top

- 16+ with parental consent or 18+ years old **AND**
- Six months of maximally tolerated Gender Affirming Hormone Therapy (GAHT) (including but not limited to antiandrogens such as spironolactone; T blockers such as leuprolide; and hormones such as: estrogen) appropriate to their desired gender, unless medically contraindicated (e.g., GAHT may be contraindicated when not consistent with members gender identity such as non-binary) **OR**
- In testicular bodied patients, testosterone <100 **OR**
- History of orchiectomy

NOTE: Hair removal is not covered for members using exogenous testosterone, as hair growth is expected

Body Hair Removal*

- 16+ with parental consent or 18+ years old **AND**
- Taking Gender Affirming Hormone Therapy (GAHT) (including but not limited to antiandrogens such as spironolactone; T blockers such as leuprolide; and hormones such as: estrogen) appropriate to their desired gender, for 2-3 years unless medically contraindicated (e.g., GAHT may be contraindicated when not consistent with members gender identity such as non-binary) **AND**
- In testicular bodied patients, testosterone <100 **OR**
- History of orchiectomy

NOTE: Hair removal is not covered for members using exogenous testosterone, as hair growth is expected

Preoperative hair removal for genital reconstructive surgery – as indicated based on surgical plan, see element IV below.

Note: Patients who have not had gender reassignment surgery (gonadectomy or vaginoplasty) should continue hormone/anti-androgen therapy unless contraindicated during and after hair removal to prevent recurrence.

II. **Requirements for Mastectomy** (i.e., initial mastectomy, with nipple sparing or tattooing) for members assigned female at birth. Member must meet **ALL of the following**:

A. Age 18 years or older (Note: age requirement will not be applied to mastectomy for members assigned female at birth if the surgeon, the primary care provider, and the qualified mental health professional unanimously document the medical necessity of earlier intervention)

B. Single letter of referral from a qualified mental health professional** within the past 18 months; and the letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question.

D. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated). **Note:** a trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy for members.

E. Patient has already undergone social transition*** or has a plan to do so after surgery

 Back to Top

III. **Requirements for breast augmentation** for members assigned male at birth:

A. Age 18 years or older

B. Single letter of referral from a qualified mental health professional** within the last 18 months; and this letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and

D. Patient has already undergone social transition*** or has a plan to do so after surgery and

E. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated)

The criteria above apply for only initial augmentation mammaplasty for members assigned male at birth, any additional breast augmentation after an initial mammaplasty is considered a cosmetic procedure, and therefore, a contract exclusion.

IV. **Requirements for gonadectomy (hysterectomy, oophorectomy or orchiectomy) and genital reconstructive surgery** (including, but not limited to: vaginectomy, vulvectomy, colpocleisis, colpectomy, metoidioplasty, vaginoplasty, perineoplasty, colovaginoplasty, penectomy, clitoroplasty, labioplasty, phalloplasty, scrotoplasty, urethroplasty, testicular prosthesis (expanders and implants), penile prosthesis, hair removal in the pubic surgical area for members assigned male at birth, hair removal on the forearm prior to phalloplasty for members assigned female at birth, mons resection:

A. Age 18 years and older; and

B. One referral letter from a qualified mental health professional** within the last 18 months; and this letter should include:

i. Gender incongruence is marked and sustained;

ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;

iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;

iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;

v. Other possible causes of apparent gender incongruence have been identified and excluded;

vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

Back to Top

C. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
D. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated); and
E. Twelve months of living in a gender role that is congruent with their gender identity (real life experience) Patient has undergone social transition*** and has been living in gender congruent identity for at least twelve months

V. Requirements for gender affirming voice modification surgery

A. Requirements for gender affirming voice modification surgery
B. Pitch lowering surgery (e.g., Type III thyroplasty) is considered medically necessary if the voice fails to deepen below speaking F0 150Hz after 1.5 years of consistent masculinization hormone therapy

OR

C. Pitch elevation surgery is considered medically necessary when speaking $F_0 < 150$ Hz

AND

D. ALL of the following are met**:**
   a. Age 18 years of age or older
   b. The health plan may require a second opinion regarding the patient's stability prior to surgery if in question; and
   c. Patient has already undergone social transition*** or has a plan to do so after surgery
   d. Stable on their gender affirming hormonal treatment regime (which may include at least 6 months of hormone treatment or a longer period if required to achieve the desired surgical result, unless hormone therapy is either not desired or is medically contraindicated)
   e. Single letter of referral from a qualified mental health professional** in support of the requested procedure(s) in the last 18 months; and the letter should include:
      i. Gender incongruence is marked and sustained;
      ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
      iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
      iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored reproductive options;
      v. Other possible causes of apparent gender incongruence have been identified and excluded;
      vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;
   f. Established with a Speech Language Pathologist (SLP) with experience working with Transgender patients for voice therapy and has engaged with voice therapy techniques with consistent follow-up, documented as attendance at ≥ 75% of sessions for at least 6 months
   g. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz (feminizing) or speaking F0 below 150Hz (masculinizing)
   h. Member agrees to follow-up post-operatively with their surgeon and voice therapist/SLP on a regular cadence (1 week, 1 month, 3 months, 6 months, 1 year, 2 years, etc.)
   i. Patient has none of the following contraindications:
      i. No active laryngeal pathology, except for muscle tension
      ii. No medical diagnoses that would impair wound healing
      iii. No medical diagnoses that would seriously impair breathing or swallowing
      iv. No planned upcoming surgeries within 2 months after pitch modification surgery

VI. **Requirements for gender affirming facial surgery**– member must meet **ALL** of the following:

A. Member is at least 18 years old; and
B. One referral letter from a qualified mental health professional** in the last 18 months; and this letter should include:
   i. Gender incongruence is marked and sustained
   ii. Meets diagnostic criteria for gender incongruence prior to gender-affirming surgical intervention in regions where a diagnosis is necessary to access health care;
   iii. Demonstrates capacity to consent for the specific gender-affirming surgical intervention;
   iv. Understands the effect of gender-affirming surgical intervention on reproduction and they have explored

Back to Top

reproductive options;
v. Other possible causes of apparent gender incongruence have been identified and excluded;
vi. Mental health and physical conditions that could negatively impact the outcome of gender-affirming surgical intervention have been assessed, with risks and benefits have been discussed;

C. Member is undergoing or has undergone other treatments to transition gender

With regard to requested gender affirming facial surgery– must meet **ALL** of the following:

A. For each requested procedure, documentation from an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery) that the member experiences dysphoria specifically associated with that facial element is required (e.g., documentation of dysphoria related to a stereotypically masculine nose for a requested rhinoplasty); **AND**

B. The goal of each procedure is to alter or reshape the facial feature to an appearance that is within the range of normal for the member's identified gender, as determined by an ABMS board-certified facial surgeon (Facial Plastic Surgery, Plastic Surgery, or Oral Maxillofacial Surgery)

Procedures for gender affirming facial surgery may include (but are not limited to): mandible contouring, brow lift, and forehead reduction, layrngochrondroplasty among others. See below for a list of common procedures* which may or may not be covered for a particular patient.

Procedures intended solely to reduce the appearance of aging that will not result in significant improvement of the condition being treated are considered not medically necessary.

*Procedures considered for gender affirming facial surgery when medical necessity criteria in the applicable policy statement listed above are met – this list represents common procedures; others will be reviewed on a case-by-case basis:

Typically covered:

- Brow lift
- Hairline advancement
- Lip lift
- Mandible contouring
- Forehead reduction and contouring
- Tracheal Shave

Sometimes covered:

- Rhinoplasty

Typically not covered:

- Blepharoplasty
- Lip augmentation
- Cheek implants
- Facelift

VIII. The following procedures are **not covered** as a part of this benefit:

- Abdominoplasty
- Calf implants
- Collagen injections
- Cryopreservation of fertilized embryos
- Drugs for hair loss or growth
- Facials
- Hair implant
- Liposuction
- Mastopexy
- Neck tightening
- Pectoral implants

Back to Top

- Removal of redundant skin
- Reversal of prior genital surgery or reversal of surgery to revise secondary sex characteristics
- Sperm preservation in advance of hormone treatment or gender surgery
- Ultrasonic Assisted Lymphatic Massage
- All other cosmetic procedures that do not meet medical necessity

**Characteristics of a Qualified Mental Health Professional for:

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; and
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; and
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria;
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; and
5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

***Social Transition: (e.g., name change, pronoun change, communication of affirmed gender identity to others) in place or judged by clinician to be unnecessary (e.g., nonbinary gender identity). This requirement is based on evidence of mental health benefits from social transition and lack of evidence to support gender affirming surgical therapy in the absence of social transition. Coverage may still be considered after additional mental health evaluation and/or explanation of not pursuing social transition.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gender Dysphoria refers to discomfort or distress that is caused by a discrepancy between a person's gender identity and that person's sex assigned at birth. Gender dysphoria is only experienced by some gender-nonconforming people.

Transgender individuals usually present to the medical profession with a sophisticated understanding of their identity, and a desired course of treatment, including hormone therapy and potentially gender-realignment surgery. The therapeutic approach to gender dysphoria consists of three elements: hormones, real life experience and, finally, surgery for some patients.

The use of hormone therapy and surgery for gender transition/affirmation is based on many years of experience treating transgender people. Research on hormone therapy is providing us with more and more information on the safety and efficacy of hormone therapy, but all of the long-term consequences and effects of hormone therapy may not be fully understood. Therefore, a careful diagnosis, differential diagnosis, and exploration of identity is absolutely vital to the patient's best interest and the patient provider relationship. A vital part of the long-term diagnostic therapy is the so-called real-life experience, in which the patient lives as a member of the desired gender continually and in all social spheres in order to accumulate necessary experience.

Hormone therapy and gender-realignment surgery are superficial changes in comparison to the major psychological adjustments necessary in affirming gender identity. One aspect of treatment should concentrate on the psychological adjustment, with hormone therapy and gender-realignment surgery being viewed as confirmatory procedures dependent on adequate psychological adjustment. Many providers and organizations are moving to an informed consent model for hormones, but surgery still needs involvement of psychology and psychiatry. Psychiatric care may need to be continued for many years after gender-realignment surgery. The overall success of treatment depends partly on the technical success of the surgery, but more crucially on the psychological adjustment of the patient, and the support from family, friends, employers and the medical profession.

Evidence and Source Documents

There was no evidence review conducted for these criteria. They were developed in response to the Washington

 Back to Top

State RCW for the coverage of gender affirming services.

Applicable Codes (not all-inclusive) – all requests require clinical review

Members Assigned Male at Birth:

CPT® or HCPC Codes	Description
55970	Intersex Surgery; male to female
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
	With diagnosis codes
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

Members Assigned Female at Birth:

CPT® or HCPC Codes	Description
55980	Intersex Surgery; female to male
	With diagnosis codes
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

Electrolysis:

CPT® or HCPC Codes	Description
17380	Electrolysis epilation, each 30 minutes

Gender Affirming Facial Surgery

Forehead Recontouring/Augmentation:

CPT® or HCPC Codes	Description
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall

Brow Lift:

CPT® or HCPC Codes	Description
15824	Rhytidectomy; forehead
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)

Hairline Correction/Scalp Advancement:

CPT® or HCPC Codes	Description
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

Back to Top

Jaw Contouring:

CPT® or HCPC Codes	Description
21299	Unlisted craniofacial and maxillofacial procedure
21209	Osteoplasty, facial bones; reduction

Chin Augmentation:

CPT® or HCPC Codes	Description
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21296	Reduction of masseter muscle and bone (e.g., for treatment of benign masseteric hypertrophy); intraoral approach

Fat Transfer:

CPT® or HCPC Codes	Description
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)

Rhinoplasty:

CPT® or HCPC Codes	Description
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)

Blepharoplasty:

CPT® or HCPC Codes	Description
15820	Blepharoplasty, lower eyelid;
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid;
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid

Dermal Filler:

CPT® or HCPC Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc

Back to Top

11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc

Suction Assisted Lipectomy:

CPT® or HCPC Codes	Description
15876	Suction assisted lipectomy; head and neck

Rhytidectomy:

CPT® or HCPC Codes	Description
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad

Voice Modification Surgery

CPT® or HCPC Codes	Description
No specific codes – *commonly submitted with CPT code 31599 Unlisted procedure, larynx*	

***Note:** Codes list is not all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
12/15/2010	01/04/2011 MDCRPC ,11/01/2011 MDCRPC, 09/04/2012 MDCRPC, 07/02/2013 MDCRPC, 05/06/2014 MPC, 11/04/2014MPC, 09/01/2015MPC, 07/05/2016MPC, 03/06/2018MPC, 02/05/2019MPC, 02/04/2020MPC, 02/02/2021MPC , 02/01/2022MPC, 02/07/2023MPC	06/06/2023

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
11/2/2015	Added Providence Health & Services and link to Sound Health & Wellness Policy & ICD-10 codes
03/08/2016	Added PEBB link
09/02/2016	Added FtM Mastectomy criteria for adolescents 16 years and older
11/01/2016	MPC approved revised indication for Electrolysis
10/02/2017	Removed the requirement for testosterone treatment for members 16-18
02/06/2018	Added criteria for M-F breast augmentation
05/01/2018	Added facials and ultrasonic assisted lymphatic massage to the non-covered list
06/05/2018	Changed the mastectomy and breast augmentation criteria
06/11/2018	Added coverage language for facial hair removal
07/10/2018	Added coverage and revised criteria language for facial hair removal
10/02/2018	Updated evaluation criteria under genital reconstructive surgery requirements
12/04/2018	Added MtF criteria to add coverage for Layrngochrondroplasty (Tracheal Shave)
04/12/2019	Added Mons Resection code to genital reconstructive surgery
01/22/2020	Minor changes to Facial Hair removal criteria
05/4/2020	Added the following procedures to section V “Requirements for genital reconstruction surgery”: vulvectomy, colpocleisis and perineoplasty
12/18/2020	MPC approved to adopt clinical criteria for Facial Harmonization and updated exclusions for the non-covered list.
02/19/2021	Included non-binary patients for facial hair removal and mastectomy indications.

Back to Top

10/04/2021	Updated terminology from female to male and male to female to assigned male at birth or assigned female at birth.
03/01/2022	MPC approved changes to criteria for hair removal, including the addition of criteria for coverage of body hair removal and updates to facial hair removal criteria.
04/05/2022	MPC approved to adopt coverage for voice modification surgery.
05/02/2023	Updated self-funded SHWT policy coverage details statement
05/08/2023	Updated additional exclusions provided by SHWT
06/06/2023	MPC has approved revisions to the clinical criteria for Gender Affirming Services, ensuring alignment with the updated guidelines from the World Professional Association for Transgender Health (WPATH). Requires 60-day notice, effective date 11/01/2023

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Genetic Screening and Testing

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage).

Prevention is the preferred labs for genetic testing, when the test(s) is/are available at Prevention and medical necessity criteria are met.*

Prevention test catalog can be found here: Prevention Test Catalog

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the genetic test(s) listed below, please use the lab specified/refer to the link attached:

- ***Cell Free Fetal DNA testing*** **– Any of these labs can be used:**
  - Ariosa (Bioreference) Diagnostics, Inc. (81507) or
  - LabCorp (81420)
  - Quest-QNatal (81420)
  - Natera (81420)

- ***Next Generation Sequencing for Advanced Cancer*** **—Any of these labs can be used:**
  - CellNetix SymGene Panel
  - Oncoplex (University of Washington)
  - Caris Life Sciences
- Prenatal Chromosomal Microarray (samples typically obtained via amniocentesis/CVS)— **Any of these labs can be used:**
  - Prevention
  - LabCorp
  - Quest (ClariSure Oligo-SNP-81229)
  - Natera (Anora-81229)
- Fetal diagnostic testing in cases of recurrent intrauterine fetal demise (definition)— **Any of these labs can be used:**
  - Prevention
  - LabCorp
- Pregnancy Carrier Screening or Preconception Counseling— **Any of these labs can be used:**
  - Prevention
  - Labcorp (Inheritest CF/SMA panel, Core panel, or Carrier screen society guided panel)
  - Quest (Prenatal Carrier Panel or QHerit expanded carrier screen)
  - Natera (Horizon panels e.g. 81443, 81490, 81408)
- Non-prenatal Chromosomal Microarray (sample obtained by blood draw)— **Any of these labs can be used:**
  - Prevention
  - LabCorp
  - Invitae

Back to Top

Related Policies:
Genetic Panel Testing
Pharmacogenomic Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2) (Applies to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) breast and ovarian cancer.) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved Companion Diagnostic tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Guardant360 TissueNext (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.) MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets)) Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) Histocompatibility Testing (190.1)
Local Coverage Determinations or Articles (LCD/LCA)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Molecular Diagnostic Tests (MDT) (L36256) MolDX: Testing of Multiple Genes (A58121) MolDX: Next-Generation Sequencing for Solid Tumors (L38121) (Applies to diagnostic lab tests using NGS for solid tumors.) MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis (L39469) MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38649) Billing and Coding: MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (A58187)

Back to Top

	Billing and Coding: MolDX: Next-Generation Sequencing for Solid Tumors (A57905) Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Testing in Cancer (A56518) Billing and Coding: MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis (A59522) MolDX: Envisia, Veracyte, Idiopathic Pulmonary Fibrosis Diagnostic Test (L37891) MolDX: Melanoma Risk Stratification Molecular Testing (L37748) MolDX: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L39003) MolDX: myPath Melanoma Assay (L37881) **RETIRED** MolDX: Oncotype DX® Breast Cancer for (DCIS) Genomic Health™ (L36947) MolDX: Pigmented Lesion Assay (L38153) MolDX: Repeat Germline Testing (L38353) ProMark Risk Score (L36706)
Decision Memo	Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451)

General Coverage Rules – LCD 24308 (retired)

1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.
527
3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

Back to Top

The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. MolDX has determined that testing for the below genes is a statutorily excluded service. Unless indicated otherwise, panels that include these genes will be denied. Please see the individual Test Coding and Billing Guidelines for each gene.

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

Local Coverage Decisions and Articles (LCD/LCA) *not all-inclusive – refer to the MolDX® Program link above*

ID	Title	Codes *(not all-inclusive)*
L36163	08/20/2022 Noridian retired LCD MolDX: BRCA1 and BRCA2 Genetic Testing These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432, 81433, 0102U, 0103U, 0129U
L36386	MolDX: Breast Cancer Assay: Prosigna	81520
L37824	MolDX: Breast Cancer Index® Gene Expression Test	81518
L36186	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	81206, 81207, 81208, 81219, 81270, 81279, 81338, 81339, 81450, 0027U, 0040U
L36159	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240, 81241, 81291
L36374	08/20/2022 Noridian retired LCD MolDX: Genetic Testing for Lynch Syndrome These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36374 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81317, 81318, 81319, 81432, 81433, 0101U
L36192	MolDX: MGMT Promoter Methylation Analysis	81287
L36544	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544) **not covered per LCD*	81383
L36256	MolDX: Molecular Diagnostic Tests (MDT)	See LCA*: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527) **Presence of a code on this LCA does not indicate coverage*
L38333	MolDX: Blood Product Molecular Antigen Typing	0001U, 0084U

Back to Top

L36329	08/08/2022 Noridian retired LCD MolDX: ConfirmMDx Epigenetic Molecular Assay These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36329 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT)	81551
L38341	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease *(Decipher and similar, i.e., Prolaris)* MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39007) Billing and Coding: MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (A58724)	81541, 81542, 0047U
L36452	01/01/2018 Noridian retired LCD MolDX: Chromosome 1p/19q Deletion Analysis (L36452). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36452 for determining medical necessity, along with L36256 MolDX: Molecular Diagnostic Tests (MDT).	
L36891	MolDX: Percepta© Bronchial Genomic Classifier	81479
L38329	MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer *(DetermaRx™)* Billing and Coding: MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	0288U
L38816	MolDX: Minimal Residual Disease Testing for Cancer L38816 MolDX: Minimal Residual Disease Testing for Hematologic Cancers A58997 (refers to coverage for ClonoSEQ for specific cancers)	81479, 0340U, 0364U

For Non-Medicare Members

Members must meet **ALL the following** criteria:

1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

Back to Top

Carrier Screening is limited to once per lifetime.

*For **specific tests listed** below the member must meet the criteria above **AND** the specific test criteria below:*

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access

Cardiology	Criteria
Arrhythmogenic Right Ventricular Cardiomyopathy – ARVC Genes	MCG* A-0627
Brugada Syndrome Channelopathy Genes	MCG* A-0594
Catecholaminergic Polymorphic Ventricular Tachycardia – Gene and Gene Panel Testing	MCG* A-0636
Coronary Artery Disease - 9p21 Allele	MCG* A-0657: This is not covered per MCG*
Coronary Artery Disease - KIF6 Gene	MCG* A-0656: This is not covered per MCG*
Coronary Artery Disease Genetic Panel	There is insufficient evidence in the published medical literature to show clinical utility.
Familial Dilated Cardiomyopathy – Gene and Gene Panel Testing	MCG* A-0648
Familial Hypertrophic Cardiomyopathy, Nonsyndromic – Gene and Gene Panel Testing	MCG* A-0633
Thoracic Aortic Aneurysm and Aortic Dissection (Hereditary) - Gene Panels	There is insufficient evidence in the published medical literature to show clinical utility.
Ehlers-Danlos Syndrome (Vascular) - COL3A1 Gene	MCG* A-0910
Loeys-Dietz Syndrome - Gene and Gene Panel Testing	MCG* A-0909
Long QT Syndrome (Hereditary) - Gene Panel	MCG* A-0918

Endocrinology	Criteria
Diabetes Mellitus, Type 2 - KCNJ11, KCNQ1, PPARG, SLC16A11 and TCF7L2 Genes	MCG* A-0826: This is not covered per MCG*
Diabetes Mellitus (Maturity-Onset Diabetes of the Young) - ABCC8, APPL1, BLK, CEL, GCK, HNF1A, HNF1B, HNF4A, INS, KCNJ11, KLF11, NEUROD1, PAX4, and PDX1 Genes	MCG* A-0598

Gastroenterology	Criteria
HLA Testing for Celiac Disease:	1. Is medically appropriate for symptomatic patients a. Despite being on a gluten free diet **OR** b. With indeterminate serology/biopsy results 2. It is not covered for a. Asymptomatic people **OR** b. Screening
Hemochromatosis - HFE Gene	Medical necessity review no longer required.
Pancreatitis, Hereditary – CFTR, CPA1, CTRC, PRSS1, and SPINK1 Genes	MCG* A-0646

Genomic Testing Methods and Technologies	Criteria
Broad Spectrum Tumor Molecular Profiling – Next Generation Sequencing (NGS)	There is insufficient evidence in the published medical literature to show clinical utility.

Back to Top

Genomic Testing Methods and Technologies	Criteria
Tacrolimus Pharmacogenetics - CYP3A4 and CYP3A5 Genes	MCG* A-0775: This is not covered per MCG*
Chromosomal Microarray Testing	1) Chromosomal microarray testing may be considered medically necessary for genetic evaluation of an individual when **ALL** of the following criteria are met: a) Testing has been requested following evaluation and genetic counseling by a medical geneticist, pediatric neurologist, or neurodevelopment pediatrician; and b) Results have the potential to affect clinical management of the patient; and c) The patient meets one or more of the following: • Multiple anomalies not specific to a well-delineated genetic syndrome • Apparently non-syndromic developmental delay/intellectual disability • Autism spectrum disorder • Dysmorphic facial features • Abnormal growth not otherwise explained 2) Chromosomal microarray testing (CPT 81228, 81229) may be considered medically necessary for patients undergoing invasive prenatal genetic testing (i.e., amniocentesis, chorionic villus sampling (CVS), or fetal tissue sampling), or a patient who has had recurrent (two or more) intrauterine fetal demise. Genetic counseling is required. Prior authorization is not required if done at Labcorp or Prevention but is required for all other vendors in advance of submitting a claim for payment. 3) Chromosomal microarray testing may be considered medically necessary for testing of one or both parents when a chromosomal deletion or duplication has been identified in one or more of their offspring and: a. Parental testing is necessary to guide a reproductive decision, or b. Parental testing is necessary to determine the clinical significance of the chromosome abnormality found in the child, and c. The result is expected to directly affect clinical management of the child The following are not covered: 4) Chromosomal microarray testing to confirm the diagnosis of a disorder or syndrome that is routinely diagnosed based on clinical evaluation alone.
Genome-Wide Association Studies	Does not require medical review
MicroRNA Detection - Cancer	There is insufficient evidence in the published medical literature to show clinical utility.
MicroRNA Detection – Heart Failure	There is insufficient evidence in the published medical literature to show clinical utility.
MicroRNA Detection - Inflammatory Bowel Disease	There is insufficient evidence in the published medical literature to show clinical utility.
MicroRNA Detection - Ischemic Heart Disease	There is insufficient evidence in the published medical

Back to Top

Genomic Testing Methods and Technologies	Criteria
	literature to show clinical utility.
MicroRNA Detection – Kidney Disease	There is insufficient evidence in the published medical literature to show clinical utility.
Molecular Profiling	MCG* A-0789: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Microdeletion Syndromes *81331 not medically necessary when performed using cell-free fetal DNA, 81422*	MCG* A-0848: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Monogenic Disorders	MCG* A-0849: This is not covered per MCG*
Noninvasive Prenatal Testing (Cell-Free Fetal DNA) - Sex Chromosome Disorders	MCG* A-0850: This is not covered per MCG*
Septin 9 (SEPT9) DNA Methylation Testing	MCG* A-0706: This is not covered per MCG*
Telomere Analysis	MCG* A-0672: This is not covered per MCG*
Integrated Molecular Pathology Testing (Topographic Genotyping) - PathFinderTG	MCG* A-0632: This is not covered per MCG*
Whole Exome Sequencing (WES)	Whole exome sequencing (WES) is considered medically necessary for a phenotypically affected individual when **ALL** of the following criteria are met: 1. Individual has been evaluated by a board-certified medical geneticist (MD) or other board-certified physician specialist with specific expertise in the conditions and relevant genes for which testing is being considered 2. Results have the potential to directly impact clinical decision-making and clinical outcome for the patient 3. A genetic etiology is the most likely explanation for the phenotype as demonstrated by **EITHER** of the following: A. multiple abnormalities affecting unrelated organ systems OR B. **TWO** of the following criteria are met: a. abnormality affecting a single organ system b. significant intellectual disability, symptoms of a complex neurodevelopmental disorder (e.g. self-injurious behavior, reverse sleep-wake cycles), or severe neuropsychiatric condition (e.g. schizophrenia, bipolar disorder, Tourette syndrome) c. family history strongly implicating a genetic etiology d. period of unexplained developmental regression (unrelated to autism or epilepsy) e. dysmorphic facial features f. abnormal growth not otherwise explained 4. No other causative circumstances (e.g. environmental exposures, injury, infection) can explain symptoms 5. Clinical presentation does not fit a well-described syndrome for which single-gene or targeted panel testing is available 6. The differential diagnosis list and/or phenotype warrant testing of multiple genes and ONE of the following: a. WES is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis b. WES results may preclude the need for multiple and/or invasive procedures, follow-up, or

Back to Top

Genomic Testing Methods and Technologies	Criteria
	screening that would be recommended in the absence of testing *All requests must be approved by a KP geneticist, regardless of whether they have seen the patient.*

Hematology	Criteria
Alpha Thalassemia - HBA1 and HBA2 Genes	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0808
Beta Thalassemia - HBB Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0815
Fetal and Neonatal Alloimmune Thrombocytopenia - Human Platelet Antigen (HPA) Genotyping	MCG* A-0793
Factor V Leiden Thrombophilia-F5 gene	Does not require medical review
Fanconi Anemia - FANC Genes and Gene Panel Testing	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0683
Hemoglobin C and E – HBB Gene	MCG* A-0604
Hyperhomocysteinemia - MTHFR Gene	MCG* A-0629
Post-Transfusion Purpura - Human Platelet Antigen (HPA) Genotyping	There is insufficient evidence in the published medical literature to show clinical utility.

Hematology	Criteria
Prothrombin Thrombophilia - F2 Gene	Does not require medical review
Sickle Cell Disease - HBB Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0864
Von Willebrand Disease-VWF Gene	MCG* A-0688

Metabolic and Developmental Disorders	Criteria
Angelman Syndrome - UBE3A Gene *Note: Guideline indications are related to tests performed using amniocentesis or chorionic villus sampling. Not medically necessary when performed using cell-free fetal DNA (see MCG A-0848).*	MCG* A-0708
Ashkenazi Jewish Genetic Panel	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0592
Autism Spectrum Disorders – Gene Panels	MCG* A-0914 This is not covered per MCG*
Beckwith-Wiedemann Syndrome - CDKN1C Gene	MCG* A-0765
Bloom Syndrome - BLM Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0682
Canavan Disease - ASPA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0595
Deafness and Hearing Loss, Nonsyndromic - Gene and Gene Panel Testing	MCG* A-0823
Deafness and Hearing Loss, Nonsyndromic - GJB2, MT-RNR1, MT-TS1, POU3F4, PRPS1, and SMPX Genes	There is insufficient evidence in the published medical literature to show clinical utility.
Developmental Delay - Gene Panels	MCG* A-0925 This is not covered per MCG*
Fragile X-Related Disorders-FMR1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0602
Fragile X-Associated Primary Ovarian Insufficiency - FMR1 Gene	There is insufficient evidence in the published medical literature to show clinical utility.

Back to Top

Metabolic and Developmental Disorders	Criteria
Fragile X-Associated Tremor/Ataxia Syndrome - FMR1 Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Gaucher Disease - GBA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0603
Glycogen Storage Disease, Type 1 G6PC and SLC37A4 Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Intellectual Disability - Gene Panels	MCG* A-0923 This is not covered per MCG*
Joubert Syndrome – Gene Testing and Gene Panels	MCG* A-0785
Lesch-Nyhan Syndrome - HPRT1 Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Maple Syrup Urine Disease, Type 1 or Type 2 – BCKDHA, BCKDHB, and DBT Genes	MCG* A-0681
Maple Syrup Urine Disease, Type 3 - DLD Gene	MCG* A-0776
Mucolipidosis IV - MCOLN1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0686
Niemann-Pick Disease (Acid Sphingomyelinase Deficiency) - NPC1, NPC2, and SMPD1 Genes	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0611
Noonan Syndrome – Gene and Gene Panel Testing	MCG* A-0915
Prader-Willi Syndrome DNA Methylation Testing *Note: Guideline indications are related to tests performed using amniocentesis or chorionic villus sampling. Not medically necessary when performed using cell-free fetal DNA (see MCG A-0848).*	MCG* A-0707
Rett Syndrome – CDKL5, FOXG1 and MECP2 Genes	MCG* A-0687
Tay-Sachs Disease and Variants - HEXA Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0614
Usher Syndrome - ADGRV1 (GPR98), CDH23, CIB2, CLRN1, DFNB31, HARS, MYO7A, PCDH15, USH1C, USH1G, and USH2A Genes	MCG* A-0802
Fabry Disease - GLA Gene	MCG* A-0916

Miscellaneous	Criteria
Autosomal and X-Linked Recessive Disease Carrier Screening - Expanded Gene Panels	MCG* A-0768: This is not covered per MCG*
Familial Mediterranean Fever - MEFV Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Hereditary Hemorrhagic Telangiectasia - ACVRL1, ENG, GDF2, and SMAD4 Genes	MCG* A-0704
Male Infertility - Y Chromosome Microdeletion Analysis	There is insufficient evidence in the published medical literature to show clinical utility.
Malignant Hyperthermia Susceptibility - CACNA1S and RYR1 Genes	There is insufficient evidence in the published medical literature to show clinical utility.

Nephrology	Criteria
Donor-derived cell-free DNA testing (e.g., Allosure)	*Please see separate criteria for **Lab Tests for Detectom of Organ Transplantation Rejection**
Polycystic Kidney Disease (Autosomal Recessive) – DZIP1L and PKHD1 Genes and Gene Panels	There is insufficient evidence in the published medical literature to show clinical utility.

Back to Top

Neurology	Criteria
Alzheimer Disease – (Early Onset) APP, PSEN1, and PSEN2 Genes	MCG* A-0590
Alzheimer Disease (Late Onset) - APOE Genotyping CPT codes: 81401, 81405, 81406 HCPC: S3852	**Effective until June 1st, 2024** MCG Alzheimer Disease (Late Onset)- APOE Genotyping A-0809 Current Role Remains Uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See the Inconclusive or Non-Supportive Evidence section for more detailed analysis of the evidence base. **Effective June 1st, 2024** Alzheimer Disease - APOE Genotyping APOE genotyping for risk stratification of Amyloid-Related Imaging Abnormalities (ARIA) may be indicated when ALL of the following are present: • Clinical diagnosis of Alzheimer disease • Monoclonal Antibody Amyloid Targeted Therapy (e.g., aducanumab, lecanemab) is being considered. APOE for all other indications including genotyping for risk of developing Alzheimers disease: Current Role Remains Uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology. See the Inconclusive or Non-Supportive Evidence section for more detailed analysis of the evidence base.
Amyotrophic Lateral Sclerosis (ALS) - SOD1 Gene	No additional criteria need to be met beyond numbers 1 - 4 at the top of the Non-Medicare criteria (page 4).
Ataxia-Telangiectasia - ATM Gene	MCG* A-0593
CADASIL (Cerebral Autosomal Dominant Arteriopathy with Subcortical Infarcts and Leukoencephalopathy) - NOTCH3 Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Charcot-Marie-Tooth Hereditary Neuropathy – Gene and Gene Panel Testing	MCG* A-0691
Epilepsies (Hereditary) - Gene Panels	MCG* A-0905 This is not covered per MCG
Epilepsies, Hereditary - SCN1A Gene	MCG* A-0904
Familial Dysautonomia - ELP1 Gene	Does not require medical review in the prenatal setting. For all other indications refer to MCG* A-0685
Familial Frontotemporal Dementia - C9orf72, GRN, and MAPT Genes	There is insufficient evidence in the published medical literature to show clinical utility.
Friedreich Ataxia - FXN Gene	MCG* A-0907
Huntington Disease - HTT Gene	MCG* A-0605
Muscular Dystrophies (Duchenne, Becker) - DMD Gene	MCG* A-0608
Myotonic Dystrophy – Type 1 - DMPK Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Myotonic Dystrophy, Type 2 - CNBP Gene	There is insufficient evidence in the published medical literature to show clinical utility.
Narcolepsy - HLA Testing	MCG* A-1005 This is not covered per MCG
Nemaline Myopathy – Gene and Gene Panel Testing	MCG* A-0792
Parkinson Disease – Gene Testing and Gene Panels	MCG* A-0671 This is not covered per MCG

Back to Top

Neurology	Criteria
Spinal Muscular Atrophy - SMN1 and SMN2 Genes **Spinal Muscular Atrophy – Carrier Testing** References: American College of Obstetricians and Gynecologists (2017). Carrier screening for genetic conditions. Committee Opinion No. 691. *Obstet Gynecol. 129*:e41-45. Retrieved 10/20/21 from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/03/carrier-screening-for-genetic-conditions Gregg, A. R., Aarabi, M., Klugman, S., Leach, N. T., Bashford, M. T., Goldwaser, T., Chen, E., Sparks, T. N., Reddi, H. V., Rajkovic, A., & Dungan, J. S. (2021). Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG). *Genetics in Medicine, 23*(10), 1793–1806. Retrieved 10/20/21 from: https://doi.org/10.1038/s41436-021-01203-z	Preconception or prenatal carrier testing for spinal muscular atrophy (SMA) with analysis of the SMN1 gene (CPT code **81329**), as described by the American College of Medical Genetics (ACMG) and the American College of Obstetricians and Gynecologists (ACOG), is considered medically necessary for a prospective biologic parent with the capacity and intention to reproduce. Testing is covered once in a lifetime. Kaiser Permanente will cover carrier testing for SMA (CPT 81329) without prior authorization when performed at a Kaiser Permanente lab or Prevention. Prior authorization will still be required for SMA carrier testing at any other lab in advance of submitting a claim for payment. All other spinal muscular atrophy genetic testing: Medical necessity review will be required for all other indications for SMN1/SMN2 gene testing using MCG* **KP-0659**. *Note – this is a KP hybrid, not MCG A-0659* (Includes CPT codes: 81336, 81337, 0236U)
Spinocerebellar Ataxia - Gene Testing and Gene Panels	MCG* A-0908
Transthyretin Amyloidosis - TTR Gene	There is insufficient evidence in the published medical literature to show clinical utility.

Oncology	Criteria
Acute Lymphoblastic Leukemia - BCR-ABL1 Fusion Gene Testing	Does not require medical review
Acute Promyelocytic Leukemia - PML-RARA Fusion Gene Testing	Does not require medical review
Breast Cancer - HER2 Testing	MCG* A-0766
Breast Cancer Gene Expression Assays CPT - 81519	See Oncotype Dx
Breast Cancer - PALB2 Gene	MCG* A-0989
Breast or Ovarian Cancer, Hereditary - BRCA1 and BRCA2 Genes CPT 81211, 81212, 81213, 81162	MCG* A-0499
Cancer of Unknown Primary: Gene Expression Profiling – 81540; CancerTYPE ID	MCG* A-0673 This is not covered per MCG
Chronic Eosinophilic Leukemia/Hypereosinophilic Syndrome - FIP1L1-PDGFRA Fusion Gene Testing	MCG* A-0770
Chronic Myelogenous Leukemia - BCR-ABL1 Fusion Gene Testing	Does not require medical review
ClonoSEQ – 0364U	ClonoSEQ is a new test whose current use is confined to clinical trials. It is not currently covered by KPWA
Cologuard	See Fecal DNA Testing
Colon Cancer - Oncotype DX	MCG* A-0651: This is not covered per MCG*
Colon Cancer Gene Expression Assay - GeneFx Colon	MCG* A-0821: This is not covered per MCG*

Back to Top

Oncology	Criteria
Colorectal Cancer (Hereditary) – Gene Panel	MCG* A-0774: This is not covered per MCG*
Cowden Syndrome - PTEN Gene	MCG* A-0585
DecisionDx - Choroidal/Uveal Melanoma	DecisionDX is covered for dx of choroidal/uveal melanoma
DecisionDx - Cutaneous Melanoma	There is insufficient evidence in the published medical literature to show clinical utility.
Familial Adenomatous Polyposis - APC Gene	MCG* A-0534
Gastric Cancer, Hereditary - CDH1 Gene	MCG* A-0779
Gastrointestinal Stromal Tumor (GIST) - KIT and PDGFRA Genes	Does not require medical review
Ovarian Cancer (Hereditary) - Gene and Gene Panel Testing	MCG* A-0782
Li-Fraumeni Syndrome - TP53 Gene	MCG* A-0584
Lymphoma - T-Cell Antigen Receptor (TCR) Gene Rearrangement Testing	Does not require medical review
Lynch Syndrome - BRAF V600, EPCAM, MLH1, MSH2, MSH6, and PMS2 Genes and Gene Panel	MCG* A-0533
Malignant Melanoma (Uveal), Hereditary - BAP1 Gene	MCG* A-0836: This is not covered per MCG*
Malignant Melanoma (Cutaneous) – BAP1, CDK4 and CDKN2A Genes	MCG* A-0601: This is not covered per MCG*
Melanoma (Cutaneous) - Gene Expression Profiling	MCG* A-0837: This is not covered per MCG*
Melanoma (Uveal) - Gene Expression Profiling	MCG* A-0670: This is not covered per MCG*
Multiple Endocrine Neoplasia (MEN) Syndrome, Type 2 - RET Gene	MCG* A-0842
Multiple Endocrine Neoplasia (MEN) Syndromes - MEN1 Gene	MCG* A-0582
MUTYH-Associated Polyposis - MUTYH Gene	MCG* A-0828
Myelodysplastic Syndromes (Somatic) - Gene Panels	MCG* A-0791: This is not covered per MCG*
Myeloproliferative Neoplasms - JAK2 Genes	Does not require medical review
Myeloproliferative Neoplasms - MPL Gene	Does not require medical review
Neuroblastoma - ALK, MYCN, and PHOX2B Genes and Gene Expression Profiling	MCG* A-0610
Neurofibromatosis - NF1 Gene	MCG* A-0581
Neurofibromatosis - NF2 Gene	MCG* A-0846
Non-Small Cell Lung Cancer – Gene Testing (Somatic or Therapeutic	MCG* A-0795 Includes indications for: Anaplastic Lymphoma Kinase (ALK) Fusion Gene Testing – medically necessary when indications met EGFR Gene Testing – medically necessary when indications met KRAS Gene Testing – not medically necessary for NSCLC per MCG*
OVA1- Assessment for Ovarian Cancer	There is insufficient evidence in the published medical literature to show clinical utility.
Pancreatic Cancer (Hereditary) -	MCG* A-0797

Back to Top

<table>
<tr><th>Oncology</th><th>Criteria</th></tr>
<tr><td>Gene Panel</td><td></td></tr>
<tr><td>Paraganglioma-Pheochromocytoma (Hereditary) - Gene Testing and Gene Panel</td><td>MCG* A-0798</td></tr>
<tr><td>Peutz-Jeghers Syndrome - STK11 Gene</td><td>MCG* A-0799</td></tr>
<tr><td>Prostate Cancer - BRCA1 and BRCA2 Genes</td><td>MCG* A-0612</td></tr>
<tr><td>Prostate Cancer – ConfirmMDx (CPT Code 81551)</td><td>ConfirmMDx (81551) for men with prior negative biopsy when repeat biopsy is being considered, and the following criteria are met (must be ordered by treating urologist):

• The beneficiary would benefit from treatment of prostate cancer and has greater than 10-year life expectancy
• Previous biopsy within the past 12 months negative or atypical small acinar proliferation (ASAP)
• Meets Age/PSA per table below
• Serial testing not covered (this is a one-time test)
• Concurrent testing with multiple assays is not medically necessary

TABLE 1. Age-Specific PSA Thresholds for Referral to Urology
<table><tr><th>Age Range (years)</th><th>PSA Threshold</th></tr><tr><td>40-49</td><td>>2.5 ng/ml</td></tr><tr><td>50-59</td><td>>3.5 ng/ml</td></tr><tr><td>60-69</td><td>>4.5 ng/ml</td></tr><tr><td>≥70</td><td>>6.5 ng/ml</td></tr></table></td></tr>
<tr><td>Prostate Cancer (Hereditary) – Gene Panel</td><td>MCG* A-0854: This is not covered per MCG*</td></tr>
<tr><td>Prostate Cancer - PCA3 Gene</td><td>MCG* A-0855: This is not covered per MCG*</td></tr>
<tr><td>Prostate Cancer Gene Expression Testing - Decipher</td><td>MCG* A-0856: This is not covered per MCG*</td></tr>
<tr><td>Prostate Cancer Gene Expression Testing - Oncotype DX</td><td>MCG* A-0712: This is not covered per MCG*</td></tr>
<tr><td>Prostate Cancer Gene Expression Testing – Prolaris (CPT Code 81541)</td><td>Men with confirmed prostate cancer on biopsy may be covered for Prolaris if</td></tr>
</table>

Back to Top

ALL the following indications are met (must be ordered by treating urologist):

a. Must meet NCCN category* **(one):**
   - low-risk
   - favorable intermediate-risk
   - unfavorable intermediate-risk

b. who have greater than 10 year life expectancy

c. Meet **ONE of the following**:
   - has not received treatment for prostate cancer and is a candidate for active surveillance **or** definitive therapy; or
   - has intermediate-risk prostate cancer when deciding whether to add androgen-deprivation therapy to radiation; or
   - is appropriate for conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or;
   - is appropriate for radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or;
   - is appropriate for radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, or;
   - is appropriate for radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy

d. Patient has not had a prostatectomy (***The evidence is insufficient for or against the use of Prolaris test in patients with radical prostatectomy and it is not covered***)

- Very low risk patients should be considered active surveillance, Prolaris is unlikely to be helpful
- Serial testing is not covered (this is a one-time test)
- Concurrent testing with multiple assays is not medically necessary

*NCCN Initial Risk Stratification and Staging workup for Clinically Localized Disease (see Tables)

Initial Risk Stratification and Staging Workup for Clinically Localized Disease	
Risk Group	**Clinical/Pathologic Features**
Very Low	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/ml • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core • PSA density <0.15 ng/mL/g
Low	Has all of the following but does not qualify for very low risk: • cT1-cT2a • Grade Group 1 • PSA <10 ng/mL

Back to Top

<table>
<tr><th>Oncology</th><th>Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><td>Intermediate</td><td>Has all of the following:
No high-risk group features
No very-high-risk features
Has one or more intermediate risk factors (IRFs):
cT2b-cT2c
Grade Group 2 or 3
PSA 10-20 ng/mL</td><td>Favorable intermediate</td><td>Has all of the following:
1IRF
Grade Group 1 or 2
<50% biopsy cores positive (e.g., <6 of 12 cores)</td></tr>
<tr><td></td><td></td><td>Unfavorable intermediate</td><td>Has one ore more of the following:
2 or 3 IRFs
Grade Group 3
≥50% biopsy cores positive (e.g., ≥ 6 of 12 cores)</td></tr>
<tr><td>High</td><td colspan="3">Has no very-high-risk features and has exactly one high-risk feature:
cT3a OR
Grade Group 4 or Grade Group 5 OR
PSA >20 ng/mL</td></tr>
<tr><td>Very High</td><td colspan="3">Has at least one of the following:
cT3b-cT4
Primary Gleason pattern 5
2 or 3 high-risk features
>4 cores with Grade Group 4 or 5</td></tr>
</table>
<table>
<tr><th>Grade Group</th><th>Gleason Score</th><th>Gleason Pattern</th></tr>
<tr><td>1</td><td><6</td><td><3 + 3</td></tr>
<tr><td>2</td><td>7</td><td>3 + 4</td></tr>
<tr><td>3</td><td>7</td><td>4 + 3</td></tr>
<tr><td>4</td><td>8</td><td>4 + 4, 3 + 5, 5 + 3</td></tr>
<tr><td>5</td><td>9 or 10</td><td>4 + 5, 5 + 4, 5 + 5</td></tr>
</table>
*NCCN Initial Risk Stratification and Staging Workup for Clinically Localized Disease
</td></tr>
<tr><td>Prostate Cancer – SelectMDx (CPT code 0339U)</td><td>There is insufficient evidence in the published medical literature to show clinical utility.</td></tr>
<tr><td>Proteomics - Ovarian Cancer Biomarker Panel (ROMA)</td><td>MCG* A-0858: This is not covered per MCG*</td></tr>
<tr><td>Proteomics (VeriStrat)</td><td>Epidermal Growth Factor Receptor Testing is covered when:
1) Diagnosis of NSCLC</td></tr>
<tr><td>Renal Cancer (Hereditary) - Gene Panel</td><td>MCG* A-0801: Considered medically necessary if indications in MCG A-0801 are met.</td></tr>
<tr><td>Retinoblastoma - RB1 Gene</td><td>MCG* A-0586</td></tr>
<tr><td>Thyroid Nodule Gene Expression Testing</td><td>
<table>
<tr><th>Test</th><th>Criteria</th></tr>
<tr><td>Afirma 81546
Thyroseq 0026U</td><td>There is insufficient evidence in the published medical literature to show clinical utility.</td></tr>
</table>
</td></tr>
</table>

Back to Top

Oncology	Criteria	
	ThyGeNEXT® Thyroid Oncogene Panel + ThyraMIR Thyroid miRNA Classifier (CPT Codes *0245U+0018U)*	Molecular profiling of thyroid nodules with indeterminate cytology for ThyGeNext/ThyraMIR is medically necessary when specific criteria are met: • Thyroid nodule gene expression testing may be indicated when **ALL** of the following are present: o Thyroid nodule, as indicated by **ALL** of the following: ▪ Diameter of 1 cm or greater on ultrasound ▪ Indeterminate cytology on fine needle aspirate, as indicated by **1 or more** of the following): • Atypia of undetermined significance (ie, Bethesda System for Reporting Thyroid Cytopathology category III) • Follicular lesion of undetermined significance (ie, Bethesda System for Reporting Thyroid Cytopathology category III) • Follicular neoplasm or suspicious for follicular neoplasm (ie, Bethesda System for Reporting Thyroid Cytopathology category IV, excluding Hurthle cell type)
Von Hippel-Lindau Syndrome - VHL Gene	MCG* A-0583	
Wilms Tumor - WT1	MCG* A-0615	

Ophthalmology	Criteria
Age-Related Macular Degeneration - Gene Panels	MCG* A-0913 This is not covered per MCG
Retinal Disorders - Gene Panels	There is insufficient evidence in the published medical literature to show clinical utility.
Retinal Dystrophy - RPE65 Gene	MCG* A-1011

Orthopedics	Criteria
Ankylosing Spondylitis - HLA-B27 Testing	MCG* A-0762
Osteogenesis Imperfecta - Gene and Gene Panel Testing	MCG* A-0796

Pulmonary	Criteria
Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene Ambulatory Care > Genetic Medicine > Pulmonary >Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene (A-1006)	MCG* **KP-**1006 *Note – this is a KP hybrid, not MCG A-1006*
Beta2-Agonist Pharmacogenetics- ADRB2 Gene	MCG* A-0763: This is not covered per MCG
Cystic Fibrosis-CFTR Gene and Mutation Panel:	Does not require medical review in the prenatal setting. For all other indications refer to MCG* **KP-**0597 *Note – this is a KP hybrid, not MCG A-0597*

Back to Top

Pulmonary	Criteria
Cystic Fibrosis Carrier Testing	Preconception or prenatal carrier testing for cystic fibrosis (CF) with targeted mutation analysis of 23 CFTR mutations (CPT code 81220) as described by the American College of Medical Genetics (ACMG) is considered medically necessary for a prospective biologic parent with the capacity and intention to reproduce. Any testing beyond the 23 gene CFTR mutations recommended by ACMG will not be covered as its utility has not been established. Testing is covered only once in a lifetime. ACMG Guideline - Minimum Mutation Panel for Population-Based Carrier Screening Purposes CF 3.3.1.
Congenital Central Hypoventilation Syndrome - PHOX2B Gene	There is insufficient evidence in the published medical literature to show clinical utility.

Risk Prognosticator Test	Criteria
• BREVAGen™ • Fibroblast Growth Factor Receptor 3 (FGFR3) • OVA1™ Test for the Assessment of Suspected Ovarian Cancer	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long- term outcomes than current standard services/therapies.
• MammaPrint Test (Gene-Expression Profiling Test, 70-Gene Prognostic Signature)	Medically necessary when **ALL** of the following criteria are met: 1. The patient has ER-positive, HER2-negative breast cancer ***and*** 2. One to three lymph nodes are positive for metastasis ***and*** 3. The patient is at high clinical risk for recurrence ***and*** 4. Outcome of testing will guide decision making regarding adjuvant chemotherapy.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Any genetic counseling notes if applicable Results of prior genetic testing
- Last 6 months of specialist notes of that is being reviewed (i.e., neurological notes, medical oncology notes, cardiology notes)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Afirma
Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability
ConfirmMDx for Prostate Cancer (MDxHealth Inc.)
Prolaris for Prostate Cancer
DecisionDx- Melanoma
HLA Testing for Celiac Disease
Micro Array for Evaluation of Intellectual Disability
OVA1 for Assessment of Ovarian Cancer
Risk Prognosticator Tests

Back to Top

SelectMDx for Prostate Cancer (MDxHealth Inc.)
Thyroid Nodule Gene Expression Testing (Afirma)
Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID)

Background

Genetic screening is used to identify the genetic disorders or the potential for transmission of genetic disorders in populations at risk for a particular genetic disorder. Genetic screening is only appropriate when the natural history of the disease is understood; the screening tests are valid and reliable; sensitivity, specificity, false-negative, and false-positive rates are acceptable; and effective therapy is available. A sufficient benefit must be derived from a screening program to justify its cost.

Medical Technology Assessment Committee (MTAC)

Afirma

BACKGROUND

Thyroid nodules are clinically identified in 5-7% of the population, and incidentally on ultrasonography in up to 50% of women and 20% of men over the age of 50. Thyroid nodules are typically benign, but 5-15% prove to be malignant. It is thus recommended that any identified nodule measuring one centimeter or more in diameter be diagnostically evaluated. Ultrasound-guided fine needle aspiration (FNA) biopsy is the most widely used method for clinical evaluation of a suspicious thyroid nodule. FNA is a safe and simple outpatient procedure that yields cellular material suitable for cytological analysis. It can identify approximately 50% of malignant nodules and 70% of benign nodules without the need to perform a diagnostic surgery. However, 15-30% of the biopsied nodules have indeterminate cytology and cannot be conclusively diagnosed by FNA biopsy alone. Most patients with indeterminate lesions or lesions suspicious for malignancy, according to the Bethesda classification* system, are referred to surgery for both diagnostic and therapeutic purposes. Surgery is the recommended and appropriate treatment for thyroid cancer, however 70-75% of the nodules with indeterminate FNA cytology are found to be benign on final surgical pathology. Thus, a large proportion of these patients may undergo unnecessary partial or complete thyroidectomy with its potential surgical complications and risk of long-term morbidity (Alexander 2012, Duick 2012, Walsh 2012, Ali 2013, Labourier 2015, Sacks 2016).

Molecular markers and assays have been investigated for their ability to preoperatively classify the indeterminate thyroid nodules. Each has its performance characteristics and diagnostic values. Ideally a molecular marker or panel of markers is accurate in differentiating benign from malignant in any lesion that is considered suspicious or indeterminate. Molecular tests should also be simple to use, reproducible by the different institutions/laboratories, and cost-effective.

Molecular genetic testing for cytologically indeterminate thyroid nodules fall in two approaches: the “rule in” and the “rule-out” disease approach. Tests that rule-in malignancy (such as BRAF, RAS mutations, RET/PTC and PAX8-PPAry) have high specificity and positive predictive values (PPVs) for malignancy by identifying specific mutations or gene rearrangements known to be present in thyroid cancer. However, they have limited sensitivity and negative predictive values (NPVs) and fail to detect as many as 30% of malignancies. Tests that rule-out the disease on the other hand, should have a high sensitivity and negative predictive value in order to exclude malignancy when the test results are benign. Because a majority of nodules with indeterminate cytology are found to be benign on surgical resection, a test that can preoperatively rule-out malignancy may spare a subset of these patient’s unnecessary diagnostic surgeries (Alexander 2012, Kouniavsky 2012, Ward 2013, Chaudhary 2016. Nishino 2016).

*2008 Bethesda classification system for thyroid cytology: Class I: Nondiagnostic or unsatisfactory, Class II. Benign, Class III: atypia or follicular lesion of undetermined significance (AUS/FLUS), Class IV: follicular neoplasm or suspicious for follicular neoplasm (FN), Class V: suspicious for malignancy (SUSP) and Class VI: malignant) (Kuo, 2016)

Afirma gene expression classifier (GEC) is a molecular test developed by Veracyte Inc. (San Francisco, CA) with the intention of reducing unnecessary diagnostic surgeries in patients with thyroid nodules with indeterminate FNA cytopathologic results. It represents the “rule-out” approach by preoperatively identifying the benign thyroid nodules and ruling-out malignancy. Afirma GEC uses a proprietary diagnostic algorithm that analyses the mRNA expression of 167 genes to identify the signature of benign thyroid nodules. 142 of the 167 genes are in the main classifier, and 25 genes filter out rare neoplasms. The selected gene profile is based on the gene expression identified from FNAs of surgically proven benign and malignant thyroid nodules. During the Afirma GEC test RNA is extracted from the FNA sample, amplified and hybridized to a custom microarray to examine for gene patterns. These are compared with the GEC proprietary panel, which molecularly classifies them as either ‘benign’ or ‘suspicious’. Insufficient RNA

Back to Top

in the sample leads to 'no result' conclusion in approximately 10% of cases. Nodules with benign results, in addition to clinical judgement, are typically followed up clinically and ultrasonography, while those with suspicious results undergo diagnostic thyroid lobectomy with possible total thyroidectomy (Alexander 2012, Kim 2012, Ward 2013, Kuo 2016, Witt 2016).

Afirma GEC is a proprietary test commercially owned by Veracyte Corporation and is offered through a sole source, which is a Clinical Laboratory Improvement Amendments certified [CLIA] reference laboratory. During a routine FNA of a thyroid nodule, after the aspirates are obtained for cytopathologic examination, two more needle passes are obtained for Afirma analysis and immediately stored in a preservative. These are either 1. Sent to a Veracyte independent industry partner (Thyroid Cytopathology Partners [TCP], Austin, TX) that performs cytopathologic exam of the FNA sample, and only runs the Afirma test for indeterminate diagnoses on cytopathology, or 2. In Thyroid Cytopathology Medical centers designated as "Enabled centers" cytopathology is done in-house and specimens with indeterminate results based on the Bethesda criteria are sent for Afirma GEC testing. Afirma test is run only on nodules with indeterminate cytology. If the cytopathologic evaluation reveals any other diagnosis or is nondiagnostic due to insufficient FNA samples, the preserved samples are discarded. The goal of the test is to identify the benign nodules from among those with indeterminate cytopathology. It is not intended to assist with clinical decision making for patients who have an indication for surgery or meet criteria for surgical interventions (Alexander 2012, Duick 2012, Ward 2013, Kuo 2016. Yip 2016).

03/20/2017: MTAC REVIEW
Evidence Conclusion: Analytic validity of Afirma GEC (From an earlier MTAC review)
Evaluating the analytic performance of Afirma GEC includes studying the stability of RNA in FNAs during collection, storage, and shipment; reproducibility of the test; and its analytic sensitivity and specificity under various conditions e.g. interference of the assay with bloody FNA and genomic DNA. The literature search revealed one study (Walsh and colleagues, 2012) that evaluated the analytic performance of Afirma GEC in a number of sub-studies. The investigators obtained prospective FNA samples aspirated in vivo from 43 patients from outpatient clinics, preoperatively, or immediately after surgical excision. The samples were placed in FNAProtect preservative solution and shipped chilled or frozen, then stored at -80^{o}C upon receipt. The RNA was extracted, and its yield examined for quantity and quality using positive (tissue lysate) and negative (water) as controls. Three different lots of controls were tested over several weeks of independent runs by 3 different operators to determine reliability of the test. Multiple lots of benign and malignant total RNA were manufactured and used as process controls to determine the analytic sensitivity of the test using different RNA input quantity and under different dilution of malignant FNA content. These studies indicated tolerance to variation in RNA input across a range of 5-25 ng. as well as dilution of malignant FNA material down to 20%. Analytic specificity of the test using malignant samples mixed with blood (up to 83%) and genomic DNA (up to 30%) showed minimal assay interference. However benign FNA samples mixed with relatively high proportions of blood had a potential for yielding false positive results. The investigators examined the stability of RNA in FNAs during collection and shipment and found that RNA content within FNAs preserved in FNAProtect was stable for up to 6 hours at room temperature with no change in RNA yield, and that the FNA storage and shipping temperatures had no significant effect on GEC scores. They also examined the reproducibility of the test and indicated that it was reproducible from extraction through GEC results, including variation across operators, runs, reagent lots, and laboratories. The investigators concluded that the analytical performance and reproducibility of the Afirma Gene Expression Classifier was successfully verified. The research was supported by Veracyte Corporation (the maker of Afirma GEC), and the authors of the study had financial ties to the corporation.

Clinical validity of Afirma GEC an ideal diagnostic test would have high sensitivity and specificity to correctly detect or exclude a condition. A molecular diagnostic test with high sensitivity offers a high negative predictive value (NPV) when the risk of malignancy is low and can "rule out'' malignancy. Conversely, a test with high specificity offers high positive predictive (PPV) value and can "rule in" malignancy. A preoperative diagnostic test would ideally have a high sensitivity in order not to miss a malignant nodule and have a high NPV to avoid surgery in patients with benign nodules. Predictive values do not only depend on the sensitivity and specificity of the test, but also on the prevalence of the disease; e.g. as the disease prevalence increases, the NPV decreases and vice versa. Afirma GEC test was validated in a. a double-blind prospective multicenter study (Alexander 2012 (Evidence table 1, reviewed earlier by MTAC). The study involved 265 nodules with indeterminate cytology that were selected for GEC analysis. Molecular results were compared to the gold standard of post-surgical histopathology. The malignancy rate was 32% and the Afirma sensitivity and specificity were 92% and 52% respectively with a NPV of 94-95% and PPV of 27-38% for Bethesda III/IV nodules. In the subgroup in patients with nodules suspicious for malignancy (SUSP) the NPV was only 85%, based on which, the authors concluded that GEC should not be used for cytology SUSP nodules. The study was conducted to validate the GEC accuracy by comparing it to surgical histopathology and did not compare its performance to repeat FNA or other immunochemical or molecular testing. A number of

 Back to Top

post-validation analyses were conducted by independent or industry supported investigators. In the initial validation study (Alexander 2012) the decision to resect the nodule was made independently of the GEC test results, while in the post-validation studies GEC was a factor influencing the decision whether to recommend a diagnostic surgical intervention. The published studies and analyses showed a wide variation in the NPVs and PPVs of Afirma GEC test results. The NPV and PPV of a test are neither absolute nor inherent in the test but depend on the pre-test probability of malignancy in the population studied, i.e. prevalence of malignancy in indeterminate nodules. This is made clear by Marti and colleagues (2014) who retrospectively analyzed all indeterminate thyroid nodules (ITNs) evaluated with GEC at two centers with widely different prevalence of malignancy in ITNs (Memorial Sloan Kettering Cancer Center [MSK] and Mount Sinai Beth Israel [MSBI]) (see table below).

The results of the validation study as well as post-validation studies are summarized in the following table.

Performance of GEC in the validation study and selected post-validation studies

Study	N FNA ITN undergoing GEC	Afirma results			Cancer prevalence in indeterminate FNA	NPV‡	PPV‡‡	Operative rate in GEC benign results
		Suspicious	Benign	Inadequate RNA/ no result				
Alexander 2012 (multicenter Validation study)	265	62%	38%		32%	94-95%	27-38%	NA
Alexander, 2014 (5 centers)***	339	40%	55%	5%	--	99.4%	--	6.3%*
Harrell, 2014 (One practice)	58	62%	35%	3%	33-36%	88.3-89.6%	56%	25%**
McIver, 2014	72	61%	22%	17%	17%	94%	15.6%	25%
Marti, 2015 MSK center(tertiary) MSBI comprehensive health system)	 94 71	 74% 48%	 26% 52%	 -- --	 30-38% 10-19%	 86-92% 95-98%	 57.1% 14.3%	 8% 14%
Chaudhary, 2016†	158	54%	40%	6%		100%	38%	13%
Witt, 2016 (single-practice)	32	47%	44%	9%	21%	100%	--	0
Samulski, 2016 (single institution)	294	46%	49%	5%		81% for resected nodule, 98% for unrested benign GEC	39%	12%
Sacks, 2016 (single medical center)	140	55.7%	37.1%	7.1%	31.5%	92%††	33.3%	

All studies were performed in Institutional Enabled Centers, except for Harrell (2014) study where the cytology specimens were sent to Thyroid cytopathology partners (TCP).
* 1/11 (9.1%) was malignant (false negative)
** Of the 20 benign GEC patients 5 underwent surgery 2 of which (40%) were found to be malignant (False negative),
*** There were variation between the 5 study sites in the cytology distribution and Afirma GEC performance. GEC suspicious cases proved to be cancerous in 44% of cases (False positive in 56% of cases)
‡ The NPVs (the probability of cancer in GEC benign nodules) were all estimates and could not be directly assessed because not all patients had undergone surgery to determine surgical pathology or had long-term follow-up of the GEC benign nodules.
‡‡ The reported PPVs ranged between studies from 14-57% which limits the utility of the test as a rule-in test i.e. to predict the risk of malignancy.
† A comparison between pre- and post-GEC era showed no significant difference in surgical excision rates of FNA ITN. There were differences in the accuracy and predictive values of the GEC according to the cytomorphological features of the nodules. The authors concluded that the GEC test was found to reduce surgical excision of nodules with suspicious for follicular neoplasm (SFN), but not with FLUS / AUS or Hurthle cell neoplasm (HCN). They recommended repeating FNA rather than performing Afirma GEC test for FLUS/AUS, and be cautious when ordering GEC on HCN cases. 8 (13%) of the benign affirm underwent surgery and all were found benign
†† Estimated based on the prevalence. Cold not be calculated due o the low number of GEC-benign cases with surgical pathology
-- Not provided

Based on the results of the published studies, some investigators suggest that Afirma GEC may provide useful information in practice settings where the prevalence of malignancy in indeterminate thyroid nodules is 15-21%. At this range and using the sensitivity and specificity data from the multicenter validation study the NPV would be >95% and the PPV >25%. It is suggested that GEC may also provide some useful information with the prevalence of malignancy ranging from 12-25% but is not expected to be useful in altering management if the prevalence is outside this range (Marti 2015, Zhang 2016). The Afirma GEC performance was found to be suboptimal for Hurthle cell neoplasms (HCNs). Wu and colleagues (2016) examined the clinical factors influencing the performance of GEC testing and found that the test has a limited clinical validity for HCNs due to the high rate of false positive results (specificity 22.7-26.1% and PPV 29.2%). Other studies also showed inconsistent and low performance of GEC testing for HCN nodules. In the clinical validation study only 4 of 21 (19%) FNA samples from Hurthle

Back to Top

adenomas were classified as benign with GEC.

Limitations in the published studies These include but are not limited to the following:

- All analyses were retrospective with potential bias and confounding.
- There were intra- and inter-observer differences within and between studies in the histological interpretations.
- Only data for patients with GEC testing were analyzed and with the exception of one study, the results were not compared to repeat FNA or other tests.
- The NPVs were all estimates as only a very limited number of GEC benign nodules underwent surgery, and the follow-up duration was too short to determine the true benign nature of the GEC benign nodules.
- The majority of the published studies were industry sponsored.
- The predictive values of a test vary with the prevalence of the disease in a population studied and may not be generalized to other groups. A better analysis would be the likelihood ratios which are not affected by prevalence.

Santhanam and colleagues' meta-analysis (2013, Evidence table 2) pooled the results of 7 prospective and retrospective studies to determine the sensitivity and specificity of the GEC test in classifying FNA indeterminate thyroid nodules and evaluate its clinical utility. The results of the meta-analysis are summarized in the following table:

Pooled results

Pooled values	Value (95% CI)	P value
Sensitivity	95.7% (92.2-97.9)	0.09
Specificity	30.5% (26.0-35.3)	<0.01
Positive likelihood ratio*	1.20 (0.99-1.44)	<0.01
Negative likelihood ratio**	0.2 (0.11-0.36)	0.56
Diagnostic odds ratio	7.86 (4.1-15.01)	0.42
Prevalence of malignancy	37.1%	
Positive predictive value	44.8 (40.4-49.4)	

*A good test for ruling-in a disease is the one with the largest positive likelihood ratio (LR) A positive LR of 1 means that the test does not provide any information on ruling in the disease, LR >1<5 indicates a small effect, and LR>10 indicates a large effect on increasing the probability of a disease is presence.

** The better test to rule-out a disease is the one with the smaller negative likelihood ratio. LR <0.1 indicates that the result has a large effect on decreasing the probability of the disease (rule out), LR 0.1-0.5 indicates moderate effect, and >0.5 indicates a small effect. The meta-analysis had valid methodology, but a meta-analysis is as good as the studies it includes. Due to the lack of RCTs and comparative prospective studies Santhanam and colleagues pooled the results of observational prospective and retrospective studies. There was significant heterogeneity between the studies as they were performed at different institutions and included a wide distribution of patients with different indeterminate cytology results (the test may perform better for one type of neoplasm/cancer versus the other). The meta-analysis had the advantage of calculating likelihood ratios which are not affected by prevalence the condition as the predictive values. However, likelihood ratios are calculated based on the sensitivity and specificity of the test, which may have not been accurate as the majority of GEC benign cases did not undergo surgery or were followed up for a sufficient duration to assess the actual accuracy of the test, and not all GEC suspicious cases underwent surgery. More recently in 2016, an international panel of pathologists and clinicians reclassified a clinically indolent malignant tumor (encapsulated follicular variant of papillary thyroid carcinoma [EFVPT]) as a benign neoplasm (noninvasive follicular thyroid neoplasm with papillary-like nuclear features [NIFTP]) (Niktforov 2016). This reclassification may affect the calculated performance of the current Afirma GEC as it has not been validated with these changes. In one study Samulski and colleagues (2016) reported that of 11 NIFTP cases in their cohort, only one was classified as benign with the GEC test.

Back to Top

Clinical utility of Afirma GEC the clinical utility of Afirma GEC would be guiding the management decisions by clearly ruling out malignancy in FNA indeterminate nodules to avoid unnecessary diagnostic surgery. The published studies on the impact of Afirma GEC on the management of patients with FNS ITNs were retrospective in nature, performed in different sites with intra- and inter-rater variability, which are potential sources of selection and performance bias. In addition, the studies only focused on nodules that underwent Afirma GEC testing and did not investigate the effect of FNA results on overall thyroidectomy rates, or include a comparison group to examine the impact of a repeat FNA or other tests for nodules with indeterminate cytopathology. Santhanam and colleagues (2013, Evidence table 2) discussed in the previous section on clinical validity of Afirma GEC also evaluated its clinical utility of the test. The authors calculated that for patients with FNA indeterminate nodule, one thyroid surgery can be avoided for every two Afirma GEC tests, assuming that >90% of the patients with benign GEC are followed conservatively. They noted however, that according to the American Cancer Society, the 5-year survival of stage I and stage II follicular and papillary thyroid cancer is 100%. The morbidity and mortality rates in patients with FNA indeterminate thyroid nodules are reported to be more likely low, and thus the diagnosis of suspicious nodules with GEC testing may represent a lead-time bias with little change in overall survival.

Sacks and colleagues (2016 Evidence table 3) performed a retrospective analysis to evaluate the impact of Afirma GEC testing on cytopathology diagnosis, rate of surgery, and the rate of malignancy on all indeterminate nodules (ITNs) before and after the introduction of Afirma GEC testing at a high-volume thyroid center. The study was a retrospective analysis of patient data from one institution, with no direct comparison to a control group. However, it had the advantage of reporting on outcomes of repeat FNAs, comparing two cohorts' pre-and post-Afirma, and reporting on thyroidectomy rates among all cases irrespective of GEC testing. The calculated PPV for the test was 33.3%, and the estimated NPV was 92% (an accurate NPV could not be calculated due to small number of GEC benign cases with surgical pathology). There was a significant increase Bethesda III-IV diagnosis in the post Afirma cohort compared to the pre-Afirma cohort (13.4% vs. 10.7%, $p<0.005$), with a corresponding significant decrease in benign cytology (Bethesda II) post-Afirma (74.6% compared to 68.8% pre-Afirma, $p<0.001$), despite the use of the same guidelines, practice, reporting scheme, and personnel. In an attempt to explain the reason for this shift, the authors supposed that cytopathologists, especially those with less experience, may be less likely to classify nodules as Bethesda II knowing that the GEC testing will help stratify them. No significant changes were observed for Bethesda I, V, or VI, or in the rate of repeat FNA for ITNs. The author noted that while Afirma may reduce the rate of thyroidectomy for nodules with benign GEC results, the "suspicious label" may increase it. Only 33.3% of GEC suspicious cases were found to be malignant. The analysis shows that 35.2% of patients with ITNs who underwent a repeat FNA were classified as non-ITN and avoided Afirma testing. Overall, the results of the analysis indicate that the use of Afirma GEC testing was associated with an increase in the rate of FNA indeterminate diagnosis, and a decrease in the incidence of benign diagnosis. GEC testing did not reduce the overall rate of thyroidectomies which is its main goal. As indicated earlier the study had its disadvantages, which may limit generalization of the results.

Abeykoom and colleagues (2016), performed a similar respective analysis in a single endocrine clinic comparing the rate of surgeries pre-and post GEC testing for nodules with indeterminate cytopathology (N=61 [27 before and 34 after GEC implementation]). The results were however, inconsistent with Sack's 'findings. The analysis showed no significant difference before and after GEC implementation in the rate of ITNs, but there was a significant decrease in the recommendation for surgery for patients with ITNs from 81.5% pre-GEC implementation to 50% post GEC ($p=0.01$). The surgical pathology for those who underwent an operation was read as malignant in 20% and 85.7%. of patients before and after Afirma GEC respectively ($p<0.01$). The study was retrospective, small, included patients from a single center over two-time periods with different pathologists analyzing the specimens, which are potential sources of confounding and bias that may limit generalization of the results.

Duick and colleagues (2012, Evidence table 4, from an earlier MTAC review) performed a chart review for 21 endocrinology practices in 11 states. They analyzed data for 368 patients with 395 cytologically indeterminate thyroid nodules with Afirma GEC benign results. 7.6% of these patients underwent surgery and 94.4% were managed nonoperatively.

The study did not have a comparison group, but the authors compared the 7.6% surgical rate in nodules with benign GEC results to a 74% historical rate of diagnostic surgery ($P<0.001$). The main indications for surgery for those with GEC benign results were the rapid growth or larger size of the nodules, local pressure symptoms, or the presence of a second suspicious nodule or malignant nodule.

The study was retrospective, used a historical comparison, and investigated the decision-making of endocrinologists experienced in managing patients with thyroid nodules, which may differ from that made by primary care providers or other specialists. In addition, the authors of the study did not provide data on long-term

 Back to Top

follow-up of those who were managed by watchful waiting rather than surgery.

Sipos and colleagues (2016), retrospectively analyzed data recorded for 98 patients with a benign GEC over a mean duration of 36 ±3 months (range 0-44 months) treated at multiple centers. 17 of these 98 patients (17.3%) underwent surgery during this period. 88% of the surgeries were performed in the first 2 years after the benign GEC results with the rate leveling after the first year. The most common indications for surgery were the nodules rapid growth and large size. The authors concluded that the study shows that benign GEC test results are associated with low operative rates. The study had its limitations and the authors did not provide data on the pathology results of the resected nodules.

Articles: The updated literature search revealed a number of retrospective analyses performed after the Afirma GEC validation study, a meta-analysis that pooled the results of selected studies, and three retrospective studies on the clinical utility of the test. The study on the analytic validity, the two clinical validation studies as well as two retrospective studies on clinical utility were reviewed earlier by MTAC. The meta-analysis and the more recent studies on the clinical validly and clinical utility of Afirma GEC test were reviewed and their results summarized.

04/12/2022: MTAC Review
Thyroid Nodule Molecular Testing

Evidence Conclusion: Analytical validity: One study showed that Afirma GSC test has a strong analytic performance and is reproducible. Clinical validity: Low quality evidence suggests that: Afirma GSC test has a good diagnostic performance. Comparison to ThyroSeq v3 and ThyraMIR/ThyGeNEXT: the diagnostic performance cannot be ranked due to lack of head-to-head comparisons. Clinical utility: The evidence is insufficient (very low quality) for or against the use of Afirma GSC to reduce unnecessary surgery in patients with indeterminate thyroid nodules.

Articles: PubMed was searched through October 26, 2021. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. Search terms included: (Afirma Genomic Sequencing Classifier OR Genomic Sequencing Classifier OR GSC OR Afirma OR Veracyte) AND (thyroid) through 10/21/21.
For Thyroseq v3, search terms included ThyroSeq v3Regarding ThyGeNEXT and ThyraMIR, search terms included Interpace or ThyGeNEXT or ThyraMIR. Afirma GSC: The search yielded several articles. After screening through abstracts and/or full text, 9 studies were retained and reviewed. The studies consisted of 1 analytical validity study, four clinical validity studies, and four clinical utility studies. Thyroseq v3: The search yielded several articles. Studied retained are critically appraised. ThyGeNEXT and ThyraMIR: The search yielded several articles. Studied retained are critically appraised. See Evidence tables.

The use of Thyroid Nodule Molecular Testing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability

BACKGROUND

Intellectual disability, also termed mental retardation or cognitive disability, affects approximately 1-3% of the general population and is defined as a significant impairment in cognitive and adaptive functions, with the age of onset before 18 years. It is a serious and lifelong condition that presents significant challenges to families and to public health. Determining the specific etiology of intellectual disability may help to provide answers related to prognosis, recurrence risk, and treatment. Intellectual disability can be caused by anything that damages or interferes with the growth or maturation of the brain; however, genetic (chromosomal) abnormalities are one of the main causes of intellectual disability (Galasso 2010, Sagoo 2009). Chromosomal abnormalities are deletions and duplications of genomic material and are commonly referred to as copy number variations. Conventional methods for detecting these abnormalities include karyotyping and florescent in situ hybridization (FISH). Karyotyping involves visualizing the chromosome for large gains or losses in chromosomal material and is generally the first step in cytogenetic analysis. Karyotyping can detect chromosomal abnormalities such as deletions, duplications, inversions, and translocations across the entire genome; however, it lacks the resolution necessary to detect abnormalities smaller than 3-5 megabases (Mb; 3-5 million base pairs). FISH uses florescent-labeled chromosome-specific probes to detect chromosomal abnormalities. FISH can detect submicroscopic abnormalities and is often used in situations where the karyotype is normal, but there is a high clinical suspicion of a deletion syndrome. However, FISH is a targeted method and requires prior knowledge of the chromosome region(s) of interest to request the appropriate FISH test. Additionally, FISH can only screen a limited number of genomic regions at a time (Breman 2009, Fruhman 2010, Galasso 2010, Gropman 2010). Array comparative genomic hybridization (aCGH) is a more recent technology used to identify copy number variations by comparing

 Back to Top

patient DNA with reference DNA. It is currently used as an adjunct to conventional methods. There are two types of aCGH: targeted and whole-genome. Targeted arrays are designed to interrogate areas of the genome with known clinically significant abnormalities. Whole genome arrays provide high resolution coverage of the entire genome. This can lead to the discovery of new copy number variations. Compared to conventional methods, aCGH has a higher resolution and is able to simultaneously detect copy number variations in multiple regions of the genome. Additionally, unlike FISH, knowledge of the chromosome region(s) of interest does not need to be determined in advance because a single array assay detects all genomic variants represented on the array. Array CGH is not without limitations. It cannot detect totally balanced translocations or inversions; it performs suboptimally for polyploidy; and has not been optimized for prenatal diagnosis of point mutations. Because aCGH cannot identify the exact location of a duplicated chromosome, further testing with karyotype or FISH may be necessary. Another limitation is the potential to identify novel copy number variants with unknown clinical significance (Fruhman 2010, Moeschler 2008). Array CGH is a laboratory-developed test and is commercially available from several different laboratories. Laboratory-developed tests are licensed under the Clinical Laboratory Improvement Amendments (CLIA) and do not require clearance from the FDA.

The use of Gene Expression Classifier (Afirma®) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

4/18/2011: MTAC REVIEW

Array Comparative Genomic Hybridization (aCGH) for the Genetic Evaluation of Patients with Intellectual Disability

Evidence Conclusion: Analytic validity The BCBS review identified several studies that evaluated the sensitivity of aCGH. The sensitivity of aCGH testing compared to conventional methods (karyotype and/or FISH) ranged from 73% to 100%. As false-positive rates were inconsistently reported, specificity could not be determined (BCBS 2009). Clinical validity

Articles: No studies were identified that evaluated the impact of conventional methods or aCGH on patient outcomes other than diagnostic yield. Results from the BCBS review suggest that diagnostic yield in patients with intellectual disability ranged from 5 to 16.7%, which represents a significant improvement compared to conventional methods. The number needed to test by aCGH to detect one clinically relevant abnormality ranged from 25 to 6 depending on the diagnostic yield. Limitations of these studies include: different aCGH resolution, patient selection criteria ranged from none too stringent criteria, and three different types of arrays were used (targeted, whole-genome, and those that combined targeted and whole-genome arrays) (BCBS 2009).

Diagnostic yield[1] of aCGH, karyotype, and FISH

	aCGH	FISH	karyotype
Diagnostic yield	4-7% (In those negative by karyotype and FISH)	5-6% (In those negative by karyotype)	3-5%

[1]Estimates from Stankiewicz 2007.

Clinical utility The BCBS review included two small studies with a high risk of bias and found that there was insufficient evidence to determine the clinical utility of aCGH testing (BCBS 2009). Conclusion: Analytic validity: There is fair evidence that aCGH testing had good sensitivity compared to conventional methods; however, there is insufficient evidence to determine the specificity or reproducibility of this test. Clinical validity: There is fair evidence that aCGH increases diagnostic yield over conventional methods; however, this is an intermediate outcome. Clinical utility: There is insufficient evidence that patients managed with the genetic test had better outcomes than patients managed without the genetic test.

In 2009, Blue Cross and Blue Shield (BCBS) evaluated the use of aCGH for the genetic evaluation of patients with developmental delay/ mental retardation. Studies were selected for review if they were published after the 2009 review and did not support the BCBS recommendations. No studies were identified that would change the BCBS recommendations. The following review was critically appraised: Blue Cross and Blue Shield Association.

Special report: aCGH for the genetic evaluation of patients with developmental delay/mental retardation or autism spectrum disorder. Assessment Program. Volume 23, No. 10. April 2009.

The use of Array Comparative Genomic Hybridization (aCGH) for the genetic evaluation of patients with intellectual disability does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

HLA Testing for Celiac Disease

Back to Top

BACKGROUND

Celiac disease is a chronic, autoimmune disorder that affects approximately 1% of children and adults in the United States. In individuals with celiac disease, the ingestion of gluten proteins found in wheat, rye, and barley lead to an autoimmune reaction that causes small intestine mucosal injury. Damages in the small intestine can cause gastrointestinal symptoms and interfere with the absorption of nutrients from food. This may lead to malnutrition-related problems such as anemia, vitamin deficiencies, osteoporosis, and neurological disorders. A gluten-free diet typically resolves symptoms and can prevent long-term consequences (Tack 2010). There are a variety of tests available to diagnose celiac disease. The gold-standard for diagnosing celiac disease is a small intestine biopsy. However, this test is not a perfect gold-standard as false positive and false-negative results may occur due to interobserver variability, patchy mucosal damage, low-grade histological abnormalities, and technical limitations. Additionally, histological features are not unique to celiac disease. Serum antibody tests are used as an initial screening tool to detect and support the presence of celiac disease and to select which patients should undergo a biopsy. Two of the most sensitive and specific serological tests for diagnosing celiac disease are tests that assess the presence of IgA autoantibodies against the endomysium of connective tissue (EMA) (sensitivity 62-81%, specificity 80-99%) and against tissue transglutaminase (tTGA) (sensitivity 81-88%, specificity 84-99%). While these tests are accurate, they are not without limitations. For example, the EMA test correlates with the degree of mucosal damage. As such, the sensitivity of this test is lower in patients with milder cases (higher chance of false negative results). Additionally, false negative results may occur in patients with an IgA deficiency and in patients who are already on a gluten-free diet. In patients with an IgA deficiency, serum IgA testing can be replaced by using IgG assays, which are less sensitive than IgA assays. Another test that can be used to rule out the diagnosis of celiac disease is human leukocyte antigen (HLA) genotyping. It has been reported that approximately 90-95% of patients with celiac disease are carriers of the HLA-DQ2 heterodimer and most of the remaining patients carry the HLA-DQ8 heterodimer. Since virtually all patients with celiac disease carry one of these heterodimers, celiac disease is highly unlikely when both are absent. It has been proposed that using HLA genotyping as an initial screening tool may avoid future concerns about the condition and eliminate further diagnostic testing. However, HLA typing is not a perfect solution since around 25-40% of the general population carries either HLA-DQ2 or DQ8, of which the majority never develop the disease. Other situations where HLA genotyping may be useful is when the diagnosis of celiac disease is unclear based on serological and/or histological findings. Additionally, HLA genotyping can be performed in patients who are already on a gluten free diet (Tack 2010, Hadithi 2010).

4/18/2011: MTAC REVIEW

HLA Testing for Celiac Disease

Evidence Conclusion: Analytic validity There are a variety of methods used for HLA genotyping. Each of these assays has its advantages and limitations (Monsuur 2008, Lavant 2009). Clinical validity A recent prospective cohort study evaluated the accuracy of serologic tests and HLA-DQ genotyping used alone and in combination for diagnosing celiac disease compared to small intestine biopsy. Results from this study suggest that both tTGA and EMA are sensitive and specific tests for diagnosing celiac disease. HLA-DQ testing was also highly sensitive but was not as specific as serologic testing. The addition of HLA-DQ genotyping to serum antibody tests did not increase test performance compared to serologic testing alone. Results should be interpreted with caution as only 16 patients were diagnosed with celiac disease (Hadithi 2007). Sensitivity and specificity of serologic testing and HLA-DQ typing for diagnosing celiac disease

	Sensitivity (95% CI)	Specificity (95% CI)
HLA-DQ testing		
HLA-DQ2 or DQ8	100 (79-100)	57 (52-62)
Serologic testing using IgA		
tTGA	81 (54-95.9)	99.1 (97.7-99.7)
EMA	81 (54-95.9)	99.1 (97.7-99.7)
tTGA & EMA	81 (54-95.9)	99.3 (98-99.9)
Both serologic testing & HLA-DQ testing		
tTGA & HLA-DQ	81 (54-95.9)	99.3 (98-99.3)
EMA & HLA-DQ	81 (54-95.9)	99.1(97.7-99.8)
tTGA, EMA, & HLA-DQ	100 (79-100)	99.3 (98-99.9)

Abbreviations: EMA= antiendomysium antibody; tTGA= antitransglutaminase antibody.

Another observational study investigated whether HLA genotyping would be useful to identify first-degree relatives of patients with celiac disease who do not need further screening for celiac disease. Fifty-four families with at least two siblings with celiac disease were selected to participate in the study. In total, 245 (52.5%) first-degree relatives agreed to participate. The diagnosis of celiac disease was based on duodenal biopsy and medical records. Of all of the first-degree relatives, 17.6% (N=43) did not carry any of the celiac disease risk alleles. Of these relatives, only one was diagnosed with celiac disease (Karinen 2010). Clinical utility

Back to Top

Because of its low specificity HLA genotyping may not be an ideal initial screening test for diagnosing celiac disease. However, HLA genotyping may be useful in certain situations, such as when the diagnosis of celiac disease is unclear based on serologic and histologic findings and when patients are already on a gluten free diet, to rule out celiac disease. Additionally, as negative serologic or histologic test results do not exclude the development of celiac disease later in life, the use of HLA genotyping in patients who are at increased risk for celiac disease may prevent unnecessary serologic and histologic testing. Conclusion: Analytic validity: There are a variety of methods used for HLA genotyping. Each of these assays has its advantages and limitations. Clinical validity: There is fair evidence that HLA genotyping may be a useful adjunct in the diagnosis of celiac disease as it has a high negative predictive value. Clinical utility: No studies were identified that addressed the clinical utility of HLA genotyping for celiac disease; however, early identification and treatment of the disease can prevent short- and long-term complications.
Articles: Articles were selected for review if they included at least 25 subjects and assessed the accuracy of HLA genotyping compared to the small intestine biopsy. A prospective cohort study was selected for review. The following study was critically appraised: Hadithi M, von Blomberg ME, Crusius BA, et al. Accuracy of serologic tests and HLA-DQ typing for diagnosing celiac disease. *Ann Intern Med 2007;* 147:294-302. See Evidence Table

The use of HLA testing for celiac disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Micro Array for Evaluation of Intellectual Disability
BACKGROUND
Intellectual disability, also termed mental retardation or cognitive disability, affects approximately 1-3% of the general population and is defined as a significant impairment in cognitive and adaptive functions, with the age of onset before 18 years. It is a serious and lifelong condition that presents significant challenges to families and to public health. Determining the specific etiology of intellectual disability may help to provide answers related to prognosis, recurrence risk, and treatment.

Intellectual disability can be caused by anything that damages or interferes with the growth or maturation of the brain; however, genetic (chromosomal) abnormalities are one of the main causes of intellectual disability (Galasso 2010, Sagoo 2009).

Chromosomal abnormalities are deletions and duplications of genomic material and are commonly referred to as copy number variations. Conventional methods for detecting these abnormalities include karyotyping and florescent in situ hybridization (FISH). Karyotyping involves visualizing the chromosome for large gains or losses in chromosomal material and is generally the first step in cytogenetic analysis. Karyotyping can detect chromosomal abnormalities such as deletions, duplications, inversions, and translocations across the entire genome; however, it lacks the resolution necessary to detect abnormalities smaller than 3-5 megabases (Mb; 3-5 million base pairs).

FISH uses florescent-labeled chromosome-specific probes to detect chromosomal abnormalities. FISH can detect submicroscopic abnormalities and is often used in situations where the karyotype is normal, but there is a high clinical suspicion of a deletion syndrome. However, FISH is a targeted method and requires prior knowledge of the chromosome region(s) of interest to request the appropriate FISH test. Additionally, FISH can only screen a limited number of genomic regions at a time (Breman 2009, Fruhman 2010, Galasso 2010, Gropman 2010).

Array comparative genomic hybridization (aCGH) is a more recent technology used to identify copy number variations by comparing patient DNA with reference DNA. It is currently used as an adjunct to conventional methods. There are two types of aCGH: targeted and whole-genome. Targeted arrays are designed to interrogate areas of the genome with known clinically significant abnormalities. Whole genome arrays provide high resolution coverage of the entire genome. This can lead to the discovery of new copy number variations. Compared to conventional methods, aCGH has a higher resolution and is able to simultaneously detect copy number variations in multiple regions of the genome. Additionally, unlike FISH, knowledge of the chromosome region(s) of interest does not need to be determined in advance because a single array assay detects all genomic variants represented on the array. Array CGH is not without limitations. It cannot detect totally balanced translocations or inversions; it performs suboptimally for polyploidy; and has not been optimized for prenatal diagnosis of point mutations.
Because aCGH cannot identify the exact location of a duplicated chromosome, further testing with karyotype or FISH may be necessary. Another limitation is the potential to identify novel copy number variants with unknown clinical significance (Fruhman 2010, Moeschler 2008).

Array CGH is a laboratory-developed test and is commercially available from several different laboratories.

Back to Top

Laboratory-developed tests are licensed under the Clinical Laboratory Improvement Amendments (CLIA) and do not require clearance from the FDA.

Date: 07/09/2018 MTAC REVIEW

Chromosomal microarray for Intellectual Disability (ID)/ Developmental delay (DD)

BACKGROUND

Intellectual disability is a disorder marked by deficits in intellectual and adaptive functioning and starts before 18 years of age. Its management requires early diagnosis and extensive supports. Intellectual disability is caused by any conditions disrupting brain development. Of these conditions, genetic abnormalities are the most common known etiologies (Rauch et al., 2012) with Down syndrome being the leading cause. Conventional cytogenetics (karyotype analysis and fluorescence in situ hybridization (FISH)) can identify the cause but detect less than 10% of chromosomal abnormalities in patients with intellectual disability (ID) or developmental delay (DD) (Shaffer, Beaudet, et al., 2007; Shaffer, Bejjani, et al., 2007). Chromosomal microarray analysis (CMA) has become the primary test for most patients with intellectual disability (Miller et al., 2010). CMA includes array-based comparative genomic hybridization (aCGH) or single nucleotide polymorphism (SNP) microarray analysis.

Array-based comparative genomic hybridization (aCGH), also known as oligonucleotide array comparative genomic hybridization utilizes both patient and control genomes. These DNAs are marked with fluorescent dyes and applied to the microarray. This step is followed by hybridization. Hybridization occurs when patient and control DNAs compete to attach to the microarray which is comprised of thousands of DNA segments (bacterial artificial chromosome clones of > 10 kilobases or oligonucleotides of 50–70 base pairs). Fluorescent signals are assessed by a scanner and a computer analyzes the data and generates a plot. This results in the identification of copy number changes (Theisen et al., 2008(Shaffer et al., 2008)). It is believed that the aCGH concurrently detects copy number variants (CNVs) (deletions, duplications), and/or amplifications across the genome. However, the array-based comparative genomic hybridization cannot detect low-level mosaicism or balanced chromosomal rearrangements (Brady & Vermeesch, 2012). The results of the CMA are interpreted as benign with no impact on phenotype, or pathogenic/clinical significant, or uncertain clinical significance. In the latter category, samples from parents are required for assessment of the clinical significance (Miller et al., 2010; Paciorkowski & Fang, 2009). If the CMA does not detect a cause, whole exome sequencing (WES) may be performed. Single nucleotide polymorphism (SNP) arrays is a variation of DNA sequence that occurs when there is a discrepancy between a single nucleotide and a reference sequence in the same person. Single nucleotide polymorphism is used as the probes. Only the patient sample is hybridized onto the array(Das & Tan, 2013). SNP can detect copy number changes, uniparental disomy, consanguinity, and balanced translocations (Conlin et al., 2010; Schaaf, Wiszniewska, & Beaudet, 2011; Wiszniewska et al., 2014). No FDA regulatory information was found on FDA website on March 12, 2018. However, genetic tests are controlled under the Clinical Laboratory Improvement Amendments (CLIA). The technology is being assessed for the first time on Medical Technology Assessment Committee (MTAC).

Evidence Conclusion:

Conclusion:

- **Analytic validity:** Four studies were reviewed and showed high sensitivity and specificity with high concordance in comparison to FISH or karyotyping. This suggests that chromosomal microarray can accurately detect copy number variants in children and adolescents with developmental delay or intellectual disability. The studies were retrospective in design or case series resulting in low evidence.
- **Clinical validity:** Nine studies (please refer to “other studies table” and table 2) in addition to those included in Milliman review (evidence table 1) were evaluated. In children and adolescents with unexplained developmental delay or intellectual disability, chromosomal microarray (aCGH) diagnosed genomic alterations that were not detected by conventional cytogenetic tests including karyotype or FISH. This suggests that the detection rate of chromosomal microarray is higher than conventional cytogenetic tests. However, the studies reviewed were case series or retrospective chart review resulting in low evidence.
- **Clinical utility:** Two studies (please refer to “other studies table” and table 2) in addition to those included in Milliman review (evidence table 1) were evaluated. The clinical utility revolved around referrals to specialists, recommendation for screening of other anomalies, provision of recurrent risk for affected subsequent pregnancies, and avoidance of unnecessary testing. However, the studies were surveys and retrospective review with small sample size resulting in low evidence.
- Milliman Care guidelines indicated that there is a net benefit in evaluating children and adolescents with intellectual disability with chromosomal microarray analysis (CMA). The use of CMA to detect copy number variants affects medical management and this includes referrals to specialists, treatment intervention for special findings, reduction of unnecessary procedures, and screening for associated anomalies. However, the evidence is of low certainty.

Back to Top

The use of Chromosomal microarray for Intellectual Disability (ID)/ Developmental delay (DD) meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

04/18/2011: MTAC REVIEW

Array Comparative Genomic Hybridization (aCGH)

Evidence Conclusion: Analytic validity - The BCBS review identified several studies that evaluated the sensitivity of aCGH. The sensitivity of aCGH testing compared to conventional methods (karyotype and/or FISH) ranged from 73% to 100%. As false-positive rates were inconsistently reported, specificity could not be determined (BCBS 2009). Clinical validity - No studies were identified that evaluated the impact of conventional methods or aCGH on patient outcomes other than diagnostic yield. Results from the BCBS review suggest that diagnostic yield in patients with intellectual disability ranged from 5 to 16.7%, which represents a significant improvement compared to conventional methods. The number needed to test by aCGH to detect one clinically relevant abnormality ranged from 25 to 6 depending on the diagnostic yield. Limitations of these studies include: different aCGH resolution, patient selection criteria ranged from none to stringent criteria, and three different types of arrays were used (targeted, whole-genome, and those that combined targeted and whole-genome arrays) (BCBS 2009).

Diagnostic yield[1] of aCGH, karyotype, and FISH

	aCGH	FISH	karyotype
Diagnostic yield	4-7% (In those negative by karyotype and FISH)	5-6% (In those negative by karyotype)	3-5%

[1]Estimates from Stankiewicz 2007.

Clinical utility- The BCBS review included two small studies with a high risk of bias and found that there was insufficient evidence to determine the clinical utility of aCGH testing (BCBS 2009).

Conclusion:

1. Analytic validity: There is fair evidence that aCGH testing had good sensitivity compared to conventional methods; however, there is insufficient evidence to determine the specificity or reproducibility of this test.

2. Clinical validity: There is fair evidence that aCGH increases diagnostic yield over conventional methods; however, this is an intermediate outcome.

3. Clinical utility: There is insufficient evidence that patients managed with the genetic test had better outcomes than patients managed without the genetic test.

Articles: In 2009, Blue Cross and Blue Shield (BCBS) evaluated the use of aCGH for the genetic evaluation of patients with developmental delay/ mental retardation. Studies were selected for review if they were published after the 2009 review and did not support the BCBS recommendations. No studies were identified that would change the BCBS recommendations. The following review was critically appraised: Blue Cross and Blue Shield Association.

Special report: aCGH for the genetic evaluation of patients with developmental delay/mental retardation or autism spectrum disorder. Assessment Program. Volume 23, No. 10. April 2009.

The use of Array Comparative Genomic Hybridization (aCGH) for the genetic evaluation of patients with intellectual disabilities does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Risk Prognosticator Test

BREVAGen

BACKGROUND

According to the American Cancer Society, breast cancer is the second leading cause of death in women in the United States after lung cancer. Current methods of assessing breast cancer risk include the Breast Cancer Risk Assessment Tool (BCRAT) otherwise known as the Gail model. This model incorporates individual risk factors such as basic demographic information, reproductive history and medical history. Recent genome wide association studies have identified several single nucleotide polymorphisms (SNPs) associated with an increased risk of breast cancer leading to an additional dimension and understanding of risk (Easton, Pooley et al. 2007; Stacey, Manolescu et al. 2007; Stacey, Manolescu et al. 2008). The BREVAGen™ (Phenogen Sciences, Inc., Charolette, NC) is a risk stratification test for sporadic breast cancer. Intended for use as an

 Back to Top

adjunct to the Gail model, the test consists of two parts, the first, a series of questions to determine clinical risk and the second, a buccal swab to analyze specific genetic markers. The latter part of the test, includes a panel of seven SNPs associated with breast cancer risk and does not include either of the BRCA mutations. Ultimately, a patient's risk is calculated by multiplying the product of the individual SNP risks by the Gail model risk. According to the BREVAGen™ website, the test is only suitable for women of European descent aged 35 years or older. No test combining the results of SNP analysis with clinical factors to predict breast cancer risk has been approved or cleared by the U.S. Food and Drug Administration (FDA). BREVAGen™ is offered as a laboratory developed tests and only requires oversight under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The development and use of this laboratory developed test is restricted to laboratories certified as high complexity under CLIA. Under the current regulatory program, CLIA requires that laboratories demonstrate quality systems which includes validation and proficiency testing.

12/16/2013: MTAC REVIEW
BREVAGen
Evidence Conclusion:
Conclusion: There is no evidence to determine the analytic validity of the BREVAGen™. There is some evidence to suggest that the addition of the BREVAGen™ panel is superior in determining breast cancer risk compared to Gail score alone. There is no evidence to determine the clinical utility of the BREVAGen™.
Articles: A search of PubMed was completed for the period through November 2013 for studies on the accuracy of BREVAGen™ for detecting the absence or presence of certain common genetic variations associated with an increased risk for developing breast cancer. The search strategy used the terms BREVAGen, Breast Cancer Risk Tool, Gail Model, genetic risk, single nucleotide polymorphism, breast cancer, and sporadic with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Articles were limited to those published in the English language with human subject enrollment. The search was supplemented by an examination of article reference lists in addition to the PubMed related articles function. The literature search for BREVAGen™ revealed one publication that clinically validates the Breast Cancer Risk Model in combination with the genetic and clinical information. The following study was selected for review: Mealiffe ME, Stokowski RP, Rhees BK, et al. Assessment of clinical validity of a breast cancer risk model combining genetic and clinical information. *Journal of the National Cancer Institute*. 2010;102(21):1618-1627. See Evidence Table.

The use of BREVAGen does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Fibroblast Growth Factor Receptor 3 (FGFR3) for Urothelial Carcinoma
BACKGROUND
It is estimated that approximately 70,530 new cases of bladder cancer will be diagnosed in the United States in 2010, and 14,680 will die of the disease (Jemal 2010). The most commonly occurring form of bladder cancer in the United States is urothelial carcinoma (also known as transitional cell carcinoma). The clinical spectrum of urothelial carcinoma can be divided into 3 categories: non-muscle-invasive, muscle-invasive, and metastatic disease. This review will focus on non-muscle-invasive urothelial cancer (NMIUC), which makes up approximately 75-80% of urothelial carcinoma. NMIUC includes stage Ta (noninvasive papillary carcinoma), Tis (carcinoma in situ), and T1 (tumor invades subepithelial connective tissue) tumors. The standard treatment for stage Ta, Tis, and T1 tumors is transurethral resection of bladder tumor (TURBT). Depending on prognosis adjuvant intravesical chemotherapy or immunotherapy may also be considered. However, despite treatment a significant number of patients will develop recurrence within 1 to 2 years of the initial treatment. Because of the high risk of recurrence careful surveillance is required for patients with NMIUC (Chou 2010, Cheng 2011, NCCN 2011, Pollard 2010). Assessing the risk of progression and recurrence is important for planning therapy. The risk for tumor progression and recurrence is estimated using factors such as histological grade, stage, depth of invasion, and extent of disease; however, the ability of these factors to predict clinical outcome is limited (Burger 2008, Cheng 2011, NCCN 2011). Recently, it has been suggested that molecular biomarkers such as fibroblast growth factor receptor 3 (FGFR3) may be useful for predicting clinical outcome and planning therapy. FGFR3 regulates cell growth, differentiation, and angiogenesis. More than 70% of low-grade noninvasive papillary urothelial carcinomas harbor FGRF3 mutations. Studies suggest that urothelial carcinomas that harbor FGFR3 mutations may be associated with improved prognosis (Cheng 2011). The CertNDx molecular grading assay (Predictive Biosciences, Inc.) was designed as a tool to be used in conjunction with clinical and histological parameters to aid in the clinical management of NMIUC. This test uses two biomarkers to determine molecular grade. The first biomarker is FGFR3 and the second is Ki-67, which is a marker of cell proliferation (Cheng 2011). Patients with molecular grade 1 (mG1) have FGFR3 mutations and low Ki-67 levels. Patients with molecular grade 2 (mG2) have FGFR3 mutations with high Ki-67 levels or wild-type FGFR3 and low Ki-67 levels. Patients with molecular grade 3 (mG3)

Back to Top

are FGFR3 wild-type and have high Ki-67 levels. Patients with molecular grade 1 have favorable prognosis, patients with molecular grade 2 have intermediate prognosis, and patients with molecular grade 3 have poor prognosis.

10/17/2011: MTAC REVIEW

Fibroblast Growth Factor Receptor 3 (FGFR3) for Urothelial Carcinoma

Evidence Conclusion: Analytic validity- No studies were identified that addressed the analytic validity of the CertNDx molecular grading assay. Clinical validity - A recent prospective observational study evaluated the prognostic value of both WHO 1973 and 2004 grading systems, markers CK20, FGFR3, and Ki-67, and molecular grade (combination of FGFR3 and Ki-67) in 221 patients with urothelial carcinoma. In univariate analysis, WHO grade 1973, WHO grade 2004, pathological stage, FGFR3, Ki-67 status, and molecular grade were significantly associated with progression in stage; however, in a multivariate model, only WHO grade 1973 and 2004 remained significantly associated with progression in stage. None of the variables measured were significantly associated with recurrence-free survival (Burger 2008). Another study that included 255 patients with primary urothelial carcinoma also found that the combination of FGFR3 and Ki-67 status was not an independent predictor of recurrence-free or disease-specific survival (van Oers 2007). However, an observational study that included 286 patients with urothelial carcinoma found that in a multivariate analysis, the combination of FGFR3 and Ki-67 status predicted progression, recurrence rate, and disease-specific survival (van Rhijn 2003). Clinical utility -
No studies were identified that addressed the clinical utility of the CertNDx molecular grading assay.
Conclusion: Analytic validity: No studies were identified that addressed the analytic validity of the CertNDx molecular grading assay. Clinical validity: Results from observational studies regarding the prognostic value of molecular grade (FGFR3/Ki-67) are mixed. Clinical utility: No studies were identified that addressed the clinical utility of the CertNDx molecular grading assay.
Articles: No studies were identified that addressed the analytic validity or clinical utility of the CertNDx molecular grading assay. Several studies were identified that evaluated the clinical validity of the CertNDx molecular grading assay. The most recent study was selected for review. The following study was critically appraised: Burger M, van der Aa MN, van Oers JM, et al. Prediction of progression of non-muscle-invasive bladder cancer by WHO 1973 and 2004 grading and by FGFR3 mutation status: a prospective study. *Eur Urol.* 2008;54:835-843. See Evidence Table.

The use of FGFR3 for urothelial carcinoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

MammaPrint Test

BACKGROUND
Breast cancer affects almost 10% of women in western countries and is a major cause of morbidity and mortality. Most patients with lymph node negative disease may be successfully treated with surgery and local irradiation. Those with more aggressive disease may benefit from adjuvant chemotherapy and hormone therapy which could significantly improve their overall and disease-free survival. It is generally accepted that breast cancer patients with the poorer prognosis would gain the most benefits from systemic adjuvant therapy. The use of this adjuvant therapy is thus one of the most critical treatment decisions during the clinical management of breast cancer patients. Currently those with aggressive breast cancer are identified according to a combination of criteria including age, clinical stage and size of the tumor, histological type and grade of cancer, axillary node status, and hormone-receptor status. The ability of these criteria to predict outcome and disease progression is imperfect. Within a given patient population at a specific predicted risk of recurrence, there are some patients whose actual clinical outcome does not match that predicted by the indicators. As a result, some of those who need adjuvant therapy do not receive it, while others may receive unnecessary toxic therapy (Kallioniemi 2002, DeVigier 2002). To overcome these issues, scientists are attempting to identify more accurate prognostic indicators. Microarray technology is revolutionizing researchers' understanding of cancer biology through the simultaneous study of the expression of tens of thousands of genes. Molecular profiling is the classification of tissue or other specimens for diagnostic, prognostic, and predictive purposes based on multiple gene expression. The potential value of gene expression profiling in assessing the risk of post-surgical breast cancer recurrence has been extensively investigated over the last few years. This has led to important insights in the molecular heterogeneity of cancers by revealing biologically and clinically relevant subtypes of tumors previously indistinguishable by the conventional approaches (Bertucci 2005). Due to the biological heterogeneity of breast cancers, women with the same stage of the disease may vary widely in their response to treatment and prognosis. Several gene expression-based predictors for breast cancer have been developed but have not been used in routine clinical practice. According to researchers, this is mainly due to the limited validation and the limited clinical description of the molecular subtypes. Validation is a major challenge for microarray studies especially those with clinical implications as it

Back to Top

requires a large sample size and because the results are influenced by the patient selection and by choice of the methods used to analyze gene expression data (Calza 2006, Hu 2006, Ioannidis 2007). The Amsterdam 70-gene profile (MammaPrint ®) was first developed using supervised gene expression profiling analysis of frozen tumor samples from two distinct patient populations. All were <55 years of age and had lymph node negative disease. 44% had distant metastases within 5 years of completing treatment and 56% did not. By comparing the gene expression profile of patients with or without metastases, a signature 70-gene set that correlated with the outcome was identified and internally validated with the same group (van't Veer 2002), and externally validated in two retrospective groups (Van De Vijver 2002 and Buyse 2006, see evidence tables). MammaPrint ® from Agendia is a qualitative in vitro diagnostic test service performed in a single laboratory using the gene expression profile of breast cancer tissue samples to assess a patient's risk for distant metastases. The MammaPrint assay uses a panel of the Amsterdam 70-gene profile described above. It is a microarray-based gene expression analysis of RNA extracted from breast tumor tissue. The MammaPrint ® analysis is designed to determine the activity of specific genes in a tissue sample compared to a reference standard. Its index ranges from -1.0 to +1.0. Tumor samples with an index above the threshold of +0.4 are classified as low risk, and those with an index equal to or less than the threshold is classified as high risk. The test requires fresh frozen samples which are shipped to the Agendia reference laboratory in the Netherlands. It is performed for breast cancer patients <61 years old, with Stage I invasive breast cancer or Stage II node negative invasive breast cancer, with tumor size <5 cm. It is indicated for use by physicians as a prognostic marker only, along with other clinicopathological factors. It is not intended for diagnosis, or for predicting or detecting response to therapy, or to help select the optimal therapy for patients (FDA).

08/06/2007: MTAC REVIEW
MammaPrint Test
Evidence Conclusion: The identification and validation of gene expression panels to improve risk prediction or treatment outcomes is a multistep process that starts by 1. Identifying the candidate genes (analytic validity), followed by 2. Evaluating the genetic panel associations with risk prediction or treatment outcomes in preliminary performance studies in relevant population (clinical validity), and 3. Determining whether the use of the multigenetic assay would direct the management of patients and improve outcomes (clinical utility). The most reliable method for validation is to derive a prognostic/predictive gene set from a training set and then apply it to a completely independent set, the test set, (Simon 2003, Ionnidis 2006, and Hu 2006). The MammaPrint test was developed based on research performed in the Netherlands Cancer Institute, The training set was derived from a study by van't Veer and colleagues that included 98 women < 55 years of age at diagnosis, with primary breast cancer (34 developed distant metastases within 5 years, 44 were disease free after at least 5 years). All patients were lymph node negative. 5 µg total RNA was isolated from frozen tumor material for each patient. The authors used inkjet-synthesized oligonucleotide microarrays that included 25,000 genes. Following several techniques 5000 genes were selected from the microarray, and then optimized to 70 genes with which a prognosis profile was established. The authors conducted a cross validation and concluded that a classification system based on these 70 genes outperformed all clinical variables in predicting the likelihood of distant metastases within five years.
They noted however, that a selection of the patients based on the outcome (distant metastases or disease free in 5 years) was a limitation to the study. The same research team followed the initial study with a validation study (Van De Vijver, 2002) that included 295 women with either lymph node negative or lymph node positive breast cancer. The authors calculated the correlation coefficient of the level of expression of the 70- predictor genes identified in their initial study. They then classified the women with a correlation coefficient > 0.4 as having a good prognosis gene expression signature, and all the others as having a poor prognosis gene expression signature. In this validation set however the authors included 61 patients from the original training group used to derive the RNA expression signature, which could overestimate the relative risk and inflate the discriminating power of the test.
The validation study included women < 55 years of age, with small tumors and at stage I or II of the disease which may not represent the entire spectrum of patients with breast cancer. Adjuvant hormone therapy or chemotherapy or both were given to most of the patients with lymph node positive disease. The Translational Research Network of the Breast International group (TRANSBIG) also conducted an independent validation study of the prognostic signatures in a retrospective series of 302 untreated patients in five European countries. The study included only women node negative early stage breast cancer who had not received systemic adjuvant therapy, and thus may not represent the all patients with breast cancer. Its overall results showed that the 70-gene signature provided prognostic information on time to distant metastases and overall survival independent of the other clinical predictors.
In conclusion, the selection of the 70- predictor genes were based on analyses of tumors from patients < 55 years of age with lymph node negative cancer who do not represent all women with breast cancer. The test proved to perform well as an independent prediction tool among the selected women studied. This, however, does not necessarily indicate that it would predict treatment response. To date there are no published studies that show if modification of adjuvant therapy based on this test would improve disease free or overall survival. A large

Back to Top

randomized controlled trial (Microarray for Node negative Disease may Avoid Chemotherapy [MINDACT]) that will evaluate the clinical utility of MammaPrint is underway. The trial will directly compare the use of prognostic information provided by the standard clinicopathological criteria vs. the MammaPrint test to decide whether to offer adjuvant chemotherapy to node-negative breast cancer patients. The MINDACT plans to prospectively include 6000 women and follow-them up for a long duration in order to determine 5-year disease free-survival rate.

Articles: The literature search revealed multiple articles on molecular and gene-expression profiling in general. For the MammaPrint test in particular, there was a published study on the training set (to develop or derive the predictive classifier or model) by Van't Veer and colleagues, and three validation studies to evaluate the predictive accuracy of the model (Van De Vijver 2002, Buyse 2006, and Glas 2006). All studies were reviewed but only the first two validation studies were critically appraised, Glas, et al's study was not selected for critical appraisal due to patient overlap with the van De Vijver study. It is to be noted that Van De Vijver, van't Veer, and several other principal authors are named inventors on a patent application for the 70-gene signature used in the studies. All studies also had financial ties to the manufacturer. *The following studies were critically appraised:*

Van De Vijver MJ, He YD, van't Veer LJ, et al. A gene expression signature as a predictor of survival in breast cancer. N Engl J Med 2002:347:1999-2009. See Evidence Table. Buyse M, van't Veer, L, Viale G et al on behalf of the TRANSBIG Consortium. Validation and clinical utility of a 70-gene prognostic signature for women with node negative breast cancer. J Natl Cancer Inst 2006:98:1183-1192. See Evidence Table.

The use of the MammaPrint test in the treatment of recurring cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

OVA1™ Test for the Assessment of Suspected Ovarian Cancer

BACKGROUND

In the United States, ovarian cancer is the fifth leading cause of all cancer-related death among women. It is estimated that in 2010, there were 21,880 new cases of ovarian cancer and 13,850 deaths from ovarian cancer (Jemal 2010). The incidence of ovarian cancer increases with age with approximately two thirds of cases being diagnosed in women over the age of 55. Women with a family history of ovarian or breast cancer or who are carriers of the BRCA gene mutations are also at increased risk for ovarian cancer (Clarke-Pearson 2009). For patients with early stage disease, survival rates are greater than 90%; however, they are less than 30% for patients with advanced disease. Because of the lack of specific symptoms during the early stage approximately 70% of cases are diagnosed with advanced disease (Carter 2011). The most commonly used tests for the detection of ovarian cancer are transvaginal ultrasound (TVS) and serum CA-125. Recently, the FDA approved the OVA1™ test (Quest Diagnostics, Inc.) to be used as an adjunct to clinical/radiological evaluations for women planning surgery for an adnexal mass. This test measures the serum levels of 5 potential biochemical markers for ovarian cancer (transthyretin, apolipoprotein A1, transferring, CA-125, and β2-mocrogloublin). The results of the test are then interpreted using a proprietary algorithm to yield a single score ranging from 0 to 10 to indicate the likelihood that the adnexal mass is benign or malignant. A high probability for malignancy is defined as a score of at least 5.0 in premenopausal women or 4.4 in postmenopausal women. The goal of the OVA1™ test is to provide additional information to aid in identifying patients who should be referred to a gynecologic oncologist for surgery (Carter 2011, Muller 2010). Studies suggest that women who receive their initial surgical care from an experienced gynecologic oncologist have improved outcomes and greater overall survival. Because of this the National Comprehensive Cancer Network (NCCN) recommends that all patients should undergo surgery by an experienced gynecologic oncologist (NCCN 2011). It is important to emphasize that this test is not approved for ovarian cancer screening and is not intended for use as a standalone test. Another limitation of this test is that assay interference may occur in patients with rheumatoid factor levels of at least 250 IU/mL and triglyceride levels greater than 4.5 g/L (Muller 2010). In 2009, the FDA approved the use of this test for women over the age of 18 with an ovarian adnexal mass for which surgery is planned and have not yet been referred to an oncologist.

10/17/2011: MTAC REVIEW

OVA1™ Test for the Assessment of Suspected Ovarian Cancer

Evidence Conclusion:

Conclusion: Analytic validity: No studies were identified that evaluated analytic validity of the OVA1™ test. Clinical validity: Results from a recent observational study suggest that the when added to physician assessment or substituted for CA 125, the OVA1™ test increased the sensitivity and negative predictive value of these assessments but decrease the specificity and positive predictive value. Clinical utility: No studies were identified that evaluated the clinical utility of the OVA1™ test.

Articles: No studies were identified that assessed the analytic validity or clinical utility of the OVA1™ test. Two studies were identified that addressed the clinical validity of the OVA1™ test. Both of these studies were selected for review. The following studies were selected for critical appraisal: Ueland FR, Desimone CP, Seamon LG, et al.

Back to Top

Effectiveness of a multivariate index assay in the preoperative assessment of ovarian tumors. *Obstet Gynecol 2011;* 117:1289-1297. See Evidence Table. Ware Miller R, Smith A, DeSimone CP, et al. Performance of the American College of Obstetricians and Gynecologists' ovarian tumor referral guidelines with a multivariate index assay. *Obstet Gynecol.* 2011; 117:1298-1306. See Evidence Table.

The use of OVA1 for ovarian tumors does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Review

SelectMDx for Prostate Cancer (MDxHealth Inc.)

According to the testing laboratory, the SelectMDx test is a noninvasive, urine-based molecular screening test that, when combined with patient clinical risk factors, can aid physicians in determining if a patient is at higher risk (defined by laboratory as detecting GS ≥ 7 prostate cancer upon biopsy) or lower risk for prostate cancer and can avoid biopsy (MDxHealth, 2019a). The test is intended for men who have not been previously diagnosed with prostate cancer. The SelectMDx test requires a first void post-digital rectal examination (DRE) urine sample, which is analyzed for the mRNA level of 2 cancer-related biomarkers, DLX1 and HOXC6 (MDxHealth, 2016; MDxHealth, 2019b).

Hayes Rating: D2

For use of the SelectMDx for Prostate Cancer test to aid physicians in determining if a patient is at higher risk (defined by laboratory as detecting Gleason score (GS) ≥ 7 prostate cancer upon biopsy) or lower risk for prostate cancer and can avoid biopsy.

Conclusion: There is insufficient evidence supporting use of the SelectMDx test. Additional studies are needed to demonstrate the clinical validity and, ultimately, clinical utility of the test and whether the test results would improve patient management outcomes, including avoiding unnecessary prostate biopsies.

Reference

Hayes. Hayes Molecular Test Assessment. SelectMDx for Prostate Cancer (MDxHealth Inc.). Dallas, TX: Hayes; February 25, 2021. Retrieved November 29, 2021 from https://evidence.hayesinc.com/report/gte.selectmdx3769

Thyroid Nodule Gene Expression Testing (Afirma)

BACKGROUND

Thyroid nodules are very common; they are clinically identified in 5-7% of the population, and incidentally on ultrasonography in up to 50% of women and 20% of men over the age of 50. The thyroid nodules are typically benign, but 5-15% prove to be malignant. It is thus recommended that any identified nodule measuring one centimeter or more in diameter be diagnostically evaluated. Thyroid fine needle aspiration (FNA) biopsy is the most widely used method for clinical evaluation of a suspicious thyroid nodule. FNA is a safe and simple outpatient procedure that yields cellular material suitable for cytological analysis. However, 15-30% of the biopsied nodules has indeterminate cytology and cannot be conclusively diagnosed by FNA biopsy alone. Most patients with indeterminate lesions (defined in the Bethesda System as Atypia of Undetermined Significance or Follicular Lesion of Undetermined Significance, suspicious for Follicular or Hurthle Cell neoplasm and suspicious for malignancy) are referred to surgery. Currently, surgery is performed for both diagnostic and therapeutic purposes in these patients with indeterminate aspirates. Surgery has high operative efficacy in removal of thyroid cancer, however approximately three-quarters of the nodules with indeterminate FNA cytology are ultimately found to be benign on final surgical pathology. Thus, a large proportion of patients with indeterminate nodules may undergo unnecessary partial or complete thyroidectomy with its potential surgical complications and risk of long-term morbidity (Alexander 2012, Duick 2012, Walsh 2012, Ali 2013). In an attempt to preoperatively classify the indeterminate thyroid nodules different novel diagnostic tests and molecular markers have been investigated. These include immunohistochemistry, mutation and gene rearrangement testing, and gene expression and microarray analysis. Each has its performance characteristics and diagnostic values. Ideally a molecular marker or panel of markers would be accurate in differentiating benign from malignant in any lesion that is considered suspicious or indeterminate. It should be simple to use, reproducible by all institutions, and cost-effective. Genetic markers associated with malignancy such as mutation markers (e.g. BRAF, RAS) and gene rearrangements (e.g. RET/PTC and PAX8-PPAry) have high specificity and positive predictive values; and when detected they can “rule in” the diagnosis of thyroid cancer, However, they have limited sensitivity and negative predictive values as they fail to detect a large proportion of malignant samples that do not contain one of the mutations or rearrangements being tested, i.e. mutation or rearrangement markers cannot ‘rule out’ malignancy when not detected (Alexander 2012, Kouniavsky 2012, Ward 2013). Microarray techniques seek to identify patterns of expressed RNA in the human

Back to Top

genome that are predictive of benign or malignant thyroid disease. Unlike single gene mutations or rearrangements, microarray diagnostic tests involve tens to hundreds of expressed genes. The currently available diagnostic microarray for use in thyroid nodule analysis is the Afirma Gene Expression Classifier (GEC) recently developed by Veracyte, Inc. It is a genomic test designed with the intention of preoperative identification of benign thyroid nodules in patients with indeterminate FNA cytopathological results. The test assesses gene expression from mRNA isolated from thyroid FNA samples by comparing the mRNA expression detected in a thyroid FNA against a panel of 167 molecular genes. It uses a multidimensional algorithm to identify the thyroid FNA samples with a benign gene expression pattern (Alexander 2012, Kim 2012, Ward 2013). Afirma GEC is commercially owned by Veracyte Corporation; South San Francisco, California and is offered through a sole source, Clinical Laboratory Improvement Amendments (CLIA), a certified reference laboratory. Afirma CEC analysis is indicated only for nodules with indeterminate cytology, and is not performed on cytologically benign, malignant, or nondiagnostic (insufficient FNA samples) nodules. The assay classifies nodule as either benign or suspicious for malignancy. With a preoperative identification of a nodule that is benign rather than malignant, observation or ultrasound follow-up could be recommended instead of thyroid surgery, i.e. potentially avoids unnecessary surgery (Alexander 2012, Duick 2012, Ward 2013).

10/21/2013: MTAC REVIEW
Thyroid Nodule Gene Expression Testing (Afirma)
Evidence Conclusion: Analytic validity Evaluating the analytic performance of Afirma GEC includes studying the stability of RNA in FNAs during collection, storage, and shipment; reproducibility of the test; and its analytic sensitivity and specificity under various conditions e.g. interference of the assay with bloody FNA and genomic DNA. The literature search revealed one study (Walsh and colleagues, 2012) that evaluated the analytic performance of Afirma GEC in a number of sub studies. The investigators obtained prospective FNA samples aspirated in vivo from 43 patients from outpatient clinics, preoperatively, or immediately after surgical excision. The samples were placed in FNAProtect preservative solution and shipped chilled or frozen, then stored at -80^{o}C upon receipt. The RNA was extracted, and its yield examined for quantity and quality using positive (tissue lysate) and negative (water) as controls. Three different lots of controls were tested over several weeks of independent runs by 3 different operators to determine reliability of the test. Multiple lots of benign and malignant total RNA were manufactured and used as process controls to determine the analytic sensitivity of the test using different RNA input quantity and under different dilution of malignant FNA content. These studies indicated tolerance to variation in RNA input across a range of 5-25 ng. as well as dilution of malignant FNA material down to 20%. Analytic specificity of the test using malignant samples mixed with blood (up to 83%) and genomic DNA (up to 30%) showed minimal assay interference. However benign FNA samples mixed with relatively high proportions of blood had a potential for yielding false positive results. The authors also examined the stability of RNA in FNAs during collection and shipment and found that RNA content within FNAs preserved in FNAProtect was stable for up to 6 hours at room temperature with no change in RNA yield, and that the FNA storage and shipping temperatures had no significant effect on GEC scores. They also examined the reproducibility of the test and indicated that it was reproducible from extraction through GEC results, including variation across operators, runs, reagent lots, and laboratories. The authors concluded that the analytical performance and reproducibility of the Afirma Gene Expression Classifier was successfully verified. The research was supported by Veracyte Corporation, (the maker of Afirma GEC), and the authors of the study were either employed by or were consultants to the corporation. Clinical validity A perfect test would have high sensitivity and high specificity in correctly detecting or excluding a condition. A molecular diagnostic test with high sensitivity offers a high negative predictive value when the risk of malignancy (ROM) is low and can “rule out’’ malignancy. Conversely, a test with high specificity offers high positive predictive value and can “rule in” cancer. To be of use in avoiding surgery, a test that better distinguishes benign from malignant nodules needs to have high sensitivity and high negative predictive value. The literature search identified two published studies on the validation of Afirma GEC (Chudova et al, 2010, and Alexander et al. 2012); both funded by Veracyte Corporation the maker of Afirma GEC. The more recent and larger validation study by Alexander and colleagues (evidence table 1), was a double-blind prospective multicenter validation study. 4,812 thyroid FNAs were obtained from 3,789 patients. 577 (12%) samples were classified as indeterminate, and less than half (46%) were ultimately selected for GEC analysis. Molecular results were compared to the gold standard of post-surgical histopathology interpreted by a panel of blinded endocrine histopathologists for clinical validation. The overall sensitivity of the Afirma test was 92% with a negative predictive value (NPV) of 93% (95% for atypical or follicular lesions of undetermined significance (AUS/FLUS), 94% for a follicular neoplasm, and 85% for a lesion suspicious for malignancy). It is to be noted that the predictive values of a test vary with the prevalence of the disease in the population studied and may not be generalized to other groups. A better analysis would be the likelihood ratios which are not affected by prevalence. Seven of the 85 (8.2%) overall cancers were diagnosed incorrectly by the GEC as benign (false negative). The authors attributed the false negative results to insufficient RNA in the FNA sample used for GEC. The test had an overall low specificity and positive predictive values (52% and 47% respectively). Atypical or follicular lesions of undetermined significance (AUS/FLUS) accounted for almost

Back to Top

50% of the indeterminate thyroid FNAs samples. 43% of these FNA were reclassified with the GEC as benign and 57% remained in their suspicious category. Other investigators showed that repeat FNAs without a molecular test can also accurately reclassify >50% of the nodules in the AUS/FLUS category as benign (Faquin 2013). The study was conducted to validate the GEC accuracy by comparing it to surgical histopathology, and the authors did not compare its performance to repeat FNA or other immunochemical testing. Clinical utility: The clinical utility of Afirma GEC was evaluated in a retrospective study by Duick and colleagues, 2012, (Evidence table 2). They obtained their data from 21 endocrinology practices in 11 states. The authors conducted a chart review of 368 patients with 395 cytologically indeterminate thyroid nodules that were GEC benign. 7.6% of these patients with Afirma GEC benign nodules underwent surgery and 94.4% were managed nonoperatively. The study did not have a comparison group, but the authors compared the 7.6% surgical rate to a 74% historical rate of diagnostic surgery (P<0.001). The indications for surgery for those with GEC benign results included a large size or rapid growth of the nodules, local pressure symptoms, or the presence of a second suspicious nodule or malignant nodule. The authors explained that these were similar to indications for surgery on nodules with benign FNA cytologically. The study was retrospective, used a historical comparison, and investigated the decision-making of endocrinologists experienced in managing patients with thyroid nodules, which may differ from that made by primary care providers or other specialists. In addition, the authors of the study did not provide data on long-term follow-up of those who were managed by watchful waiting rather than surgery. In conclusion, there is insufficient evidence to determine whether Afirma GEC is more accurate than repeat FNA or immunochemical testing in reclassifying cytologically indeterminate thyroid nodules. There is also insufficient evidence to determine the impact of Afirma GEC on clinical management and net health outcomes in patients with indeterminate thyroid nodules.

Articles: The literature search for gene expression classifier for preoperative identification of benign thyroid nodules with indeterminate fine needle aspiration cytopathology revealed a number of articles on molecular diagnostic tests. Many were reviews, editorials, letters, or were unrelated to the current review. The search identified a study on the analytic validity of the test, two on its clinical validity, and retrospective study on its clinical utility. The following studies were selected for critical appraisal. Alexander EK, Kennedy GC, Baloch ZW, et al. Preoperative diagnosis of benign thyroid nodules with indeterminate cytology. *N Engl J Med*. 2012; 367:705-715. See Evidence Table Duick DS, Klopper JP, Diggans JC, et al. The impact of benign gene expression classifier test results on the endocrinologist-patient decision to operate on patients with thyroid nodules with indeterminate fine- needle aspiration cytopathology. *Thyroid.* 2012 22:996-1001. See Evidence Table

The use of does Afirma® Thyroid FNA Analysis (Gene Expression Classifier) for Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ConfirmMDx for Prostate Cancer

BACKGROUND

Prostate cancer is the second most leading cause of cancer in men around the globe (Fitzmaurice et al., 2017). In the United States, one in six men has a lifetime risk of prostate cancer (Siegel, Ward, Brawley, & Jemal, 2011). Prostate cancer screening is subject to controversy due to overdiagnosis, overtreatment, and harms. Major guidelines highlight the importance of informed decision-making. Despite the controversy, prostate specific antigen (PSA) and or digital rectal examination (DRE) can be performed.

After undetermined or abnormal results are reported on prostate cancer screening, more tests such as prostate biopsy is indicated for prostate cancer diagnosis. A high proportion (62%) of initial biopsies are negative and up to 43% will have second/repeat biopsies. Of these repeat biopsies, 26% – 35% will be diagnosed with prostate cancer (Auprich et al., 2012). False negative results are non-negligible since biopsy can miss cancer (Bhindi et al., 2017). In addition, prostate biopsies may result in several complications. As a result, it is crucial to find other ways to avoid or decrease repeat biopsies and predict with accuracy prostate cancer in patients with negative initial biopsies. ConfirmMDx is an assay that evaluates molecular alterations of three genes to detect prostate cancer.

The following description of the test is from the manufacturer website (https://mdxhealth.com/confirmmdx-physician/). ConfirmMDx is a tissue test to enhance the detection of previously negative biopsy patients at high risk for clinically significant prostate cancer. It rules out patients with no cancer and prevent them from unnecessary repeat biopsies and screening procedures, thus alleviating stress and reduce complications. According to the manufacturer, ConfirmMDx is believed to be the most significant predictor of patient outcome among all currently available clinical factors.

ConfirmMDx uses methylation-specific PCR (MSP) and epigenetic biomarkers to detect prostate cancer. The MSP, unlike histopathology, can detect DNA methylation changes (molecular alterations) in tissues surrounding cancer foci. This epigenetic effect is the molecular mechanism by which MSP detects occult prostate cancer in men with negative

Back to Top

initial biopsy. ConfirmMDx measures DNA methylation of 3 genes including GSTP1, APC, and RASSF1. In patients with negative prostate biopsies results, the test can enhance accuracy for predicting repeat biopsy outcome in comparison to the standard risk factors (Waterhouse et al., 2019). The test can also indicate the likelihood of detecting Gleason score ≤ 6 (low grade) and ≥7 (high grade) prostate cancer upon repeat biopsy. Patient report indicates if DNA methylation is positive, the likelihood of detecting prostate cancer, probability of detecting Gleason score ≤ 6 and ≥7 prostate cancer on repeat biopsy (https://mdxhealth.com/wp-content/uploads/2020/07/MDX-C152-ConfirmMDx-Case-Study-1-v3.pdf).

The test is indicated when there is a need to perform repeat biopsy on patients with initial negative biopsy result (benign, high-grade prostatic intraepithelial neoplasia (HGPIN), or atypical small acinar proliferation (ASAP)) within the past 24 months and high-risk clinical factors for occult prostate cancer. The results of the test should be interpreted in addition to clinical and other laboratory data.

Eligible patients include those with the following biopsy results:

- Negative/benign
- HGPIN (high-grade prostatic intraepithelial neoplasia)
- Atypia (atypical glands suspicious for malignancy)
- ASAP (atypical small acinar proliferation)
- PIA (proliferative inflammatory atrophy, or lesion)

07/11/2022: MTAC REVIEW
ConfirmMDx for Prostate Cancer
Evidence Conclusion:

- Analytical validity: Very low-quality study shows that the assay can measure the methylation status of the three genes including GSTP1, APC, and RASSF1.
- Clinical validity: Low quality evidence support ConfirmMDx in ruling out prostate cancer on repeat biopsy.
- Clinical utility: There is insufficient evidence for or against the clinical utility of ConfirmMDx for prostate cancer.
- **Overall, the evidence is insufficient for or against the use of ConfirmMDx.**

Articles: PubMed was searched on 03/29/2022 with the search terms ConfirmMDx OR Episcore OR MDxHealth OR (GSTP1 AND APC AND RASSF1 AND prostate) OR (Epigenetic assay AND prostate cancer) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded a number of articles. Seven studies were reviewed (1 analytical validity study, 4 clinical validity studies, and 2 clinical utility studies). See Evidence Table.

The use of ConfirmMDx for Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Hayes Review

ConfirmMDx for Prostate Cancer (MDxHealth Inc.)

According to the laboratory, ConfirmMDx is for men with a previous histopathologically cancer-negative prostate biopsy within the past 24 months who have clinicopathological risk factors for prostate cancer to (MDxHealth, 2017; MDxHealth, 2018a):

- Identify men at risk for undetected prostate cancer (a false-negative biopsy result).
- Rule out men who are prostate cancer free to prevent unnecessary repeat biopsies and screening procedures, resulting in reduced complications, patient anxiety, and healthcare expenses.

In addition, the ConfirmMDx test result claims to predict the likelihood of (MDxHealth, 2017):

- Detecting Gleason score ≤ 6 prostate cancer on repeat biopsy.
- Detecting Gleason score ≥ 7 prostate cancer on repeat biopsy.

Hayes Rating: **D2**
For use of ConfirmMDx test, using residual prostate biopsy specimens, to: (1) rule out men who are prostate cancer free; and (2) identify men at risk for undetected prostate cancer by predicting the likelihood of detecting Gleason score ≤ 6 and ≥ 7 prostate cancer on repeat biopsy in men with an initial negative biopsy yet high-risk

Back to Top

clinicopathological features suggestive of prostate cancer.

Conclusion: There is positive but insufficient evidence supporting the use of the ConfirmMDx test to help rule-out prostate cancer in repeat biopsy and insufficient evidence for the use of the test to predict the likelihood of Gleason score ≤ 6 prostate cancer and Gleason score ≥ 7 prostate cancer on repeat biopsy. Available studies do not evaluate whether the test results, when used to influence patient repeat biopsy decisions, result in improved patient outcomes in men with high-risk clinicopathological features suggestive of prostate cancer.

Reference

Hayes. Hayes Molecular Test Assessment. ConfirmMDx for Prostate Cancer (MDxHealth Inc.). Dallas, TX: Hayes; February 14, 2021. Retrieved November 29, 2021 from https://evidence.hayesinc.com/report/gte.confirm2766

Prolaris for Prostate Cancer

BACKGROUND

Prostate cancer is the second most leading cause of cancer in men around the globe (Fitzmaurice et al., 2017). In the United States, one in six men has a lifetime risk of prostate cancer (Siegel, Ward, Brawley, & Jemal, 2011). Its natural history varies and is difficult to predict. Some men have indolent disease that can be safely managed with active surveillance, whereas others have an aggressive cancer and are treated with a variety of therapeutic options. Accurate prediction of disease behavior is critical because radical treatment is associated with high morbidity (J. Cuzick et al., 2012).

Clinical variables including Gleason score, tumor stage, and PSA have been considered at the time of diagnosis to predict disease outcome. However, predictions based on these variables are not accurate, resulting in hesitation among physicians and patients about the best course for initial treatment (J. Cuzick et al., 2012). Tests to make accurate prediction and determine treatment decision are necessary.

Description:

Prolaris is a genetic test that measures the growth of tumor cell. In combination with PSA and Gleason score, the test determines the aggressiveness of prostate cancer. PSA and Gleason only show the progression of prostate cancer. However, when these tests are combined to Prolaris test, the aggressive progression of the cancer over the next ten years is determined. The information on the aggressiveness of cancer is specific to each individual.

Testing process:

The same tissue from the original biopsy is utilized to run the test. Therefore, additional biopsies are not required. The tissue sample is sent to Myriad to determine the aggressiveness of the prostate cancer. After the test is complete, the results are sent back to the provider. The result is comprised of a personalized Prolaris Score and a 10-year prostate cancer mortality risk and the risk of metastasis.

The Prolaris Molecular Score is computed by measuring the expression of 31 cell cycle progression (CCP) genes (measured by qRT-PCR and normalized by 15 housekeeping genes). Most of the scores range between 1-11. The higher the score, the more aggressive the cancer. Over- and under-expression of the 31 CCP genes results in positive and negative CCP score, respectively (Shangguan et al., 2021).

Benefits of Prolaris test:

The benefits are to identify mortality risk, the risk of metastasis, and to help determine the best course of treatment.

Prolaris is supported by NCCN guidelines as a 2A recommendation which is considered standard of care. Prolaris testing is indicated in men who have been diagnosed with localized prostate cancer.

07/11/2022: MTAC REVIEW
PROLARIS FOR PROSTATE CANCER
Evidence Conclusion:

- **PROLARIS BIOPSY TEST**
  - Low quality evidence shows that CCP testing is reproducible and precise.
  - Very low to low quality evidence indicate that CCP & CCR scores may help predict prostate cancer mortality and metastasis. It may help improve risk stratification in men with localized prostate cancer.
  - Low quality evidence shows that Prolaris test may influence physician treatment decision.
  - Overall, low quality evidence supports Prolaris test to predict prostate cancer related clinical outcomes.

Back to Top

➢ PROLARIS POST-PROSTATECTOMY

- The evidence is insufficient for or against the use of Prolaris test in patients with radical prostatectomy.

Articles: PubMed was searched through April 11, 2022 with the search terms (Prolaris OR cell cycle progression OR CCP OR cell cycle risk OR CCR) AND (prostate) with variations. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. ***See*** **Evidence Table.**

The use of Prolaris Prostate Cancer (Biopsy and Post-Prostatectomy) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/20/2015: MTAC REVIEW
DecisionDx - Melanoma
Evidence Conclusion:
DecisionDx - Melanoma
BACKGROUND
Skin cancer is extremely common accounting for nearly half of all cancers in the United States. Melanoma, the most aggressive type of skin cancer, occurs as a result of abnormal melanocytes, most often caused by over- exposure to ultraviolet radiation from the sun. When detected early, cutaneous melanoma can be surgically excised resulting in a 5-year overall survival rate of 91%-97%. Despite these odds, however, the clinical behavior of cutaneous melanoma is highly variable and some melanomas, that appear less risky, will develop into advanced disease and require extensive treatments such as additional surgery, immunotherapy, targeted therapy, chemotherapy and radiation therapy (ACS 2015). As with all cancers, a primary challenge is predicting prognosis. Conventional methods of melanoma staging are characterized by the American Joint Committee on Cancer (AJCC) TNM System. The TNM system specifically refers to Tumor thickness, spread to nearby lymph Nodes, and Metastasis. Based on history and physical exam, as well as, biopsy, imaging and pathology, the TNM system groups patients with melanoma into stages, 0-IV based on the advanced nature of the disease (Balch, Gershenwald et al. 2009). The stage of the melanoma is an estimate of prognosis and will ultimately guide treatment options. Recently, gene expression profiling (GEP) has been proposed for use in cancer management. The technique specifically analyzes the patterns of genetic material contained in tumor cells and has the potential ability to predict clinical outcomes associated with cancer. One such test, the DecisionDx-Melanoma™, developed by Castle Biosciences Inc. (Friendswood, TX), is described to more accurately classify stage I and II melanoma.
Proposed as an adjunct to conventional staging systems, the DecisionDX-Melanoma test includes 31 genes, 28 of which have previously been associated with melanoma and the remaining three, controls (Winnepenninckx, Lazar et al. 2006). The results of the DecisionDx-Melanoma test is further claimed to stratify stage I and II melanomas into one of two classes; class one identifying patients as low risk of metastasis, or class two indicating high risk.
The developer claims that the information provided by the DecisionDx-Melanoma test enables physicians to tailor, patient specific, surveillance and treatment plans informing, for example, the intensity of surveillance, need for referral to specialists, evaluation of adjuvant treatments and clinical trial eligibility (CastleBiosciencesInc. 2015).

04/20/2015: MTAC REVIEW
DecisionDx - Melanoma
Evidence Conclusion: The study aimed to develop a prognostic genetic signature based on previous analyses of cutaneous melanoma tumors. To do this, the investigators included 268 archived tissue samples and divided the sample into two cohorts, development (n=164) or validation (n=104). The investigators compared the patient clinical outcomes at five years with the GEP test prediction. Overall, Kaplan-Meier analysis indicated that the five-year disease-free survival (DFS) rates in the validation cohort were 97% and 31% for predicted class 1 and 2, respectively ($p<0.0001$). These results were comparable to the DFS rated in the development cohort, 100% and 38% for class 1 and class 2, respectively ($p<0.0001$). The investigators ultimately concluded that in patients with primary cutaneous melanoma, the GEP signature accurately predicts metastasis risk (Gerami, Cook et al. 2015). [Evidence Table 1] The investigators had the clear intent to develop and validate a GEP for predicting metastatic risk in stage I and II cutaneous melanoma. The patient sample was well defined and the study design, cohort, appeared to be appropriate for the development of the genetic signature. To validate the test, however, the study relied on archived tumor samples with at least five years of follow-up. While this is a sufficiently long time to detect the outcome of interest, and the investigators used an independent sample, a prospective study would be a more appropriate design for validation. With that said, the investigators report that samples were collected at a similar point in the course of the disease, diagnosis, however the diseases progression at diagnosis may have varied between patients and it is not clear if the investigators were blinded to prognostic factors. On a final note, the study was funded by the test manufacturer and at least two of the investigators have financial ties with Castle

Back to Top

Biosciences, Inc. Conclusions: There is limited evidence to conclude that the DecisionDx-Melanoma test is valid. There is insufficient evidence to conclude that the DecisionDx-Melanoma test has prognostic accuracy in predicting metastatic risk. There is insufficient evidence to conclude that the DecisionDx-Melanoma test is not harmful to patients. There is insufficient evidence to establish the clinical utility and therapeutic impact of the DecisionDx-Melanoma test.
Articles: The literature search was carried out to identify studies relating to the prognostic value of the DecisionDx-Melanoma test. The search revealed a variety of publications discussing the use of GEP and one publication identifying the genes associated with melanoma progression and prognosis (Winnepenninckx, Lazar et al. 2006). No studies were identified in which the DecisionDX-Melanoma was prospectively analyzed and followed- up in populations with Stage I and II melanoma. A search of the NIH Clinical Trials database identified two manufacturer sponsored prospective studies currently in the enrollment stage. The best, currently available, evidence was a development and validation study published by Castle Biosciences, Inc. The following articles were selected for critical appraisal: Gerami P, Cook RW, Wilkinson J, et al. Development of a prognostic genetic signature to predict the metastatic risk associated with cutaneous melanoma. Clinical Cancer Research. 2015:21(1);175-183. See Evidence Table.

The use of DecisionDx-Melanoma does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

OVA1 Assessment for Ovarian Cancer

BACKGROUND

Ovarian cancer is the most lethal gynecological malignant worldwide. The five-year overall survival is over 90% in patients with stage I disease and only 20-40% for stages III and IV. Unfortunately, because of the lack of specific symptoms during the early stage approximately 70% of cases present with an advanced stage disease. Detection of ovarian cancer at an early stage would have a significant impact on reducing mortality, however to date; there is no screening or biomarker test that meets the criteria for a beneficial screening test in asymptomatic women with early ovarian cancer (Carter 2011, Cohen 2014, Leung 2014). Serum CA-125, a high molecular weight glycoprotein, remains the most widely used biomarker for the confirmation of diagnosis and management of ovarian cancer. Serum CA-125 however, is more prominently expressed in patients with late stage serous tumors; it is elevated in 50-60% of women with stage I epithelial ovarian cancer, and in 75-90% of patients with advanced stage disease. Elevated circulating CA-125 has also been documented in uterine fibroids, endometriosis, pregnancy, menstruation, benign ovarian neoplasms, liver cirrhosis, and other malignancies making it a less useful marker for the detection of ovarian cancer (Autelitano 2012, Cohen 2014). Improvements have been made in the preoperative diagnosis of ovarian cancer by combining serum CA-125 concentration with ultrasound score and menopausal status, into a Risk of Malignancy Index (RMI) which was found to outperform CA-125 alone in discriminating between a benign and malignant pelvic mass. Over the past two decades diagnostic triage methods incorporating clinical algorithms, serum biomarkers, imaging, or a combination of these techniques have been investigated to improve its diagnostic efficiency in predicting ovarian malignancy in women with adnexal masses. The Risk of malignancy Algorithm (ROMA) and OVA1 test are two algorithms recently developed for the assessment of malignancy risk in these women. These are not screening tests but are potential tools to further triage women to the appropriate provider once the decision for surgical intervention has been made (Autelitano 2012, Bristow 2013, Cohen 2014). Combining multiple variables or markers in a single biomarker assay (in vitro diagnostic multivariate assay [IVDMIA, or MIA]) has the potential advantage of complementing the information provided by a single-valued index. The inclusion of biomarkers in an IVDMIA requires that they are complementary and collectively outperform a single marker with respect to its intended uses. CA-125 remains the best tumor marker, and the selection of additional biomarkers is based mainly on their ability to detect malignancy in cancer patients with low CA-125 level or to reduce false positive results among non-cancer patients with elevated serum CA-125 levels (Zhang 2012). Ova1™ test (developed by Vermillion and licensed to Quest Diagnostics, Inc.) is the first IVDMIA of protein biomarkers cleared by the FDA to be used as an adjunct to clinical and radiological evaluations for women over the age of 18 who have planned to undergo surgery for an adnexal mass and have not been referred to a gynecologic oncologist. Studies suggest that women who receive their initial surgical care from an experienced gynecologic oncologist are more likely to have better outcomes including surgical staging, optimal debulking, and improved median and overall-5-year survival. Ova1™ test is a qualitative test that measures the serum levels of 5 potential biochemical markers for ovarian cancer (CA-125, prealbumin, apolipoprotein A-1, β2-microgloublin, and transferrin). The results of the test are then interpreted using a proprietary algorithm to yield a single score ranging from 0 to 10 to indicate the likelihood that the adnexal mass is benign or malignant. A high probability for malignancy is defined as a score of ≥ 5.0 in premenopausal women or ≥ 4.4 in postmenopausal women. The decision for selecting these cutoff values was made to emphasize the need for high sensitivity to minimize the risk of false negative results for patients who actually have a malignant lesion. A limitation to OVA1™ is that all the included markers with the exception of CA-125 are acute phase reactants that may be nonspecific for ovarian cancer. Another limitation is interference of triglyceride levels greater than 4.5g/L or

 Back to Top

rheumatoid factor levels more than 250IU/mL with the biomarkers assay (Muller 2010, Carter 2011, Zheng 2012, Leung 2014).

04/20/2015: MTAC REVIEW
OVA1 Assessment for Ovarian Cancer

Evidence Conclusion: The main purpose of adding biomarkers to an established tumors biomarker as CA-125, in a multivariate index assay (MIA), is to achieve a very high sensitivity without sacrificing the specificity. However, the published studies evaluating OVA1™ showed the test improved the sensitivity of the physicians' assessment in predicting ovarian malignancy in women with adnexal masses, but at the cost of reducing the specificity and positive predictive value. The FDA cleared the OVA1™ test based on the results of Ueland and colleagues' study that was reviewed earlier by MTAC in 2011. The study compared the sensitivity, specificity, and predictive values of physician assessment with or without adding the multivariate index assay (MIA) in identifying high-risk ovarian tumors. The study enrolled 590 women (524 evaluable with both MIA and CA-125-II) with a documented ovarian mass on imaging and planned surgery within 3 months of imaging. 53% of the women were enrolled by non-gynecologic oncologists and the rest by gynecological oncologist. The MIA index assay test was performed on preoperative serum samples, and the results were correlated with preoperative physician assessment. There was no specific protocol for the clinical assessment. Using surgical pathology as the gold standard, 161 women were diagnosed with a malignant and 363 with a benign ovarian tumor. The results of the analysis showed that the sensitivity of non-gynecologic oncologists' assessment increased from 72% to 92% with the addition of the MIA test (78% and 99% respectively for gynecologic oncologists). The negative predictive value increased slightly with the addition of the MIA test. On the other hand, the specificity and positive predictive values dropped significantly with the addition of the assay (the specificity was reduced from 83% to 42% for non-gynecologic oncologists and from 75% to 26% for gynecologic oncologists and the positive predictive value dropped from 60% to 36% and from 63% to 43% in the two groups of respectively).The studies published after that pivotal study were conducted mainly by the same group of investigators who either analyzed the results of women enrolled in some or all 44 sites participating in the study. The studies were sponsored by Vermillion Inc., and the investigators had financial ties to the company. The largest and most recent of these studies (Longoria et al 2014) (Evidence table 1) compared the accuracy and predictive values of the multivariate index assay, OVA1™ to clinical assessment, CA-125-II, and the modified American Congress of Obstetricians and Gynecologists (ACOG) guidelines, for the detection of early-stage ovarian cancer in 1,016 women undergoing surgery for an adnexal mass. The authors did not indicate whether the assessors were blinded to the other tests and/or clinical evaluation results. The study did not include women without adnexal masses or with other disorders that may lead to elevated levels of CA-125 or any of the other biomarkers included in the assay. Overall, similar to the Ueland and colleagues' study, as well as the other published studies using MIA test, Longoria, et al's study showed that the addition of OVA1™ to clinical assessment may significantly improve the sensitivity of detecting early-stage ovarian cancer, but at the expense of reducing the specificity, which would result in referral of more patients with benign conditions to gynecologic oncologists for surgery. The overall results of the study show the following: ***Comparative performance for evaluable women in all cancer cases (from evidence table 1)***

	Sensitivity %	Specificity %	PPV %	NPV %
OVA1	92.2%	49.4%	37.9%	94.9%
Clinical assessment*	74.5%	86.3%	64.6%	91.0%
OVA1 + clinical assessment	95.3%	44.2%	36.4%	96.6%
CA 125-II	70.6%	89.6%	69.5%	90.1%
Modified ACOG guidelines**	80.0%	76.5%	53.3%	91.9%

*The authors did not clearly explain that clinical assessment included CA125-II for all women
** Included: very elevated CA125 (>67U/mL), ascites, and evidence of abdominal or distant metastasis for premenopausal women. For postmenopausal women the ACOG criteria were Elevated CA125 (>35 u/mL, nodular or fixed pelvic mass, ascites, and evidence of abdominal or distant metastasis.

The studies had enrolled selected groups of women with adnexal masses who were referred to surgery in multiple centers with no standardized process for data collection or referral practice. The referral pattern was retrospectively analyzed, and the impact of the test on health outcomes was not evaluated. In addition, the studies were funded by Vermillon Inc, the developer of the test, and the principal investigators had financial ties to the company. The performance of OVA1™ was not compared to other risk assessment algorithms as ROMA,

Back to Top

ultrasound-based risk assessment models, or other diagnostic tools that may lead to similar sensitivity and superior specificity to OVA1™. Conclusion: The published studies do not provide sufficient evidence to determine the clinical utility and impact of using OVA1™ assay on health outcomes of women with ovarian tumors.

The use of OVA 1 does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Date: 07/09/2018 MTAC REVIEW

Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID)

BACKGROUND

Intellectual disability is a disorder marked by deficits in intellectual and adaptive functioning and starts before 18 years of age. Its management requires early diagnosis and extensive supports. Intellectual disability is caused by any conditions disrupting brain development. Of these conditions, genetic abnormalities are the most commonly known etiologies (Rauch et al., 2012) with Down syndrome being the leading cause. Conventional cytogenetics (karyotype analysis and fluorescence in situ hybridization (FISH)) can identify the cause but they detect less than 10% of chromosomal abnormalities in patients with intellectual disability (ID) or developmental delay (DD) (Shaffer, Beaudet, et al., 2007; Shaffer, Bejjani, et al., 2007). Chromosomal microarray analysis (CMA) has become the primary test for most patients with intellectual disability (Miller et al., 2010). However, if CMA fails to identify the etiology, whole genome/exome sequencing may be considered.

Whole genome sequencing (WGS) is a process that determines the complete DNA sequence of the entire genome. In contrast, whole exome sequencing (WES) determines the DNA sequence of a small part of the genome. The small part which is the coding part of the genome is 1% of the entire genome.

(Biesecker & Green, 2014) Genome and exome sequencing (GES) begins with extraction of DNA from white cells followed by disintegration of DNA and determination of sequences with sequencing instrument. Using computer, the sequences are placed into specific positions in the human genome reference sequence for assessment of similarities and differences. This results in the determination of the specific genotype at each position in the exome or genome. This leads in output file which is filtered for variants that explain the phenotype. Sequencing can be performed on unaffected or affected parents or affected siblings. Clinical GES can detect single-nucleotide substitutions and insertions or deletions of 8 to 10 nucleotides or smaller. However, it is less accurate for other types of genomic variation. GES is indicated in patients with suspicion of mendelian genetic disease. It is also considered when CMA fails to identify the cause of intellectual disability. (Biesecker & Green, 2014)

This review focuses on developmental delay (DD) or intellectual disability (ID).

As this is a laboratory test, no FDA approval is required. Genetic tests are controlled under the Clinical Laboratory Improvement Amendments (CLIA). The technology is being assessed for the first time on Medical Technology Assessment Committee (MTAC).

Evidence Conclusion:

Conclusion:

- **Analytical validity:** Studies assessing analytical validity were scarce. Only two studies reported that the performance of WES/WGS was high. However, the evidence is insufficient to draw conclusion on analytical validity.
- **Clinical validity:** Thirteen studies were evaluated. Most studies have included children with moderate to severe intellectual disability/developmental delay. In most studies, WES or WGS was performed in patients on whom previous genetic evaluations (molecular karyotyping, microarray) failed to diagnose the etiology or were negative. The diagnostic yield ranged from 21% to 60% (including new mutations) suggesting higher detection rate than traditional genetic tests including microarray. Nevertheless, the studies provide low evidence and demonstrate that WES/WGS has high detection rate overall and even in children with undiagnosed or unexplained intellectual disability or developmental delay.
- **Clinical utility:** The evidence on clinical utility is conflicting. More studies are warranted.
- Milliman Care Guidelines was reviewed and indicated that the evidence is poor, or conflicting, or insufficient to assess the net benefit of this test versus harm; additional research is recommended.

The use of Whole Genome/Exome Sequencing for Developmental Delay (DD)/Intellectual Disability (ID) doesn't meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Next Generation Sequencing (NGS) - Broad Spectrum Tumor Molecular profiling

Background

All cancers begin in cells. A normal become cancerous largely because of mutations in their genes. Often many mutations are needed before a cell becomes a cancer cell. Some gene changes may increase production of a protein that makes cells grow and others may result in the production of a misshape leading to a nonfunctional

 Back to Top

form of a protein that normally repairs cellular damage. Genetic changes that promote cancer may be inherited (germline) or more commonly acquired (somatic) during a person's lifetime, either because of errors that occur as cells divide or from exposure to DNA-damaging carcinogens. There are many types of DNA genetic changes; these may affect just one unit of DNA (a nucleotide) or involve larger stretches of DNA (NIH, American Cancer Society).

Somatic mutations include point mutations, small insertions/deletions, and copy-number alterations that direct therapeutic options. Thus, in some cases, knowledge of the genetic alterations in a cancer patient can help determine a treatment plan as some treatments, particularly targeted therapies, are effective only for people whose cancer cells have specific genetic alterations that cause the cells to grow out of control (Wagle 2011, National Cancer Institute).

In the past decade, investigators have focused on searching for oncogenes and tumor suppressor genes that drive cancer. This is moving systemic cancer treatment away from the paradigm of treating histologically defined disease with cytotoxic chemotherapy, towards the use of molecularly targeted drugs prescribed to selected subsets of patients across multiple tumor types. Theoretically targeted therapies that inhibit the abnormally activated proteins, are more specific to cancer cells, potentially safer and more efficacious than the cytotoxic gents that target cell replication (Frampton 2013, Uzilov 2016, Tourneau 2015, Beaubier 2018).

To deliver personalized cancer targeted therapy, it is essential to use diagnostic tests that would accurately and comprehensively characterize the genomic alterations within individual tumors. Several technologies including Sanger sequencing (SGS, the gold standard), PCR, mass spectrometric genotyping, and other tests are currently used for the clinical assessment of a limited number of oncogenic markers. These tests may not perform parallel investigations of multiple targets and cannot address the increasing number and variety of therapeutically relevant gnomic alterations that occur in hundreds of cancer related genes with the amount of material obtained from biopsies (Frampton 2013, Rehm 2013, Arsenic 2015, Beaubier 2018).

Next generation sequencing (NGS), is becoming an attractive clinical diagnostic technology to detect most genomic alterations in the therapeutically relevant cancer genes in a single assay. NGS is not a test. but is an umbrella term for massively parallel DNA sequencing technology. The term NGS is used to emphasize the difference from the initial traditional gold standard single gene-based sequencing approaches that involve sequencing of one DNA strand at a time. NGS encompasses a variety of technologies that permit rapid parallel sequencing of millions of DNA segments, up to the entire genomes. These can perform three main levels of analysis: exome sequencing, genome sequencing, and disease targeted gene panels (Frampton 2013, Regier 2018).

A NGS cancer panel involves a complex 2-step process: 1. Wet bench process, which includes the handling of patient samples, extraction of nuclei acid, fragmentation and barcoding, target enrichment, adaptor ligation, library preparation, and generation of sequence reads. 2. Bioinformatics analysis of sequence data. This includes mapping sequence reads to the human reference genome, variant calling, annotation, and reviewing data in the right clinical context. Each of these steps require separate standards (Behjati 2013, Frampton 2013, McCourt 2013, Rehm 2013, American College of Medical Genetics and Genomics).

The number and scope of genes to be tested depend on the purpose of the test. A companion diagnostic test for standard care would require a limited number of genes, whereas NGS-based tests used for stratifying patients require the interrogation of a broader range of genes. Currently, there are several NGS platforms that perform sequencing of millions of small fragments of DNA in parallel. The platforms use different sequencing technologies, and due to the complexity and amount of sequencing data, and concerns about the reliability of the different NGS panels, several working groups (including the College of American Pathologists (CAP) and the American College of Medical Genetics and Genomics [ACMG]) have issued guidelines for NGS clinical testing. The assays or platforms should have a high-test sensitivity as cancer specimens may have a low percentage of tumor cells, i.e. high level of normal cell contamination. The test should also have a high specificity as a false positive result will have a negative impact on the choice of therapy (Frampton 2013, Kim 2017).

Cancer panel tests are mainly focused on actionable genomic alterations (variants) whose presence may help identify the most promising treatment approach. Different definitions of "actionable variants" have been used by researchers. While the majority defined it as the variant that can be targeted by a currently available drug (either FDA approved, off label use of an FDA approved drug, or a drug under investigation), others expanded the definition to include change in patient management on the prognostic implication or change in risk stratification. It is estimated that as many as one third of actionable changes in tumor analysis may be incorrectly classified as

Back to Top

somatic changes. It is thus recommended to use matched tumor-normal DNA for genomic analysis to accurately identify and interpret actionable somatic and genetic changes that would have an important impact on the diagnosis and therapeutic management of cancer patients (Jones 2015, Kim 2017, Tan 2017, Regier 2018).

In recent years, several academic centers have adopted the use of NGS panels at the point of care to study cancer genomics and personalize patient care (precision oncology). However, the application of the NGS technology in the clinical context as a routine test to support the selection of therapy for cancer patients has its challenges. Most of cancer specimens are formalin-fixed paraffin embedded tissue (FFPE) which can degrade the DNA and RNA. This would require the application of robust nucleic acid extraction and sequencing library construction. In addition, many samples available for testing contain limited amount of tissue and in turn a limited amount of nucleic acid. The assays also need to be sensitive enough to detect gene alterations in specimens with a low tumor percentage. The use of the technology requires an infrastructure e.g. computer capacity and storage, as well as the application of rigorous statistical and analytical approaches to validate the accuracy of NGS technology for use in the clinical setting. An additional reported challenge is the personnel expertise required to comprehensively analyze and interpret the subsequent data, as well as skillfully extract and manage the clinically important information from the volume of data obtained. NGS has the potential to uncover a significant quantity of complex clinically and non-clinically actionable results with wide ranging implications for the patients and their families. Targeted therapies are limited by several factors including the availability, effectiveness and /or specificity of molecular inhibitor (targeted drug therapies) based on patients 'genetic information, heterogeneity the disease, resistance to a targeted therapy, and access to the treatment. It has also been reported that targeted therapies may be successful for some tumor types but not for others (Behjati 2013. Frampton 2013, Radovich 2016, Beaubier 2018).

FoundationOne CDx™ (F1CDx, Foundation Medicine, Inc.) a NGS test, was granted marketing approval by the US Food and Drug Administration (FDA) on November 30, 2017 to detect genetic mutations in 324 genes and two genomic signatures in any solid tumor type. The test can also identify which patients with non-small cell lung cancer (NSCLC), melanoma, breast cancer, colorectal cancer, or ovarian cancer may benefit from 15 different FDA-approved targeted treatment options (FDA website).

01/14/2019: MTAC Review
Evidence Conclusion:

- As indicated earlier in the report, it is difficult to set standards for assuring the analytical validity of NGS tests due to the amount and complexity of cancer genome sequencing and the different NGS technologies used. In general, however, the published validation studies suggest that NGS tests may have a high analytic validity, and lower clinical validity.
- There is insufficient evidence from published randomized clinical trials to determine that incorporating NGS into cancer care improves patient outcomes, such as treatment response and disease-free survival, or to support the use of molecularly targeted agents outside their indications based on tumor molecular profiling.
- More RCTs are needed to provide evidence on the utility of cancer genomics in clinical practice.

Articles: The literature search identified over 1,000 articles on NGS; the great majority of which were reviews, abstracts or articles not related to the current review. The search was filtered and narrowed down according the inclusion criteria based on PICO. Selected studies comparing the performance of NGS versus Sanger sequencing as well as randomized or nonrandomized studies evaluating the effectiveness and safety of applying the technology to cancer patients were included in the review. See Evidence Table

The use of Broad-Spectrum Tumor Molecular Profiling - Next Generation Sequencing (NGS) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Decipher Prostate Genomic Classifier

10/10/2022: MTAC Review
Evidence Conclusion:

Decipher genomic testing using biopsy specimen

- There is insufficient evidence for or against the analytical validity and clinical utility of Decipher test. Low quality evidence supports the clinical validity of Decipher test. Overall, the evidence is insufficient for or against the use of Decipher genomic testing using biopsy specimen.

Decipher genomic testing using radical prostatectomy specimen

- Analytical validity: There is a lack of studies.

Back to Top

- Clinical validity: Low quality evidence from retrospective studies demonstrate that the Decipher Genomic Classifier is consistently superior in its prognostic and discriminatory ability in comparison to clinicopathologic variables for metastasis & prostate cancer-specific mortality.
- Clinical utility: Low quality evidence supports the clinical utility of Decipher testing. Decipher may influence treatment recommendations change in post prostatectomy patients with adverse pathologic characteristics.
- Overall, low quality evidence supports the use of Decipher genomic testing using radical prostatectomy specimens.

Articles: PubMed was searched through September 2022 with the search terms (Decipher OR genomic classifier OR 22-gene) AND (prostate). The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. The search yielded several studies. See Evidence Table.

The use of Decipher Prostate Genomic Classifier does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
1997	10/04/2011[MDCRPC], 8/07/2012[MDCRPC], 11/06/2012[MDCRPC], 04/02/2013[MDCRPC], 05/07/2013[MDCRPC], 06/04/2013[MDCRPC], 08/06/2013[MPC], 03/04/2014[MPC], 06/03/2014[MPC], 07/01/2014[MPC], 10/07/2014[MPC], 11/04/2014[MPC], 02/03/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC],06/06/2023[MPC]	01/09/2024

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
05/11/2015	Array-Based Comparative Genomic Hybridization (aCGH): Removed MCG and reactivated GHC insufficient evidence criteria
06/02/2015	MPC approved MTAC recommendation of insufficient evidence for OVA1 & DecisionDx-Melanoma Testing
06/04/2015	Added Cologuard
06/30/2015	Added LCD link for cytogenetic studies
08/27/2015	Add LCD for CYP Genes
09/08/2015	Revised LCD CYP2C19 (CPT-81225), CYP2D6 (CPT-81226), CYP2C9(CPT81227), and VKORC1(CPT-81355) Genetic Testing (L36311), Cytogenetic Studies L34067
10/13/2015	Added Medicare molecular testing LCD
10/27/2015	Added codes that do not need review
11/18/2015	Added Medicare MolDX links
03/01/2016	Discontinue review for Factor II & V
08/30/2016	Combined Risk Prognosticator Test to Genetic Screening criteria
09/06/2016	Added Prostate Cancer Gene Expression Testing- Oncotype DX MCG A-0712 to criteria

Back to Top

10/24/2016	Changed Veristrat to match Pharmacogenomic policy
11/01/2016	MPC approved to accept the genetic testing recommendations from the MCG 20th edition as outlined
01/23/2017	Added LCD 36544 & LCD 36186
04/04/2017	Added MTAC Review
05/16/2017	Added Percepta LCD
08/28/2017	Added ThyGeNEXT Oncogene Panel
09/18/2017	HFE gene – review no longer required CPT 81256
10/03/2017	Adopted MCG 21st ed. guidelines: A-0910, A-0909, A-0916, A-0907, A-0904, A-0908, A-0918, A-0926
10/11/2017	Removed MCG A-0917
12/05/2017	Adopted clinical criteria for Cystic Fibrosis testing
02/06/2018	MPC approved to adopt criteria for Decision Dx- Choroidal/Uveal Melanoma
03/26/2018	Added Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer
04/25/2018	Added language to BRAF testing
05/03/2018	Updated name changes with the MCG 22nd Edition
06/05/2018	MPC approved to adopt MCG* A-0823 and MCG* A-0957
08/07/2018	Added MTAC review from 7/9/18 for Microarray and Whole Exome for DD/ID
08/29/2018	Move code 81301 to no review at this time.
10/02/2018	Updated Micro Array for Evaluation of Intellectual Disability criteria
12/04/2018	MPC approved to adopt MCG* A-0598 Diabetes Mellitus (Maturity-Onset Diabetes of the Young)
01/08/2019	MPC approved to adopt criteria for Whole Exome Sequencing
02/05/2019	MPC approved to adopt policy of no coverage for Next Generation Sequencing (NGS) - Broad Spectrum Tumor Molecular profiling; added 01/2019 MTAC review
02/26/2019	Mammaprint: Send all cases to MD for review until criteria has been developed
04/02/2019	MPC approved to adopt criteria for Mammaprint
12/03/2019	MPC approved a non-coverage policy for Donor-derived cell-free DNA testing (e.g., Allosure)
04/07/2020	MPC approved non-coverage policy for 81540 CancerTYPE ID
04/29/2020	Removed code 81528
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees.”. Requires 60-day notice, effective date 10/01/2020. Moved CPT codes 81402, 81403 and 81270 under Applicable Codes section that do not need review.
06/23/2020	Added CPT codes 81277, 81307, 81308, 81309, 81522, 81542, 81552, 875630087U, 0080U, 0081U, 0088U, 0089U, 0090U, 0091U, 0092U, 0105U, 0106U, 0107U, 0108U, 0109U, 0110U, 0111U, 0112U, 0113U, 0114U, 0115U, 0116U, 0117U, 0118U, 0119U, 0120U, 0121U, 0122U, 0123U, 0124U, 0125U, 0126U, 0127U, 0128U, 0129U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U
07/22/2020	Removed CPT codes that do not require review: 81220, 81221, 81240, 81241, 81261, 81340, 81341, 81342, 81372, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81402, 81403, 81270.
10/06/2020	MPC approved to adopt MCG 24th ed. guidelines for the following: Narcolepsy - HLA Testing: A-1005, Transthyretin Amyloidosis - TTR Gene: A-1010, Retinal Dystrophy - RPE65 Gene: A-1011, Breast Cancer- PALB2: A-0989, Alpha-1 Antitrypsin Deficiency - SERPINA1 Gene: KP-1006, Paraganglioma-Pheochromocytoma (Hereditary) - Gene Testing and Gene Panel: A-0798; added exception for NGS for Advanced Cancer (CellNetix lab) to Invitae as preferred lab section. Removed codes section; will defer to pre-authorization code check tool.
05/04/2021	Updated Medicare LCD links, MCG Guideline information, and applicable codes. MPC approved to adopt MCG 25th edition guidelines for the following: Malignant Melanoma (Cutaneous) – BAP1, CDK4, and CDKN2A; Malignant Melanoma (Cutaneous) – BRAF V600 Testing; Renal Cancer (Hereditary) – Gene Panel; and Noonan Syndrome – Gene and Gene Panel Testing. Requires 60-day notice, effective date 10/1/2021.
08/03/2021	Updated Nephrology section, referencing separate criteria for Donor-derived cell-free DNA testing for Kidney Transplant Rejection (e.g., AlloSure).

Back to Top

11/02/2021	MPC approved to expand coverage for Spinal Muscular Atrophy (SMA) Carrier Testing. Requires 60-day notice, effective date 04/01/2022.
12/07/2021	MPC approved to adopt expansion of coverage for Chromosomal Microarray testing to members who are undergoing invasive prenatal genetic testing (i.e., amniocentesis). Requires 60-day notice, effective date 05/01/2022.
12/07/2021	MPC approved to adopt a policy of non-coverage for the ConfirmMDx and SelectMDx genetic tests for prostate cancer. Requires 60-day notice, effective date 05/01/2022.
04/05/2022	MPC approved to adopt MCG* A-0782 with new indications in the 26th edition. Gene/gene panel testing for hereditary ovarian cancer criteria are in the process of being updated and will all be reviewed by the Medical Director on a case-by-case basis until finalized.
06/07/2022	MPC approved to adopt MTAC's recommendation of non-coverage and to continue the existing policy of insufficient evidence.
08/16/2022	MCG* A-0822 and A-0847 were deleted from the 26th edition guidelines; deleted from criteria
09/22/2022	Added Oncoplex (University of Washington) and Caris Life Sciences as preferred lab vendors for NGS
11/01/2022	Updated criteria for Chromosomal Microarray Testing to remain compliant with revisions to the WAC; also updated other related prenatal genetic testing that were mandated to no longer require medical review. Effective immediately to comply with WAC 246-680-010. 60-day notice required.
11/01/2022	MPC approved to adopt criteria for Thyroid Nodule Gene Expression Testing (ThyraMIR/ThyGeNEXT CPT 0245u+0018U), Prostate Cancer Gene Expression Testing (Prolaris 81541) and Prostate Cancer (ConfirmMDx CPT 81551). Requires 60-day notice, effective date 04/01/2023.
11/14/2022	Added the July 2022 MTAC reviews for ConfirmMDx and Prolaris for Prostate Cancer. Replaced SelectMDx temporary CPT code 81479 with new CPT code 0339U, effective 10/1/22.
12/06/2022	MPC approved to remove NRAS genetic test from this page as it is currently on pharmacogenomic page. MPC approved to remove BRAF testing from genetic screening page and move to Pharmacogenomic page. Effective immediately.
12/12/2022	Added ClonoSEQ 81479 to flag for medical director review.
01/03/2023	Clarified language on ClonoSEQ indications. Added Medicare LCD L38816 and LCA A58997.
01/18/2023	Added the MTAC review for Decipher Prostate Genomic Classifier.
01/25/2023	For Prolaris-clarified use in setting of radical prostatectomy.
04/03/2023	Updated Medicare links and applicable code 0340U for Medicare LCD L38816.
04/24/2023	Added Quest-QNatal as a preferred vendor for Cell Free Fetal DNA testing.
08/14/2023	Updated applicable MCG 27th edition guidelines with updated name changes and guidelines that were marked as deleted to *"There is insufficient evidence in the published medical literature to show clinical utility."* Please refer to the MCG 27th edition summary of changes for more detail.
12/21/2023	Added NCD 190.1 Histocompatibility Testing
01/09/2024	MPC approved to revise the medical policy for APOE genotyping. Requires 60-day notice, effective date 06/01/2024
03/07/2024	Updated list of preferred lab vendors for Preconception or Pregnancy Carrier Screening.
03/22/2024	Updated Medicare links

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Genetic Panels using Next Generation Sequencing (germline/blood testing, excluding Advanced Cancer)

Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage).

Prevention and Invitae Corporation are the preferred labs for genetic testing, when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

Invitae's test catalog can be found here: Invitae Test Catalog
Prevention test catalog can be found here: Prevention Test Catalog

**Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae*

PPO/POS members may use non-preferred labs at the out of network cost share.

Exceptions
For the NGS testing for Advanced Cancer, see below:

- ***Next Generation Sequencing for Advanced Cancer***

Related Policies:

Genetic Screening and Testing
Pharmacogenomic Testing

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Next Generation Sequencing (NGS) (90.2) (Applies to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) breast and ovarian cancer.) Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) ***FDA-approved tests*** *(not all-inclusive)* FoundationFocus™ CDxBRCA Assay (Foundation Medicine, Inc.) FoundationOne CDx (Foundation Medicine, Inc.) FoundationOne Liquid CDx (Foundation Medicine, Inc.) Guardant360® CDx (Guardant Health, Inc.) Oncomine™ Dx Target Test (Thermo Fisher Scientific, Inc.) Praxis™ Extended RAS Panel (Illumina, Inc.)

Back to Top

	MSK-IMPACT™ (Memorial Sloan Kettering Cancer Center's (MSK) IMPACT (Integrated Mutation Profiling of Actionable Cancer Targets))
Local Coverage Determinations (LCD)	9/30/2015 - Noridian retired LCD for Genetic Testing (L24308). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search. MolDX: Next-Generation Sequencing for Solid Tumors (L38121) (Applies to diagnostic lab tests using NGS for solid tumors.)

General Coverage Rules – LCD 24308

1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured. Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules. For example, Medicare does not cover genetic tests based on family history alone.

3. A covered genetic test must be used to manage a patient. Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).

5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.

6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agree to post-test counseling is required. This consent form must be available on request by Medicare.

7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:

The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. MolDX has determined that testing for the below genes is a statutorily excluded service. Unless indicated otherwise, panels that include these genes will be denied. Please see the individual Test Coding and Billing Guidelines for each gene.

Palmetto GBA is the Medicare contractor for Molecular Diagnostic Testing – this site has the most up to date Medicare coverage guidelines for genetic testing.
MolDX® Program (Administered by Palmetto GBA)

Local Coverage Decisions (LCD)/Articles (LCA) *not all-inclusive – refer to the MolDX® Program link above*

ID	Title	Codes *(not all-inclusive)*

Back to Top

L36163	8/20/2022 Noridian retired LCD MolDX: BRCA1 and BRCA2 Genetic Testing. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81162, 81163, 81164, 81165, 81166, 81167, 81212, 81215, 81216, 81217, 81432, 81445, 81455, 0102U, 0103U, 0129U
L36386	MolDX: Breast Cancer Assay: Prosigna	81520
L37824	MolDX: Breast Cancer Index® Gene Expression Test	81518
L36186	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	81206, 81207, 81208, 81219, 81450, 0027U
L36159	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240, 81241, 81291
L36374	8/20/2022 Noridian retired LCD MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L38974 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer.	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299, 81300, 81301, 81317, 81318, 81319, 81433, 81435, 81436, 0101U
L36192	MolDX: MGMT Promoter Methylation Analysis	81287
L36544	MolDX: HLA-DQB1*06:02 Testing for Narcolepsy (L36544) **not covered per LCD*	81383
L36256	MolDX: Molecular Diagnostic Tests (MDT)	*See LCA: Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) (A57527)
L38333	MolDX: Blood Product Molecular Antigen Typing	0001U, 0084U
L36329	08/08/2022 Noridian retired LCD MolDX: ConfirmMDx Epigenetic. Molecular Assay. MolDX: Genetic Testing for Lynch Syndrome. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36163 for determining medical necessity, along with L39007MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer.	81551, 81313 Billing and Coding: MolDX: Molecular Biomarkers to Risk Stratify Patients at Increased Risk for Prostate Cancer

Back to Top

L38341	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease *(Decipher and similar, i.e., Prolaris)*	81541, 81542
L36339	MolDX: NRAS Genetic Testing	81311, 81479
L36557	01/01/2018 Noridian retired LCD MolDX: Chromosome 1p/19q Deletion Analysis (L36557). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L36557 for determining medical necessity, along with L36256 MolDX: Molecular Diagno2stic Tests (MDT).	
L36891	MolDX: Percepta© Bronchial Genomic Classifier	81479

For Non-Medicare Members

Kaiser Permanente considers genetic testing panels medically necessary when the results are expected to directly affect treatment, management, surveillance or reproductive decisions and when all genes or genetic variants included in the panel have high quality, evidence-based guidelines established to direct clinical management based on results.

Testing for individual components of a panel may be medically necessary in some clinical situations. Separate clinical criteria for these components may apply.

Members must meet ALL the following criteria:

1. The member is at clinical risk for a genetic condition because of current documented symptoms being displayed or a strong family history of the condition.
2. The test is scientifically valid and can be adequately interpreted.
3. The results will directly affect a member's clinical management or reproductive decisions.
4. After appropriate clinical work-up, and informed consent by the appropriate practitioner, the genetic test is indicated.

Genetic testing is not covered for the medical management of a family member who does not have Kaiser Permanente coverage.

1.) If Kaiser Permanente Clinical criteria for BRCA genetic testing using MCG* A-0499 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Breast Cancer STAT Panel
      ii. Invitae Breast Cancer Guidelines – Based Panel
      iii. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
      iv. Prevention – Breast Cancer- High Risk Panel

2.) If Kaiser Permanente Clinical Review Criteria for Lynch syndrome genetic testing using MCG* A-0533 are met AND
   a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
   b. One of the following NGS panels can be covered:
      i. Invitae Lynch Syndrome Panel
      ii. Invitae Colorectal Cancer Guidelines – Based Panel
      iii. Prevention Lynch Syndrome Panel

3.) If Kaiser Permanente Clinical Review Criteria for both BRCA and Lynch syndrome genetic testing are met

Back to Top

a. Member has had consultation with a medical geneticist or certified genetic counselor who is recommending the test and who has documented the indication for testing, as well as its expected impact on clinical management or surveillance
b. The following NGS panel can be covered
    i. Invitae Breast and Gynecological Cancers Guidelines – Based Panel
    ii. Prevention Hereditary Breast and Ovarian Cancer – High Risk and Lynch Syndrome Panel

***If a member has had prior negative BRCA1 & 2 gene testing:** In most cases, further genetic testing would not be considered necessary. However, in cases where there is a very strong personal or family history suggesting a genetic disposition, testing for additional evidence-based cancer susceptibility genes is warranted. One of the Invitae NGS panels listed in section 1b above could be covered.

Criteria for other Genetic Panel Tests:
Refer to the Genetic Screening and Testing clinical review criteria to see information about review criteria for specific genetic tests *not* described above; please also check Invitae Test Catalog or Prevention Test Catalog

*For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

*MCG are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following genetic panels are **not considered medically necessary** because the current scientific evidence is not yet sufficient to establish how test results from all components of these panels should be used to direct treatment decisions. There is also insufficient evidence to establish that use of these genetic panels to guide treatment decisions results in improved patient health outcomes.

This list is not all-inclusive as new genetic panel tests are frequently being developed.

Test	Laboratory
Anser TM ADA for Adalimumab (Humira) Antibodies Anser TM IFX test for Infliximab (Remicade) Antibodies	Prometheus Laboratories See the Medical Policy "Prometheus Lab Testing"
BrainTumor Next®	Ambry Genetics™
BRCANext™ or BRCANext-Expanded™	Ambry Genetics™
BRCAplus®	Ambry Genetics™
BROCA Cancer Risk Panel	University of Washington
CancerNext: *Expanded*®	Ambry Genetics™
CancerNext™ or CancerNext-Expanded™	Ambry Genetics™
CancerTYPE ID®	Biotheranostics
Cell Search	Veridex
ColoNext®	Ambry Genetics™
ColoNext™	Ambry Genetics™
ColoSeq™	University of Washington
Comprehensive Mitochondrial Nuclear Gene Panel	GeneDx
Counsyl™ Panel	Counsyl Genomics
CustomNExt-*Cancer*®	Ambry Genetics™
Cxbladder	Pacific Edge Laboratory
DetoxiGenomic®	Profile Test Genova®

Back to Top

Test	Laboratory
FirstStepDx PLUS©	Lineagen
FoundationOne™	Foundation Medicine, Inc.
Galleri®	Grail, Inc
Gene Trails AML/MDS Genotyping Panel	Oregon Heath & Science Univ
Gene Trails NSCLC Genotyping Panel	Oregon Heath & Science Univ
Gene Trails Solid Tumor Panel	Oregon Heath & Science Univ
GeneSight® Psychotropic test	Myriad®
Genomind Professional PGx Express	Genomind, Inc.
Guardant360 CDx	Guardant Health
Leigh Syndrome Nuclear Gene Panel	GeneDx
MelanomaNext®	Ambry Genetics™
Monogenic Hypertension Evaluation Panel	Athena Diagnostics
myRisk® Hereditary Cancer Panel	Myriad®
NeurodevelopmentNext™	Ambry Genetics™
OncotypeDx Genomic Prostate Score **MCG* A-0712**	Genomic Health
PancNext™	Ambry Genetics™
PGLNext®	Ambry Genetics™
Prometheus IBD sgi® Diagnostic (Serology)	Prometheus Laboratories
ProstateNext®	Ambry Genetics™
Proteomics – Ovarian Cancer Markers (OVA1) **MCG* A-0709**	
Proteomics – Prostate Cancer Markers	
Providence Personalized Medicine Panel, Solid Tumor (ProvSeq 523)	Providence Health and Services - Oregon
RenalNext®	Ambry Genetics™
Signatera™	Natera™
Tempus xG Hereditary Cancer Panel	Tempus labs
Vascular Aneurysm Genetic Panel	University of Washington
X-linked Intellectual Disability Panel	NTD Genetics
X-linked Intellectual Disability Sequencing Panel	Greenwood Genetic Center

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The emergence of new genetic testing technology, including next generation sequencing and chromosomal microarray, has made possible the ability to examine many genes simultaneously. This in turn has resulted in a proliferation of new genetic testing panels. The intended use for these panels varies.

For example, for hereditary disorders, a clinical diagnosis may already be established, in which case genetic testing is performed to determine the specific causative mutation and a diagnostic genotype. In other cases, the clinical findings may suggest a number of possible etiologies, in which case genetic testing is performed in the hope of making a specific diagnosis.

For cancer panels, intended uses also differ. Some panels may be intended to identify the presence of a hereditary syndrome predisposing to the development of certain cancers. Other panels look for somatic mutations in a tumor biopsy specimen with the intent of identifying a cancer's primary site of origin and/or identifying a molecular target to help in selecting treatment.

Panels using next generation sequencing technology are currently available in the areas of cancer, cardiovascular disease, neurologic disease, and for prenatal testing and screening. These panels are intuitively attractive to use in clinical care because they can analyze multiple genes quickly and may lead to greater efficiency in the work-up of genetic disorders. It is also possible that in some cases these "bundled" gene tests can be performed more cost efficiently than individual sequencing, although this may not be true in all cases.

Back to Top

On the other hand, the use of newer sequencing techniques is associated with a higher rate of results which may be of uncertain clinical significance and/or for which there are no reliable evidence-based guidelines regarding management or surveillance. This can potentially lead to unnecessary follow-up testing and procedures, which have their own inherent risks and cost.

The design and composition of genetic panel tests are not standardized. The make-up of each panel is determined by the specific laboratory that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new genetic variations are discovered and added to the existing panels.

Evidence and Source Documents

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)
Coloseq ™ Colon Cancer Panel

Medical Technology Assessment Committee (MTAC)

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

BACKGROUND

Understanding the underlying genetic contribution to cancer can give insight to individual and familial risk. This is especially important with hereditary cancer since risk-reducing strategies for additional primary cancers can vary based on molecular diagnosis. Identifying an underlying genetic cause can also aid in the diagnostic process since relying on family history alone can be challenging. Numerous genetic mutations are associated with certain types of hereditary cancer. Traditionally, Sanger sequencing has been considered the gold standard in mutation detection and is still the method of choice for most diagnostic labs. However, since multiple genes are implicated in each type of cancer, testing by traditional sequencing can be burdensome and expensive. Advancements in sequencing technologies have made it possible to generate a large amount of data quickly and cost effectively (Choi, Scholl et al. 2009). Next generation sequencing (NGS) provides investigators with the required capacity to analyze large panels of genes or whole genomes in a single run (panel testing) (Previati, Manfrini et al. 2013). As a result, these technologies are enabling new tailor-made approaches to diagnostic testing with an increasing number of commercially available genetic panels (Walsh, Lee et al. 2010; Michils, Hollants et al. 2012). Ambry Genetics offers four different genetic testing panels for hereditary cancers (Keiles 2013). These panels address three specific types of cancer that may be inherited including breast, ovarian and colorectal. The mutations included in these panels are associated with varying levels of risk of developing cancer, and only some of the mutations are associated with well-defined cancer syndromes which have established clinical management guidelines (Burke, Petersen et al. 1997).

TABLE 1: PANEL NAME AND DESCRIPTION

PANEL NAME	DESCRIPTION
BreastNext™	Next-generation sequencing panel that simultaneously analyzes 16 genes that contribute to increased risk for breast cancer including BRCA1 and BRCA2.
OvaNext™	Next-generation sequencing panel that simultaneously analyzes 21 genes that contribute to increased risk for breast ovarian and/or uterine cancers.
Colonext™	Next-generation sequencing panel that simultaneously analyzes 14 genes that contribute to increased risk for colon cancer.
CancerNext™	Next-generation sequencing panel that simultaneously analyzes 24 genes that contribute to increased risk for breast colon, ovarian, uterine and other cancers.

There is no standardization to the make-up of genetic panels. Composition of the panels is variable, and different commercial products for the same condition may test a different set of genes. The make-up of the specific panels is determined by the specific lab that has developed the test. In addition, the composition of any individual panel is likely to change over time, as new mutations are discovered. The majority of cancer panel tests are laboratory derived tests that are not subject to U.S. Food and Drug Administration (FDA) approval. Labs are subject to Clinical Laboratory Amendment (CLIA) regulations that monitor high-complexity testing.

10/21/2013: MTAC REVIEW

Ambry Genetics' Next-Generation Panels (BreastNext, OvaNext, CancerNext)

Evidence Conclusion: Analytic Validity According to Ambry Genetics, the analytic sensitivity for the 22 genes analyzed on their cancer susceptibility panels by next generation sequencing is 96-99% (Keiles 2013), however, no publications were found to support these claims. No published literature addressed the analytic validity of the Ambry Genetics' Next-Gen Cancer Panels. Clinical Validity While it may be possible to evaluate the clinical validity

Back to Top

of sequencing of individual genes found on these panels, the clinical validity of Ambry Genetics' Next-Gen Cancer Panels, which include mutations associated with unknown or variable cancer risk, is uncertain. No published literature addressed the clinical validity of panel testing for cancer susceptibility with NGS. Clinical Utility Theoretically, identifying an individual with a genetic mutation that indicates a high risk of developing cancer could lead to changes in clinical management and improved health outcomes including modifications in cancer surveillance and treatment guidance. However, identifying mutations that have intermediate or low risk of developing cancer is of limited clinical utility. With potential harms, such as psychological stress and unnecessary prophylactic intervention, the management for patients found to have one of these mutations is not well defined. No published literature addressed the clinical utility of the Ambry Genetics' Next-Gen Cancer Panels. Conclusion There is insufficient evidence to determine the analytic validity, clinical validity or clinical utility of the Ambry's Next-Gen Cancer Panels.

Articles: A search of PubMed was completed for the period through August 2013 for studies on the accuracy of NGS for predicting risk of hereditary breast ovarian and colon cancer. The search strategy used the terms *next generation, cancer panel, BreastNext, breast cancer, ColoNext, colon cancer, OvaNext, ovarian cancer and CancerNext* with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Articles were limited to those published in the English language with human subject enrollment. The search was supplemented by an examination of article bibliographies in addition to the PubMed *related* articles function.

The use of Ambry next generation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Coloseq™ Colon Cancer Panel

BACKGROUND

Approximately 2% to 5% of colorectal cancer (CRC) can be attributed to inherited syndromes such as Lynch syndrome (also known as hereditary non-polyposis colon cancer), familial adenomatous polyposis (FAP), and MUTYH-associated polyposis. Patients with these syndromes are at higher risk for CRC and, therefore, require more intensive surveillance programs. Lifetime CRC risk is 50-80% for patients with Lynch syndrome, 100% for patients with FAP, and 80% for patients with MUTYH-associated polyposis compared to 5-6% for patients without these syndromes (Kaz and Brentnall 2006; Jasperson, Tuohy et al. 2010). There are several different strategies used to identify families at high-risk for developing these syndromes, however, genetic testing is the gold standard for diagnosing Lynch syndrome and FAP. To date, clinical diagnostic criteria for MUTYH- associated polyposis have not been fully established; however, genetic testing may be warranted in individuals with more than 10 colorectal adenomas who are negative for APC mutations (Jasperson, Tuohy et al. 2010). Genetic testing of high-risk families allows for a more accurate diagnosis and more specific targeting of clinical screening and surveillance protocols to gene carriers in the family. Additionally, genetic testing allows for the identification of family members who did not inherit the mutation and therefore do not warrant intensive surveillance programs. Coloseq™ is a comprehensive genetic test for the prediction and diagnosis of hereditary colon cancer that uses next generation sequencing to detect mutations in multiple genes associated with Lynch syndrome, FAP, and MUTYH-associated polyposis. Initially, the panel was developed to include seven genes that have a well-established role in clinical decision making for patients with Lynch or polyposis syndromes. Since then, however, the panel has undergone several evolutions to include four additional genes in June of 2012, two more genes in January of 2013 and, most recently, the addition of six genes in October of 2013. With a total of 19 genes now included, the panels utility has now expanded into the realms of endometrial, breast, and thyroid cancer, to name a few. Coloseq is not approved by the Food and Drug Administration (FDA) but clinical laboratories that develop and validate tests for in-house use are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

10/16/2013: MTAC REVIEW

Coloseq™ Colon Cancer Panel

Evidence Conclusion: *Analytic Validity* One publication from the Journal of Molecular Diagnostics was identified that addressed the analytic validity of ColoSeq™ (Pritchard, Smith et al. 2012). The study presents 99.4%-100% sensitivity and 99.4%-100% specificity. The paper was limited to the seven genes that were included on the original panel and thus does not provide sufficient evidence for the 19 gene panel that is currently used. No publications were identified that validated the entire 19 gene panel that has since evolved. *Clinical Validity* Pritchard and colleagues present that the clinical validity is achieved by targeting and validating only genes that, when mutated, are well-established causes of hereditary colon cancer leading to the conclusion that incorporating the results of the ColoSeq™ testing into clinical-decision making was now straightforward. The addition of new genes and inclusion of additional cancers compromise this claim. No publications were identified that addressed the clinical validity of the ColoSeq™ cancer panel. *Clinical Utility* Originally, the ColoSeq panel was designed to focus only on genes that have a well-established role in clinical decision making and patient management. The

Back to Top

recent expansion of the ColoSeq panel compromises the overall clinical utility. No published literature addressed the clinical utility of the ColoSeq™ cancer panel.
Conclusion**:** There is insufficient evidence to determine the analytic validity, clinical utility and clinical validity of Coloseq™ for the identification of hereditary colon cancer.
Articles: A search of PubMed was completed for the period from April 2012 to November 5th, 2013 for studies on the accuracy of ColoSeq™ for detecting hereditary colon cancer. The search strategy used the terms *Coloseq™, genetic testing, Lynch syndrome, familial adenomatous polyposis (FAP), MUTYH-associated polyposis,* and *colon cancer* with variations. To identify ongoing clinical trials, a search of the National Institute of Health Clinical Trials website was also conducted using the same methodology. Selected articles were limited to those published in the English language enrolling human subjects. The search was supplemented by an examination of article reference lists in addition to the PubMed *related articles* function. **Screening of articles:** The literature search for ColoSeq™ revealed one July 2012 publication on the development and validity of the assay (Pritchard, Smith et al. 2012). Due to recent additions (October 2013) to the Coloseq™ cancer panel, this publication is no longer applicable and was not reviewed.

The use of Coloseq™ does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

***Note:** Codes listed in the criteria above may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
3/04/2014	3/04/2014MPC, 6/3/2014MPC, 01/06/2015MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	12/14/2023

MPC Medical Policy Committee

Revision History	Description
06/30/2015	Added Medicare LCD links and PROOVE® panels.
08/27/2015	Added LCD 35850 and LCD 35504
09/08/2015	Revised LCD Circulating Tumor Cell Marker Assays LCD L35096 and L34066, Breast Cancer Genetic Assay L35500 and L36316, GeneSight® Assay for Refractory Depression L36324 and L36325, Genetic Testing L34101, LCD for ConfirmMDx Epigenetic Molecular Assay (L36328),
12/06/2016	Added Cx Bladder & My Risk Panel to the non-covered list
05/16/2017	Added Percepta LCD
06/15/2017	Added Invitae Stat Panel coverage
10/19/2017	Added Health Diagnostics to the non-covered panel list
03/26/2018	Added Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer
06/13/2018	Moved 81381 to the no review list
08/29/2018	Moved 81307 to no review at this time
06/02/2020	Added section: “Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees.” Requires 60-day notice, effective date 10/01/2020. Moved CPT codes 81402, 81403 and 81270 under Applicable Codes section that do not need review.
06/24/2020	Added CPT codes 0084U, 0085U, 0093U, 0094U, 0095U, 0097U, 0098U, 0099U, 0100U, 0101U, 0102U, 0103U, 0104U
07/07/2020	MPC approved to adopt updates to the clinical indications for Non-Medicare. Requires 60-day notice, effective date 12/01/2020. Removed CPT codes that do not require review: 81220, 81221, 81240, 81241, 81261, 81340, 81341, 81342, 81372, 81374, 81375, 81376, 81377, 81378, 81379, 81380, 81381, 81402, 81403, 81270.

Back to Top

10/06/2020	Removed codes section; will defer to pre-authorization code check tool.
05/04/2021	Removed genetic panel tests that are no longer available. Updated Medicare LCD links and applicable codes.
09/27/2022	Added Prevention as a preferred lab vendor for genetic panel testing. Removed Caris and Oncoplex from the non-inclusive list of genetic panel tests. 60-day notice required; effective 03/01/2023.
01/19/2023	Removed Prolaris from the non-covered list. MPC approved to adopt criteria for Prostate Cancer Gene Expression Testing (Prolaris 81541) and Prostate Cancer (ConfirmMDx CPT 81551), effective 4/1/2023- see Genetic Screening Criteria for details.
03/08/2023	Added Signatera to the non-covered panel list
05/15/2023	Updated Medicare Links including—newly retired policies L36163, L36329 and L36374
06/07/2023	Added Tempus xG Hereditary Cancer Panel test to the non-covered list.
11/15/2023	Added ProvSeq 523 test to the non-covered list
12/14/2023	Added multi-gene panel tests from Ambry Genetics™ to the non-covered list
04/16/2024	Removed Horizon from the non-covered list.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Treatment of Gastroesophageal Reflux Disease - GERD

- CR BARD's Endoscopic Suturing System
- Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter
- LINX Reflux Management System
- Stretta Procedure
- Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)

Criteria

For Medicare members

Procedure(s):	CPT Code(s)	CMS Coverage Guidelines – NCD, LCD, LCA	Kaiser Permanente Medical Policy
Transesophageal radiofrequency energy ***Examples:*** CSM Stretta™ System, or the Stretta procedure	43257	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines.
Transoral incisionless fundoplication (TIF) ***Examples:*** EsophyX	43210	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical Review Criteria, ***Transoral (Endoluminal) Gastroplication or Suturing*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	Kaiser Permanente has elected to use the Transoral (Endoluminal) Gastroplication or Suturing (A-0205) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines.
LINX® Reflux Management System	43284, 43285	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use non-Medicare Clinical	Kaiser Permanente has elected to use the Implantable Magnetic Esophageal Ring (Linx) (A-0990) MCG* Care Guideline for medical necessity determinations.

Back to Top

		Review Criteria, ***Implantable Magnetic Esophageal Ring (Linx)*** for medical necessity determinations. Refer to the Non-Medicare criteria below.	This is not covered per MCG guidelines.
Endoscopic injection of a bulking agent ***Examples:*** pyrolytic carbon-coated zirconium oxide spheres (Durasphere®)	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Endoscopic submucosal implantation or injection of a biocompatible polymer ***Examples:*** • Enteryx, • polymethylmethacrylate [PMMA] beads (1) the Gatekeeper Reflux Repair system	43192, 43201	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).
Transesophageal endoscopic gastroplasty ***Examples:*** • EndoCinch • Plicator • StomaphyX	No specific codes – *often submitted using 43499*	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria of "insufficient evidence" for medical necessity determinations. Use the Non-Medicare criteria below.	Kaiser Permanente Medical Policy of insufficient evidence (see below).

For Non-Medicare members

Service	Criteria
Implantable Magnetic Esophageal Ring (LINX® Reflux Management System)	Kaiser Permanente has elected to use the Implantable Magnetic Esophageal Ring (Linx) (A-0990) MCG* Care Guideline for medical necessity determinations. This is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta)	Kaiser Permanente has elected to use the Radiofrequency Energy Delivery to Gastroesophageal Junction (Stretta) (A-0209) MCG* Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Transoral (Endoluminal) Gastroplication or Suturing (Esophyx)	Kaiser Permanente has elected to use the Transoral (Endoluminal) Gastroplication or Suturing (A-0205) MCG*

Back to Top

	Care Guideline for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
• CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) • Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

***The MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (GI, general surgeon)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastroesophageal reflux disease (GERD) is a common disease worldwide with an estimated prevalence of 10-20% in the Western population. It is defined as a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications. GERD has a wide clinical spectrum ranging from mild reflux symptoms to severe regurgitation but is typically characterized by heartburn and acid regurgitation. Other symptoms of GERD include epigastric pain, dysphagia, chronic cough, chronic laryngitis, and asthma (Vakil 2006, Zhang 2016, Savarino 2017).

Therapeutic approaches to GERD included lifestyle modification, medical therapy with gastric acid secretion inhibitors, and surgical interventions. Proton pump inhibitors (PPIs) are the standard medical therapy and aim at suppressing the normal acid production in the stomach to alleviate the acid reflux symptoms. PPIs can only inhibit gastric acid secretion, but do not prevent reflux nor address the incompetent lower esophageal sphincter (LES). It is reported that up to 40% of the GERD patients fail to respond either partially or completely to PPIs and will continue to have reflux symptoms or endoscopic evidence of esophagitis (Reynolds 2016, Saino 2016, Chen 2017).

Laparoscopic Nissen fundoplication (LNF) is currently the gold standard surgical treatment for patients who fail medial therapy. Nissen fundoplication reconstructs the defective LES to restore its normal function as an anti-reflux barrier. The surgery is safe and very effective in reducing GERD symptoms. However, the procedure is technically demanding and requires significant anatomical disruption to mobilize the gastric fundus and wrap it around the esophagus. It may also be associated with side effects including difficulty swallowing, bloating, early satiety, and inability to vomit or belch. As a result, only very few GERD patients will opt for the surgery (Saino 2015, Reynolds 2016, Zadeh 2018).

The Magnetic sphincter augmentation device (MSA) (LINX®, Torax Medical Shoreview, MN) was introduced in 2008 as a potential less invasive anti-reflux surgical option for patients with uncomplicated GERD who do not respond to PPIs, and still have some LES function. I.e. it is not indicated for patients with complete LES failure or with complicated GERD. The MSA device is a small expandable bracelet- like string of consisting of 10 or more beads with a magnetic core and interlinked with independent titanic wires. The device is laparoscopically placed around the gastroesophageal junction (GEJ) with minimal dissection of the hiatus to preserve the native LES. The magnetic attraction between the beads augments the existing LES barrier function to prevent reflux, and the mobile wires connecting the beads allow the device to expand during swallowing, belching, or vomiting (Reynolds 2017, Siddiqi 2017, Zadeh 2018, Guidozzi 2019).

Back to Top

The LINX® device should not be placed in patients with suspected or known allergies to titanium, stainless steel, nickel or ferrous material, or in those with pacemakers, defibrillators or metallic implants in the abdomen. In addition, it may not be appropriate for patients with a history of dysphagia, previous upper abdominal surgery, previous endoluminal anti-reflux procedures, large sliding hiatal hernia, or Barrett's esophagus. Reported adverse events and complications associated with magnetic sphincter augmentation include inability to belch or vomit, bloating, and dysphagia. The latter is the most common complication of the MSA, and severe cases may require a second surgery for dilatation, and removal of the device if endoscopic dilatation fails. Other reported adverse events include device failure, device migration, device erosion, and ring eroding into the esophageal lumen (Fass 2017, Chen 2017, Zadeh 2018, Guidozzi 2019).

The LINX® Reflux Management System received U.S. Food and Drug Administration (FDA) approval on March 22, 2012 for patients with GERD as defined by abnormal pH testing, and who continue to have chronic symptoms despite the use of a maximum medical therapy.

Medical Technology Assessment Committee (MTAC)

CR BARD's Endoscopic Suturing System (EndoCinch Therapy, Endoluminal Plication) for the Treatment of GERD

BACKGROUND

Gastroesophageal reflux disease (GERD) is a chronic disorder that affects as many as 14 million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently endoscopic or endoluminal approaches for treating GERD have either been FDA approved or are still under investigation. These various methods can be divided in three broad categories: 1. Methods that attempt to create a fundoplication (plicating techniques), 2. Methods that create a controlled stricture (radio frequency), and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective over a long term, and would not affect future surgical options. Currently, there are three plicating devices: The EndoCinch (C.R. Bard's endoscopic suturing system, the ESD, and the Full-Thickness Plicator. The first two have been approved by the FDA, and the last was not approved to date. Endoluminal plication uses mechanical techniques to hinder reflux by approximation of tissue at or below the gastroesophageal junction. The EndoCinch (CR BARD Endoscopic technologies, Massachusetts, USA) system was the first FDA approved endoscopic sewing machine method for treating GERD. It was developed by Swain CP et al in London UK, in the mid-1980s. In the Bard method, an oroesophageal tube (19.7 mm in diameter and 30 cm long) is placed to facilitate passage of the suturing device. The suture capsule, which is similar to a sewing machine, is attached to an endoscope and loaded with a suture. After placing the suture capsule, under vision, over the selected site at the gastroesophageal junction, suction through the external vacuum line is applied. This pulls a fold of tissue into the capsule cavity, and the needle driver places the suture. Suction is released, and the tissue is withdrawn from the capsule. The procedure is repeated on an adjoining site. Drawing two sutured sites together creates a plication. It is reported that the procedure is technically difficult, has a steep learning curve, and that the results are likely to be operator dependent. Conscious sedation might not be sufficient, and a general anesthesia may be needed. Adverse effects associated with the procedure include pharyngitis, vomiting, abdominal pain, chest pain, mucosal tear, hypoxia, and bleeding. The Bard's Endoscopic Suturing system was FDA approved in March 2000, for the treatment of GERD. The ESD (Wilson-Cook Medical, Winston-Salem, N.C.) another endoscopically assisted endoluminal suturing device was also approved by the FDA for soft-tissue apposition. The Full-Thickness Plicator (Ndo Surgical, Inc, Mansfield, Mass) is another plication device that had not been approved by the FDA at time the search was made.

02/13/2003: MTAC REVIEW

Endocinch Therapy in the Treatment of GERD

Evidence Conclusion: The studies reviewed show that the procedure is associated with a reduction in the frequency and severity of heartburn and regurgitation symptoms. Patients had an improved quality of life, and

Back to Top

there was a significant reduction in the use of antisecretory medications in two of the studies. However, the procedure was performed on a highly selected group of patients (those with hiatal hernia >3 cm, esophageal stricture and Barrett's esophagus were excluded). Moreover, the follow-up duration of all studies was short, and insufficient to determine the recurrence rate and long term-efficacy of the procedure. Filipi's study was an RCT, yet the patients were randomized to two different suture configurations of the same procedure and not to an alternative treatment. Randomized controlled studies with long-term follow-up are needed to compare the procedure with other medical and surgical anti reflux therapies and assess the sustained effect of the procedure and the long-term relief from symptoms without using antisecretory medications.

Articles: The search yielded 12 articles, all on the Bard technique. There was one randomized controlled trial, one case-control study and one case series. The rest were reviews, tutorials, letters or dealt with the technical aspect of the procedure. There were no published studies on the Wilson-Cook ESD, or the Ndo Full-Thickness Plicator. Evidence tables were created for the three studies identified in the search:
Filipi CJ, Lehman GA, Rothstein RI, et al. Transoral flexible endoscopic suturing for treatment of GERD. A multicenter trial. Gastrintest Endosc 2001; 53:416-422. See Evidence Table. Mahmoud Z, McMahon BP, Arfin Q, et al. Endocinch therapy for gastro-esophageal reflux disease: a one-year prospective study. *Gut* 2003, 52:34-39. See Evidence Table. Velanovich V, Ben-Menachem T, and Goel S. Case-control comparison of endoscopic gastroplication, with laparoscopic fundoplication in the management of gastroesophageal reflux disease. Early symptomatic outcomes. *Surg laparosc Endosc Percutan Tech* 2002, 12:219-223. See Evidence Table.

The use of Endocinch therapy in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Endoscopic Placement of a Bulking Material at the Lower Esophageal Sphincter for the Treatment of GERD

BACKGROUND

Gastro-esophageal reflux disease (GERD) is a chronic disorder that affects as many as fourteen million Americans. It is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmaco-therapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up ((Lafullarde, 2001). More recently endoscopic or endoluminal approaches for treating GERD have either been approved or are still under trial. These various methods can be divided in three broad categories: 1. Methods that create a controlled stricture (radiofrequency), 2. Methods that attempt to create a fundoplication, and 3. Methods that bulk the gastroesophageal junction (injecting bulking agents). The ideal procedure should be safe, effective, with long-term effects, and do not affect future surgical options. Endoscopic injection of an inert material into the submucosa of the distal esophagus has been tried with the intention to impede the reflux. The bulking effect results from both the material injected and the tissue response. Examples of the bulking agents used are bovine collagen, ethylene vinyl alcohol, polytetrafluoroethylene and others. These are injected through long catheters and small gauge needles under endoscopic guidance. In the experiments conducted the resulting improvement in reducing the LES pressure and GERD symptoms were temporary, and did not last long, either due to the biodegradation or migration of the injected material. Other non-biodegradable substances injected into the submucosa or muscle, and with the use of different application techniques are still under trial. These methods are still in the investigational stage and are not approved by the FDA.

02/13/2003: MTAC REVIEW
Bulking Material in the Treatment of GERD

Evidence Conclusion: There is insufficient evidence to determine the efficacy and safety of endoscopic injection of bulking material for the treatment of GERD.

Articles: The search did not yield any study. Two studies were revealed from review articles. Both were pilot studies with no comparison groups. One included only a series of 15 patients (10 in Brussels and 5 in Rome), and the other was a case series with only ten participants.

Back to Top

The use of bulking material in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Magnetic Sphincter Augmentation – (LINX® Reflux Management System)

BACKGROUND

Gastroesophageal Reflux Disease (GERD) is an extremely common clinical manifestation of excessive reflux of acidic gastric components. Also referred to as chronic acid reflux, GERD is characterized by a chronic, often progressive dysfunction of the lower esophageal sphincter (LES) allowing acids and biles from the stomach to flow back into the esophagus. Common symptoms include heartburn, regurgitation and dysphagia and can adversely impact the quality of life by interfering with daily activities, disturbing sleep, and reducing productivity. Left untreated GERD can lead to more serious complications such as esophageal stricture, Barrett's esophagus and esophageal cancer (Gorecki 2001). Simple diet and lifestyle modifications can ease some of the symptoms associated with GERD, however, more severe or frequent cases may require pharmaceutical treatment with antacids, H2-receptor antagonists or proton pump inhibitors (PPIs). Some cases of GERD, however, will not respond to medications and may require surgical intervention. Laparoscopic fundoplication (LF), has long been considered the gold standard of antireflux surgery. The technique involves wrapping the upper part of the stomach (gastric fundus) around the lower end of the esophagus in an effort to reinforce the LES. Although LF has a high success rate, the procedure is non-reversible and has been associated with a variety of potential side-effects such as dysphagia, loss of belching and vomiting and increased flatulence and bloating. The LINX® Reflux Management System, developed by Torax® Medical (St. Paul, MN), was designed to prevent back flow into the esophagus and is suggested as an alternative to anti-reflux surgery. More specifically, the magnetic sphincter augmentation (MSA) device is a series of interlinked magnetic beads implanted laparoscopically at the junction between the esophagus and stomach that acts as a reinforcement of the LES. The device relies on small wires that allow the magnetic beads to expand and allow the flow of foods and liquids into the stomach while preventing reflux at the same time. According to the manufacturer, the LINX Reflux Management System requires less recovery time, provides immediate relief and faster return to solid foods compared with other surgical interventions. To add to this, the device can be removed if side-effects, such as dysphagia, pain and bloating, become unbearable. The LINX® Reflux Management System received US Food and Drug Administration (FDA) approval on March 22, 2012. The device is intended for use in patients with GERD who continue to have symptoms despite the use of a maximum medical therapy for the treatment of reflux. More specifically, it is intended for use in patients who would be considered candidates for anti-reflux surgery. This topic has not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and is currently under consideration due to coverage decision support.

12/15/2014: MTAC REVIEW

LINK Reflux Management System

Evidence Conclusion: A feasibility trial by Lipham and colleagues, included 44 patients and aimed to assess the long-term safety and effectiveness of the LINX Reflux Management System (up to 3.7 years). In this study, patient's baseline measurements were used as the control for comparison with post-implant measurements. In all outcome measures improvements were seen with reduced esophageal acid exposure, improved GERD-HRQL scores and decreases in use of PPIs. As a result, the investigators concluded that sphincter augmentation with LINX provides long-term clinical benefits with no safety issues (Lipham, DeMeester et al. 2012). Evidence Table 1 In the second study, a pivotal trial by Ganz and colleagues, the investigators sought to evaluate the safety and effectiveness of the LINX Reflux Management System. The study included 100 patients with GERD and assessed esophageal pH as well as manometry and barium esophagography. The investigators report that 64% (95% CI, 54%-73%) of patients achieved success with normalization of esophageal acid exposure, or a ≥50% reduction in exposure at one year. Additional endpoints were also promising with 50% or more improvements seen in 92% of patients on the GERD-Health Related Quality of Life (HRQL) questionnaire. Although the authors concluded that the LINX device resulted in a decreased exposure to esophageal acid, improved reflux symptoms and allowed cessation of PPIs in the majority of patients, they also noted that additional prospective RCTs with appropriate controls are necessary for confirmation. (Ganz, Peters et al. 2013). Finally, the third study, by Riegler and colleagues, evaluated 249 patients who had undergone MSA and LF and completed one-year follow-up. With the overall goal to compare the clinical experience of each procedure, the investigators evaluated patients reflux symptoms, PPI use, side effects and complications. At one year, both groups showed improvement in total GERD-HRQL score (20 vs. 3 in the MSA group and 23 vs. 3.5 in the LF group) and discontinuation of PPIs was higher in the MSA group with 81.8% of patients abstaining and only 63% in the LF group (*P*=0.009). The investigators concluded that both MSA and LF were comparable but that MSA should be considered as the first-line surgical option Evidence Table 3. Adverse events and complications were documented in all three of the critically appraised publications. In addition, a recent publication from Lipham and colleagues provides a safety

 Back to Top

analysis of the first 1,000 patients treated with the MSA device. The analysis included safety related events collected from the published literature, FDA databases for device related complications and information provided by the manufacturer for over 1,000 patients treated worldwide between February 2007 and July 2013. This paper was not critically appraised, however, the safety data is generally summarized in table one, below. (Lipham, Taiganides et al. 2014).

Table 1. Summary of events by source

Source of data	# of events included in analysis	Breakout
Clinical literature	32	• 9 device removal • 20 esophageal dilation • 3 hospital readmissions
MAUDE database	20	• 19 device removal (includes US and OUS) • 1 device erosion
Manufacturer's database	59	• 8 device removal • 1 intra/perioperative complication • 11 hospital readmissions • 39 esophageal dilation

Generally speaking, the body of evidence is limited by small sample sizes, short-term follow-up, as well as a lack of randomization and adequate comparators. Selection bias may be an issue in the third study as the selection of intervention was ultimately made by the surgeon at the time of surgery. It should also be noted that the majority of studies assessing the LINX Reflux Management System are either funded by the device manufacturer or authored by consultants to the manufacturer. Ultimately the body of evidence provides insufficient evidence to support the safety and effectiveness of the LINX Reflux Management System. Conclusions: There is insufficient evidence to support the effectiveness of the LINX Reflux Management System in patients with refractory GERD. There is insufficient evidence to support the safety of the LINX Reflux Management System in patients with refractory GERD.

Articles: The literature search revealed just over 100 publications relating to treatment of GERD using sphincter augmentation many of which were not directly applicable to the objective at hand. No randomized controlled trials (RCTs) were revealed comparing the LINX Reflux Management System with alternative surgical interventions such as LF. The FDA's 2012 approval relied on two publications, a pivotal clinical trial and a feasibility study, which were selected for critical appraisal. Post-approval studies of the LINX Reflux Management System, required by the FDA, are currently ongoing. In addition to the pivotal and feasibility trial, two additional studies were considered. The first was a recent observational study comparing MSA to laparoscopic fundoplication (LF) and the latter, a safety analysis of the first 1,000 patients treated with MSA (this study was not critically appraised but discussed in the evidence summary). The following articles were selected for critical appraisal: Lipham JC, DeMeester TR, Ganz RA, et al. The LINX® reflux management system: confirmed safety and efficacy now at 4 years. Surgical Endoscopy. 2012; 26:2944-2949. See Evidence Table 1. Ganz RA, Peters JH, Horgan S, et al. Esophageal Sphincter Device for Gastroesophageal reflux disease. NEJM. 2013;368(8):719-72. Reigler M, Schoppman, Bonavina L, et al. Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. Surgical Endoscopy. 2014. See Evidence Table 3.

The use of LINX Reflux Management System does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Stretta Procedure (Electro-Surgical Coagulation-Radiofrequency [RF] Application- Curon Medical Inc's CSM Stretta System) for the Treatment of GERD

BACKGROUND

Gastroesophageal reflux disease (GERD) is a one of the most common medical disorders in the United States. It is a chronic disorder that is primarily caused by transient inappropriate relaxation or abnormally low resting pressure of the lower esophageal sphincter (LES). This intermittently exposes the esophagus to gastric acid and enzymes. GERD usually manifests as heartburn, regurgitation, or dysphagia. Patients may have significant daily symptoms with a substantial effect on their quality of life. Complications of the disease include Barrett's esophagus, esophagitis, laryngeal injury, pneumonia, and esophageal stricture. Current therapy for GERD begins with lifestyle changes and medical treatment, which proved to be effective in more than three fourths of the patients. Pharmacotherapy reduces the frequency, duration and/ or potency of the refluxate. However, the long-term costs are high, and the recurrence of symptoms could be as high as 90% after the cessation of medication. Patients who do not tolerate, or respond well to medical treatment, as well as those who want to avoid life-long

 Back to Top

treatment, may be candidates for surgery. Surgical approaches are used to create barriers to the reflux. Nissen fundoplication is the most commonly used surgical procedure with a response rate as high as 90% at 5-year follow-up (Lafullarde, 2001). More recently options include injection therapy to the lower esophageal sphincter, endoscopic sewing procedures, and radiofrequency ablation therapy. The ideal procedure should be safe, effective for a long time, and would not affect future surgical options. This review evaluates the radiofrequency techniques. Radiofrequency (RF) energy has been used for the general surgical application of tissue coagulation for more than 70 years. RF energy leads to collagen shrinkage, and in turn tissue contraction and tightening. Recently RF is being used for different clinical purposes, including its application to the gastroesophageal junction. The Stretta System (Curon Medical, Sunnyvale, CA) consists of a RF control module and a flexible Stretta catheter. The catheter has a 20F soft bougie tip and a balloon, which opens in a surrounding basket. On its widest area after balloon inflation, the catheter has four nickel-titanium needle electrodes (5.5 mm long), which can be extended in the LES muscle. The catheter is introduced transorally and positioned at the Z-line (squamocolumnar junction). It aspirates and irrigates the esophageal lumen with water to prevent surface injury. The four electrodes provide 60 to 300 J of RF energy to each needle, heating the surrounding muscle tissue to the target temperature between 65^{o} and 85^{o} C while cooling the mucosal with its irrigation system. 15 to 25 lesion sets are created in the region from 2 cm proximal to 1 cm distal to the Z-line by rotating the catheter 45 degrees and varying its linear position. The RF-induced burns eventually scar down and create a reflux barrier. The mechanism of action of RF is reported to be a reduction in the frequency of LES relaxations, as well as physical alteration in tissue compliance and wall thickness of the gastroesophageal junction. The Curon Medical Inc.'s CSM Stretta System was approved by the FDA on April 18, 2000. Curon recommends the device for mild or moderate cases of GERD only. The Stretta procedure is reported to be easy to learn and apply. However, there is a concern that if the scars continue to contract, at least some patients will develop a stricture that could be difficult to manage. Other adverse events that may be associated with the procedure include chest pains, fever, mucosal tear, and dysphagia.

12/10/2003: MTAC REVIEW
Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD
Evidence Conclusion: Of the studies reviewed, an RCT compared Stretta procedure to sham treatment, and a non-randomized longitudinal study compared it to laparoscopic fundoplication. The third was just a survey from a registry with no control or comparison group. Corley et al's trial was randomized and controlled however, it was a small study, with a high dropout rate, and some baseline differences between the two groups, that were not adjusted for in the analysis. Moreover, the procedure was compared to a sham treatment and not to another intervention e.g. laparoscopic fundoplication. The follow-up duration might have been insufficient to determine the long-term sustained effects, or potential late harms that could be associated with the procedure. In addition, the patients included in the study were highly selected for the trial and may not represent typical GERD patients. Richard et al's study was not randomized and patients were highly selected for each procedure. It was not blinded, not powered, and the follow-up duration was as short as 2 months for some patients, which is insufficient to determine the long-term durability of benefits or harms of the procedure. Both Corley's and Richard's studies were financially supported by Curon Medical, the manufacturer of the Stretta system. The third study reviewed was a retrospective survey of patients who underwent the Stretta procedure in several centers, with no reference to the inclusion/exclusion criteria, or techniques used for performing the procedure. Overall, the results of the studies show that radiofrequency application to the gastroesophageal junction to selected GERD patients is associated with improvement in symptoms and quality of life compared to sham treatment or laparoscopic fundoplication. The heartburn improvement associated with GERD vs. sham treatment was significant in the per protocol analysis but not with the ITT analysis in Corley's trial.
Articles: The search yielded 9 articles. There were no meta-analyses or randomized controlled trials. There were only three empirical studies all of which were case series. One had a very small sample, and only three months follow-up. The other two with relatively larger sample sizes, and longer follow-up duration were selected for critical appraisal. In December 2001, Curon Medical announced the completion of two major clinical trials, one of which is a RCT of the Stretta vs. sham treatment. To date these studies have not been published. *Evidence tables were created for the following studies:* Triadafilapoulos G, DiBaise JK, Nostrant T, et al. The Stretta procedure for the treatment of GERD: 6 and 12-month follow-up of the U.S. open label trial. *Gastrointest Endosc* 2002, 55149-156. See Evidence Table. Houston H, Khaitan L, and Richards WO. First year experience of patients undergoing the Stretta procedure. *Surg Endosc* 2002, Nov 20. See Evidence Table.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/13/2003: MTAC REVIEW

 Back to Top

Electro-Surgical Coagulation (radio-frequency application) in the treatment of GERD

Evidence Conclusion: The two-case series reviewed show that the Stretta procedure may be a promising treatment for GERD. Patients had significant reduction in the esophageal acid exposure and use of antisecretory medication, as well as significant improvement in their quality of life scores, compared to those before the intervention. However, the studies were case series that provide the lowest grade of evidence. In the studies reviewed, participants were highly selected for the procedure. Only patients with small or no hiatal hernias, no dysphagia, stricture, or Barrett's disease as well as those whose symptoms are controlled by pharmacological treatment were included in the studies. Moreover, the interpreters of the results were not blinded to the treatment, the follow-up duration was insufficient, dropout rate was high, and there were no comparison or control groups. In conclusion, there is insufficient evidence to determine the efficacy of the Stretta procedure in the treatment of GERD. Prospective randomized studies with larger sample sizes, comparison to another intervention or treatment, and a long follow-up duration will be needed.

Articles: The search yielded seven review articles and two empirical studies: (1) An RCT comparing radiofrequency ablation to sham treatment, and (2) A longitudinal non-randomized study comparing the procedure to fundoplication. *Evidence tables were created for these two studies as well as a patient registry published prior to 2003 that was not included in the earlier review:* Corley DA, Katz P, Wo JM, et al. Improvement of gastroesophageal reflux symptoms after radiofrequency energy: A randomized, sham-controlled trial. *Gastroenterol* 2002; 125:668-672. See Evidence Table. Richards WO, Houston HL, Torquati A, et al. Paradigm shift in the management of gastroesophageal reflux disease. *Ann Surg* 2003; 237:638-649. See Evidence Table. Wolfsen HC, and Richards WO. The Stretta procedure for the treatment of GERD: A registry of 558 patients. *J Laparoendoscp Adv Surg Tech* 2002; 6:395-402. See Evidence Table.

The use of electro-surgical coagulation (radio-frequency application) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

EndoGastric Solutions Stomaphy X™ Endoluminal Fastener, InScope™ Tissue Apposition System, Transoral Incisionless Fundoplication

BACKGROUND

Over the last two decades, several less invasive endoluminal /endoscopic techniques have been developed for the management of GERD. These procedures include radiofrequency ablation (Stretta system), magnetic sphincter augmentation (LINX procedure), and transoral incisionless fundoplication, among others.

Transoral incisionless fundoplication (TIF) using the (EndoGastric Solutions, Inc., Redmond, WA) has been proposed as a less invasive alternative to traditional surgical procedures. Similar to the NF, TIF attempts to decrease the reflux of stomach acid into the esophagus through the reconstruction of an anti-reflux barrier. It involves wrapping a portion of the stomach around the esophagus without requiring any incisions.

TIF is performed in an outpatient setting under general anesthesia, and involves inserting the EsophyX™ device transorally, under direct endoscopic visualization, into the stomach and positioning it at the junction of the stomach and the esophagus. Once positioned, the device uses suction and transmural fasteners to facilitate the recreation of the esophageal gastric valve. The fundus of the stomach is folded up and around the distal esophagus utilizing the tissue mold and chassis of the device. Next, an integrated suction apparatus grasps the distal esophagus and positions it below the diaphragm. H-shaped fasteners, made of polypropylene, are then delivered through apposed layers of esophageal and fundus tissue to anchor the repair. This process is repeated to create a full thickness, partial circumference, and gastroesophageal fundoplication. Approximately 20 fasteners are implanted during the procedure resulting in the recreation of an omega shaped full-thickness gastroesophageal valve from inside the stomach 3-5 cm in length and 200-300° in circumference. This procedure may also reduce hiatal hernias that are < 2 cm in size through the use of a built-in vacuum invaginator (Jafri 2009, Louis 2010, Hunter 2015, Testoni 2014, Trad 2014, Witteman 2015).

TIF 1.0 utilizing the EsophyX™ device was first performed in 2005 and received United States Food and Drug Administration (FDA) initial 510(k) clearance in 2007. The EsophyX device is indicated for endoluminal, transoral tissue approximation, full thickness plication and ligation in the GI tract for the treatment of symptomatic chronic gastroesophageal reflux disease in
patients who require and respond to pharmacological therapy. It is also indicated to narrow the gastroesophageal junction and reduce hiatal hernia < 2cm in size in patients with symptomatic chronic gastroesophageal reflux disease (FDA website accessed June 2020).

The EsophyX technology underwent several modifications along the years. Currently, there are three generations of the device; the original EsophyX® device, EsophyX2®, EsophyX Z®. Over the same timeline, four different

 Back to Top

fundoplication procedures using the EsophyX have emerged. The initial device was used to perform the endoluminal gastro–gastric fundoplication, called “ELF”. The second procedure TIF 1.0, was a longitudinally oriented plication of gastric cardia onto the distal esophagus just proximal to the gastroesophageal junction. The third procedure TIF 2.0, incorporated a rotational wrap of the cardia and fundus around the circumference of the distal esophagus in addition to providing a 2–4 cm length of the wrap over the intra-abdominal distal esophagus. This results in tightening and reinforcing the sling fibers of the proximal stomach (the lower portion of the LES), accentuating the cardiac notch, steepening the angle of His, and reestablishing the flap valve mechanism. The fourth procedure is a combined laparoscopic hiatal hernia repair with transoral incisionless fundoplication 2.0 (HH-TIF). Each of TIF procedures described is markedly different from the others and have different clinical outcomes. The TIF-2 procedure is believed to be the most similar procedure to NF morphologically and physiologically and is accomplished by using the third generation EsophyX® Z, launched in 2015 and cleared by the FDA in 2016 (Chang 2020, Ihde 2020).

Reported adverse events associated with the procedure include gastrointestinal bleeds, esophageal laceration, pleural effusion, mediastinal abscess, and potential failure of the procedure due to the pull on the fastener used to create the valve.

04/09/2008: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: There is insufficient published evidence to determine the efficacy and safety of the EndoGastric Solutions StomaphyX™ endoluminar fastener for weight loss. There is insufficient published evidence to determine the efficacy and safety of the InScope™ Tissue Apposition System for endoscopic gastric sutures.
Articles: The literature search did not reveal any published studies, on the EndoGastric Solutions StomaphyX™ endoluminar fastener and delivery system, or on the InScope™ Tissue Apposition System. Information about the systems was obtained from the FDA and the manufacturer’s Web sites.

The use of endoluminar fasteners in the treatment of obesity does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/15/2011: MTAC REVIEW
Endoluminar Fasteners
Evidence Conclusion: Two case-series were selected for review that evaluated the safety and effectiveness of transoral incisionless fundoplication (TIF) for the treatment of GERD. The first study followed 110 subjects for a median of 7 months and the second study followed 86 subjects for 12 months. The primary outcome in both of these studies was GERD Health-Related Quality of Life (GERD-HRQL). Both studies found significant reductions in GERD-HRQL compared to baseline. However, results from these studies should be interpreted with caution as both studies were case-series (lowest-quality evidence). Serious adverse events included two perforations and a post-TIF intraluminal bleeding that required a blood transfusion. Other adverse events included: left shoulder pain, abdominal pain, sore throat, nausea, and epigastric pain (Barnes 2011; Cadière 2008). **Conclusion:**
There is insufficient evidence to determine the safety and efficacy of transoral incisionless fundoplication for the treatment of GERD.
Articles: To determine the safety and efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Screening of articles: No randomized controlled trials were identified that addressed the safety or efficacy of transoral incisionless fundoplication using the EsophyX system for the treatment of GERD. Studies were not selected for review if they included less than 25 subjects. The largest studies with the longest duration of follow-up were selected for review. The following studies were critically appraised: Barnes WE, Hoddinott KM, Mundy S, Willams M. Transoral incisionless fundoplication offers high patient satisfaction and relief of therapy-resistant typical and atypical symptoms of GERD in community practice. *Surg Innov 2011;* 18:119-129. See Evidence Table. Cadière GB, Buset M, Muls V, et al. Antireflux transoral incisionless fundoplication using EsophyX: 12-month results of a prospective multicenter study. *World J Surg 2008;* 32:1676-1688. See Evidence Table.

The use of endoluminar fasteners in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/13/2020: MTAC REVIEW
Transoral Incisionless Fundoplication with Esophyx
Conclusion:

 Back to Top

- The published RCTs evaluating the safety and efficacy of TIF 2.0 using EsophyX compared the procedure versus a sham therapy or PPI and not to laparoscopic Nissen fundoplication (LNF), the most appropriate comparator.
- There is no direct published evidence, to date, to determine the safety and effectiveness of TIF 2.0 using EsophyX compared LNF, the gold standard for the management of patients with refractory GERD.
- Indirect comparison suggests the LNF is superior to TIF 2.0 in esophageal acid control, healing of esophagitis and increasing in LES pressure.
- There is insufficient published evidence to determine the effects of TIF using EsophyX on net health outcomes, and whether it will lead to protection from long-term adverse events of GERD and Barrett's esophagus.
- TIF may be superior to sham therapy (i.e. no therapy), but not PPIs in reducing percent time pH <4.
- TIF may be superior to sham therapy in improving the quality of life, but not in reducing the incidence of persistent esophagitis.
- The published studies and MAs indicate that the efficacy of TIF may decrease over time and that most patients may still need to use PPIs, but maybe at a lower dose.
- Open label trials found significant improvements with TIF 2.0 in subjective measures, but no difference in objective outcome measures of pH normalization and esophagitis when compared with PPI therapy. This may suggest a potential placebo effect of TIF 2.0.
- There is insufficient published data to determine the long-term safety of TIF 2.0 using EsophyX in patients with GERD.

Articles:

The literature search identified 6 RCTs, one non-randomized comparative study, and over 20 noncomparative observational studies published between 2011 and 2018. The search also revealed 4 meta-analyses (MAs) of exclusively RCTs or RCTs together with observational studies. One of the meta-analyses also included a network MA (NMA). Of the published RCTs, only one trial (Svoboda et al, 2011) compared TIF vs. LNF, 2 trials compared TIF to sham therapy, and two compared the procedure to different PPIs. The Svoboda trial was a small trial (N=52) that used 2 generations of the devices and different techniques for the TIF group along the study (Plicator® method for 18 patients, and the EsophyX® in16 patients). The study was thus not included in any of the published meta-analyses as combining results of studies using different procedures and generations of the device would lead to incorrect conclusions on effectiveness of the procedure in treating reflux disease.

The meta-analysis with the more valid methodology and most inclusive of published RCTs (Huang et al, 2017) as well as the Richter and colleagues' systematic review with both a direct and network meta-analysis were selected for critical appraisal. The published RCTs that compared TIF 2.0 versus LNF, sham therapy, or PPIs were summarized in a table format. See Evidence Table.

The use of Transoral Incisionless Fundoplication with Esophyx does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/08/2019: MTAC REVIEW

Magnetic Sphincter Augmentation (MSA) (LINX® Reflux Management System) for Gastroesophageal Reflux Diseases

Conclusion:

- There is no published evidence, to date, from randomized controlled trials to determine the comparative safety and effectiveness of MSA and laparoscopic Nissen fundoplication in patients with GERD refractory to maximal medical therapy.
- Low quality evidence from short-term non-randomized comparative observational studies suggest that MSA may be associated with better postoperative ability to belch and vomit and less bloating compared to fundoplication in patients with GERD.
- There is insufficient evidence to determine the long-term safety or effectiveness of MSN in patients with medically refractory GERD.

Articles: The literature search for recently published studies after the December 2017 MTAC review did not identify any randomized controlled trial that compared magnetic sphincter augmentation (LINX® Reflux Management System) versus Nissen fundoplication. The search revealed only one RCT that compared MSA versus double-dose PPIs in patients with moderate to severe GERD who failed once daily PPI therapy for 8 weeks (Bell, 2019). One qualitative systematic review (Stanak 2018) and two more recent systematic reviews with meta-analyses (Ailofi 2018, and Guidozzi 2019) that pooled the results of nonrandomized comparative observational studies, were also identified, as well as a small retrospective study (Richards 2018) of patients who underwent the procedure by a single surgeon. The RCT comparing magnetic sphincter augmentation to double-dose PPI was excluded as the aim of the review was to compare the device to Nissen fundoplication the gold standard procedure

 Back to Top

for patients with GERD-related symptoms despite the use of a maximum medical therapy. The most recent meta-analyses of studies comparing LINX® reflux management system with Nissen fundoplication were reviewed. No evidence tables referenced for this report.

The use of Magnetic Sphincter Augmentation (MSA) in the treatment of GERD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

LINX® Reflux Management System - Considered Not Medically Necessary:

CPT® Codes	Description
43284	Laparoscopy, surgical, esophageal sphincter augmentation procedure, placement of sphincter augmentation device (ie, magnetic band), including cruroplasty when performed
43285	Removal of esophageal sphincter augmentation device

Radiofrequency Energy Delivery to Gastroesophageal Junction/Transesophageal radiofrequency energy (Ex: CSM Stretta) - Considered Not Medically Necessary:

CPT® Codes	Description
43257	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease

Transoral (Endoluminal) Gastroplication or Suturing/Transoral incisionless fundoplication (TIF) (Ex: Esophyx) - Considered Not Medically Necessary:

CPT® Codes	Description
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed

Endoscopic placement of a bulking material at the lower esophageal sphincter - Considered Not Medically Necessary:

CPT® Codes	Description
43192	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance
43201	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance

CR BARD's Endoscopic Suturing System - Considered Not Medically Necessary:

CPT® Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/13/2003	Initiated annual review because of Medicare criteria 05/03/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015MPC,	10/06/2020

Back to Top

	02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 02/06/2018[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
07/21/2016	Added LINX® Medicare Coverage
10/04/2016	MPC approved to adopt Kaiser Permanente criteria for GERD when Medicare is silent
08/06/2019	Added MTAC review for Magnetic Sphincter Augmentation- LINX® management system for GERD
02/04/2020	MPC approved to adopt Transoral (Endoluminal) Gastroplication or Suturing (Esophyx) MCG A-0205 for medical necessity determinations.
06/02/2020	Removed deleted code C9737 (LINX®)
10/06/2020	Added MTAC Review for Transoral Incisionless Fundoplication with Esophyx. MPC approved to retain existing policy of non-coverage.
10/06/2020	MPC approved MCG 24th ed. guideline for Implantable Magnetic Esophageal Ring (LINX®) A-0990

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Genicular Nerve Block for Knee Pain

- Coolief Cooled Radiofrequency Ablation for Knee Pain
- Genicular Nerve Ablation
- Genicular Nerve Ablation for Knee Osteoarthritis
- Genicular Nerve Neurolysis
- Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Nerve Blockade for Treatment of Chronic Pain and Neuropathy (L35457)
Local Coverage Article	Billing and Coding: Nerve Blockade for Treatment of Chronic Pain and Neuropathy (A52725)
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "***Genicular Nerve Ablation for Knee Osteoarthritis***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Service	Criteria
Neurolysis, Genicular Nerve • Coolief Cooled Radiofrequency Ablation for Knee Pain • Genicular Nerve Ablation for Knee Osteoarthritis	MCG* A-1047 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access
Thermal Genicular Nerve Radiofrequency Ablation (GNRFA)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies. This procedure requires review if the ablation is being done as an alternative to surgery. ***Note:** Genicular nerve ablation can also be done during surgical procedures for anesthesia, such as total knee replacement or ligament and tendon repair and does not require review for those circumstances.

Back to Top

If requesting review for these services, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Hayes Technology Assessment

A nerve block is a form of regional anesthesia. The genicular nerve is a sensory nerve that innervates the knee. Genicular nerve blocks are performed to relieve pain in patients who may not be candidates for knee surgery or in advance of total knee replacement surgery. In a genicular nerve block procedure, an anesthetic agent, (e.g., lidocaine, bupivacaine, etc.), is injected on the genicular nerve. Genicular nerve blocks may be performed as a diagnostic step to ensure that blocking the nerve provides pain relief. In these cases, after a genicular nerve block demonstrates pain relief, genicular neurotomy or genicular nerve ablation may be performed as a more permanent solution.

Hayes Rating: D^2 - Insufficient Evidence: For use genicular nerve blocks combined with a corticosteroid or alone for treatment of pain and loss of function associated with osteoarthritis of the knee or persistent chronic pain following total knee arthroplasty.

This Rating reflects a very-low-quality body of evidence that does not consistently provide proof of benefit. Substantial uncertainty remains due to conflicting evidence and limited follow-up.

Hayes. Hayes Technology Assessment. *Genicular Nerve Block for the Management of Knee Pain*. Dallas, TX: Hayes; June 24, 2020. Retrieved July 13, 2020, from https://evidence.hayesinc.com/report/htb.genicular3323

Background

Osteoarthritis (OA) of the knee is a common chronic degenerative joint disorder and one of the leading causes of physical impairment and decline in the quality of life in older adults in the US and worldwide. It is a progressive condition in which the cartilage between bones in the joint wears away leaving the bones to rub more closely against one another resulting in pain, swelling, stiffness, and loss of function.

Conservative treatment for symptomatic knee OA includes physical therapy, aquatic therapy, weight loss, oral or topical non-steroidal anti-inflammatory drugs, bracing, and orthosis. Intraarticular injection of corticosteroids, hyaluronic acid, and other treatment modalities have also been used to alleviate the pain however, the analgesic effect is short-term with the steroid injection and unproven with some other therapies. Overall, conservative measures may relieve symptoms and improve function in some patients, but they do not restore the normal knee function, reverse the damage, or slow the progression of the disease. Knee joint arthroplasty is the most effective treatment for relieving pain and improving the knee function in patients with severe knee OA, but it is an invasive surgery that may be associated with medical and postsurgical complications. In addition, older individuals with comorbidities might not be good candidates for the surgery and others may be unable or unwilling to undergo the operation (El-Hakiem 2018, Jamison 2018, Erdem 2019).

Over the years, researches have been investigating alternative less invasive therapies for the treatment of patients with refractory knee OA. Several existing and new therapies have thus been or are being evaluated for the alleviation of chronic pain in patients with musculoskeletal disorders including knee OA.

Radiofrequency ablation (RFA) is one of these modalities considered for the treatment of patients with symptomatic knee. RFA is a nonsurgical, minimally invasive procedure that uses radio waves to create an electrical current through the body. The created current delivers heat to the targeted tissue resulting in its destruction, Ablation of the nerve tissues disrupts the ability of the nerve to send pain signals. RFA was first used by a German surgeon in 1931 to treat trigeminal neuralgia and three decades later, the first radiofrequency ablation commercial machine was introduced in the market. The indications of RFA have expanded over the years and is currently being used for the treatment of a variety of medical conditions including chronic low back

Back to Top

pain, cardiac arrhythmias, tumors, varicose veins, obstructive sleep apnea, and several other disorders. More recently RFA gained popularity in alleviating pain due to musculoskeletal disorders. In 2010 Choi and colleagues investigated its use for OA knee pain based on the theory that blocking the sensory innervation for a painful structure will result in pain relief (Choi 2011, Gupta 2017).

The knee joint is innervated by the articular branches of various nerves including the femoral, common peroneal, saphenous, tibial and obturator nerves known as the genicular nerves. Several of these nerves can be approached percutaneously under fluoroscopic or ultrasound guidance to identify the anatomical landmarks around the knee and locate the targeted genicular nerves (Choi 2011, Gupta 2017).

Conventional RFA treatment uses a high temperature probe to impair/destroy the targeted nerve fibers that carry the pain signals to the brain. The high heat originating from the RF probe may potentially damage adjacent tissues as the temperature reaches 70-90^{o}C. In addition, it has been reported that the lesion produced by the heat is limited in size and thus may not reach some target areas. To overcome these limitations, two new techniques the (pulsed RFA (p-RFA) and the cooled RFA (C-RFA) have been investigated for GNRFA (Oladeji 2019).

Coolief™ RFA treatment (the focus of the current review) also known as cooled radiofrequency ablation or neurotomy, follows the same method as the conventional RFA neuronal tissue damage, but uses water-cooled technology to safely impair or destroy the sensory nerves. A radiofrequency generator transmits a small current of RF thermal energy through an insulated electrode placed within the tissue. Sterile water circulates continuously inside the Coolief™ probe to cool it and regulate its temperature while it delivers the RF thermal energy. According the investigators of the technology, the circulating water modulates the thermal heat in the tissue to ≈60^{o}C and alters the size, shape, and projection of the lesions compared to conventional RFA. It is postulated that delivering RF energy through water-cooled electrode enables more RF energy to be safely delivered to the targeted nerves creating larger spherical -shaped lesion that increases the area of denervation and minimizes the risk of excessive heating and damaging the adjacent tissues (Gupta 2017, Oladeji 2019, AVANOS report 2019).

The Cooled RFA (CRFA) procedure is performed in an outpatient setting under local anesthesia, conscious sedation and fluoroscopic or ultrasound guidance. It is performed in 2 stages (McCormick 2017, Davis 2018):

1. A diagnostic genicular nerves block procedure: After positioning the patient in a supine position on a fluoroscopy table, a 25-guage 2.5-3.5-inch Whitacre needle is placed under fluoroscopic guidance at three unique anatomic sites to block the superior lateral, superior medial, and the inferior medical genicular nerves. Accurate placement of the needle is confirmed using fluoroscopy in the AP and lateral planes, then lidocaine is injected in order to numb each genicular nerve. Patients with a positive response (≥50% reduction in pain in the 24hrs following injection) are offered radiofrequency ablation (stage 2) for a more sustained response.
2. Genicular nerve radiofrequency ablation procedure performed under fluoroscopic visualization of the anatomical landmarks for probe placement. The patient is positioned supine on the fluoroscopy table (similar to the diagnostic nerve block procedure), and given conscious sedation, and local anesthesia at each of the 3 anatomic sites for RFA. An introducer needle (50 or 70 mm 17-guage) is then placed to lesion the 3 genicular nerves after which the internally cooled RFA electrode (Coolief, 4-mm, 18-guage active tip) is inserted in the introducer needle and its positioning verified with AP and lateral fluoroscopic views. Lidocaine is then injected through the introducer needle to numb the region before the thermal ablation. Each target undergoes CRFA for 150 seconds at a set temperature of 60^{o}C which produces tissue temperature of 77^{o}C-80^{o}C surrounding the electrode. The needles are then removed, and the patients allowed to recover before they are discharged to home.

Medical Technology Assessment Committee (MTAC)

Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain

10/14/2019: MTAC REVIEW

Evidence Conclusion:

- There is insufficient published evidence to determine the safety and efficacy of cooled RFA treatment for the management of moderate to severe chronic OA knee pain that is refractory to conservative therapy in patients who are not candidates for surgery.
- There is low to moderate quality evidence from one relatively small RCT showing that genicular RFA using Coolief™ system, performed prior to total knee replacement surgery had no significant effect compared to sham ablation, on reducing post-operative pain, use of pain medications, or improving function.

Back to Top

Date Sent: 4/29/24

Articles: The literature search for studies on cooled genicular never ablation for symptomatic knee osteoarthritis, published after the March 2018 INCT review yielded less than 10 articles including a report on the 12 months follow-up results of the pivotal RCT (Davis et al 2019). The search also identified a RCT comparing the effect of CRFA versus a sham therapy performed prior to TKA, on postoperative pain. Among the other recently published articles was a randomized trial that evaluated the utility of genicular nerve blocks to predict the outcome of genicular nerve cooled radiofrequency ablation in patients with osteoarthritis (McCormick et al, 2018); a cost-effective analysis of CRFA based on Davis et al's trial (Desai 2019); one observational study with no control or comparison group (House et al, 2019), three technical reports, and a case presentation.
See Evidence Table.

The use of Coolief Cooled Radiofrequency Ablation for Knee and Hip Pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement
07/13/2020: MTAC REVIEW

Evidence Conclusion:
There is insufficient published evidence to support the use of genicular RFA for reducing postoperative pain after total knee preplacement surgery.

Articles:
There is a paucity of published literature evaluating the use of thermal genicular neve ablation for the management of persistent pain after a total knee replacement surgery. The only published randomized controlled trial identified by the literature search was a small double-blinded trial that compared the efficacy of genicular nerves RFA versus analgesic block with corticosteroids in alleviating pain and improving function and QoL in patients with pain after a TKA (Qudsi-Sinclair S et al, 2017 (Evidence Table 1).

This trial was randomized, controlled, and double-blinded, but had its limitations including the small sample size study (N=30 randomized and 28 included in the analysis), lack of power calculations, randomization method not discussed, and subjective outcomes. There were also some baseline differences between the study groups e.g. their ages, duration of a pain, knee function, QoL, and the use of medication including opioids before the intervention. The differences were not significant, but the numbers may be too small to detect statistically significant differences.

The overall results of the study show the following (details in the evidence table)

- A significant reduction in pain scores in each of the treatment arm compared to baseline values, this was more pronounced in day 1 after each of the two procedures but tended to increase during follow-up.
- At one year the NRS was almost 5 in the RFA group and >5 in the steroid group (a value of 5-10 indicates worst possible pain).,
- Knee functioning also improved vs baseline, in each of the treatment arms, but was still considered poor and unsatisfactory according to the values of the KSS and OKS.
- There were no significant differences between the 2 study groups in any of the outcome measures (pain, function, QoL, or patient satisfaction). Lack of significant difference does not necessarily indicate that the two intervention have similar results as indicated by the authors). The power of the study may have been insufficient to detect statistically significant differences.

The use of Thermal Genicular Nerve Radiofrequency Ablation (GNRFA) for continued chronic knee pain post total knee replacement does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch

Back to Top

64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch
ICD-10 Codes	**Description**
M25.561	Pain in right knee
M25.562	Pain in left knee

Non-Medicare - Considered Not Medically Necessary:

CPT® Codes	Description
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
64640	Destruction by neurolytic agent; other peripheral nerve or branch

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/07/2018	08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 03/12/2024[MPC]	09/05/2023

[MPC] Medical Policy Committee

Revision History	Description
08/07/2018	MPC approved to adopt policy of non-coverage for GNA.
12/03/2019	Added MTAC review for Coolief RFA and MPC approved a non-coverage policy for this procedure.
05/18/2020	Added comment about procedure being done for anesthesia during other surgical procedures, which does not require review.
06/23/2020	Added CPT codes 64454 and 64624
08/04/2020	Added Medicare LCD L35457, LCA A52725 and ICD-10 codes M25.561 and M25.562. Removed “hip” from non-coverage policy and added MTAC review from July 2020. MPC approved to retain policy of non-coverage for genicular nerve ablation for non-Medicare patients.
09/05/2023	MPC approved to adopt Neurolysis, Genicular Nerve: MCG A-1047.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Gynecomastia

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Plastic Surgery (L37020)
Local Coverage Article (LCA)	Billing and Coding: Plastic Surgery (A57222)

For Non-Medicare Members

Kaiser Permanente has elected to use the Mastectomy for Gynecomastia (KP-0273 v2 eff 04.01.2022) MCG* Care Guideline for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from primary care provider or specialist, addressing the indications described in the medical necessity criteria

***MCG manuals are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gynecomastia is a unilateral or bilateral enlargement of the male breast due to benign proliferation of glandular elements. Pubertal gynecomastia resolves without intervention in the majority of cases. Gynecomastia in postpubertal males may be due to persistent pubertal gynecomastia, medications, liver disease, kidney disease, testicular tumors, or endocrine disorders. The cause remains undetermined in about 25% of cases. Male breast cancer is uncommon and usually presents as a discrete breast mass.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Back to Top

Date Sent: 4/29/24

CPT® Codes	Description
19300	Mastectomy for gynecomastia

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
01/05/2016	01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	11/02/2021

[MPC] Medical Policy Committee

Revision History	Description
12/19/2017	Added Plastic Surgery LCD L37020
08/04/2020	Added Medicare LCA A57222
11/02/2021	MPC approved modifications to the hybrid criteria for non-Medicare members. Requires 60-day notice, effective date 04/01/2022.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Hearing Aids (Excludes Implantable Devices)

A separate criteria document exists for the following devices:
Cochlear Implant
Bone Anchored Hearing System (BAHA) criteria

Criteria

For Medicare Members

F	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	This service is not covered per Medicare Criteria
Local Coverage Determinations (LCD)	Non-Covered Service defer to Kaiser Permanente Medical Policy
Local Coverage Article (LCA)	None
Kaiser Permanente Medical	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Hearing Aids (Excludes Implantable Devices)"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Please note that individual riders/contracts may vary in benefit design either excluding or waiving criteria for some services. **The member's rider/contract should be reviewed before making a final coverage determination and supersedes clinical review criteria**.

Equipment	Medical Necessity
Prescription Hearing Aids Hearing Aid devices include: • Air conduction devices • Bone conduction devices	Hearing aids that are FDA-approved and dispensed by a prescription may be considered medically necessary when the following criteria are met: For adult patients (19 or older): 1. Hearing thresholds 30 dB HL or greater at **TWO or more** of the following frequencies: 500, 1000, 2000, 3000, or 4000 hertz (Hz) For pediatric patients: 1. Patient is under 18 years old or younger and has been evaluated by otolaryngologist; **AND** 2. Hearing aids have been prescribed by an audiologist or otolaryngologist.

Back to Top

Hearing Hardware covered under Hearing Services Benefit	To receive your hearing hardware benefit • You must be examined by a licensed physician (MD or DO) or audiologist (CCC-A or CCCMSPA) before obtaining hearing aids • You must purchase a hearing aid device Benefits are then provided for the following: • Hearing aids (monaural or binaural) prescribed as a result of an exam • The hearing aid instruments • Hearing aid rental while the primary unit is being repaired • The initial batteries, cords and other necessary ancillary equipment • A warranty, when provided by the manufacturer • A follow-up consultation within 30 days following delivery of the hearing aids with either the prescribing physician or audiologist • Repairs, servicing, and alteration of hearing aid equipment purchased under this benefit

Equipment	Investigational
Hearing Aids	Non-implantable intraoral (in the mouth) bone conduction hearing aids (eg, SoundBite™, Hearing System)

Equipment	Non-Covered
Over the Counter (OTC) Hearing Aids	Over the Counter (OTC) hearing assistive listening devices (ALDs)/personal sound amplification products (PSAPs), Wireless Hearing aid Accessories, and Hearables available without a prescription are not covered. These include but ar not limited to the following: • Cyberscience Amplifier • NewEar™ • Eargo • BeHear • Magic Ear • Pocketalker® • TV Ears® • Ear buds or headphones
Hearing Hardware Not covered under the Hearing Services Benefit	Batteries or other ancillary equipment other than that obtained upon purchase of the hearing aids

If requesting this service (*or these services*), please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Back to Top

Background

Traditional hearing aids are externally worn microphones that amplify sound to the ear through an ear mold that fits in the ear canal.

Selection of the hearing aid is based on the results from a complete work-up performed by a hearing professional that includes skilled hearing tests and assessment along with fitting the chosen device. The hearing aid dispensed should meet the hearing requirements of the member in the environments and under the conditions where enhanced hearing is needed.

Effective January 1, 2024, Washington state law has provisions for the coverage of hearing instruments. House Bill 1222 require that large group plan carriers shall provide coverage for hearing instruments.

Resources

American Speech-Language-Hearing Association. Hearing Aids. 2023a American Speech-LanguageHearing Association. Accessed Sep 01, 2023. Available at URL address: https://www.asha.org/public/hearing/hearing-aids/

American Speech-Language-Hearing Association. The audiogram. 2023b American Speech-LanguageHearing Association. Accessed Sep 01, 2023. Available at URL address: https://www.asha.org/public/hearing/Audiogram/

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Mar 23, 2023. Available at URL address: https://www.cms.gov/medicarecoverage-database/indexes/lcd-alphabetical-index.aspx

Centers for Medicare and Medicaid (CMS). Medicare benefit policy manual. Chapter 16 General Exclusions From Coverage. 100 Hearing aids and auditory implants. Revised 11/06/14. Accessed Sep 01, 2023. Available at URL address: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html

Ferguson, M. A., Kitterick, P. T., Chong, L. Y., Edmondson-Jones, M., Barker, F., & Hoare, D. J. (2017). Hearing aids for mild to moderate hearing loss in adults. Cochrane Database of Systematic Reviews, 2017 (9). DOI: 10.1002/14651858.CD012023.pub2.

Washington State Legislature. Hearing Instruments—Group Health Plan Coverage. July 23, 2023. Accessed on Sept 01, 2023. Available at URL address: https://lawfilesext.leg.wa.gov/biennium/2023-24/Pdf/Bills/Session%20Laws/House/1222-S.SL.pdf?q=20230917191930

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPCS Codes	Description
V5030	Hearing aid, monaural, body worn, air conduction
V5040	Hearing aid, monaural, body worn, bone conduction
V5050	Hearing aid, monaural, in the ear
V5060	Hearing aid, monaural, behind the ear
V5100	Hearing aid, bilateral, body worn
V5120	Binaural, body
V5130	Binaural, in the ear

Back to Top

V5140	Binaural, behind the ear
V5171	Hearing aid, contralateral routing device, monaural, in the ear (ITE)
V5172	Hearing aid, contralateral routing device, monaural, in the canal (ITC)
V5181	Hearing aid, contralateral routing device, monaural, behind the ear (BTE)
V5211	Hearing aid, contralateral routing system, binaural, ITE/ITE
V5212	Hearing aid, contralateral routing system, binaural, ITE/ITC
V5213	Hearing aid, contralateral routing system, binaural, ITE/BTE
V5214	Hearing aid, contralateral routing system, binaural, ITC/ITC
V5215	Hearing aid, contralateral routing system, binaural, ITC/BTE
V5221	Hearing aid, contralateral routing system, binaural, BTE/BTE
V5242	Hearing aid, analog, monaural, CIC (completely in the ear canal)
V5243	Hearing aid, analog, monaural, ITC (in the canal)
V5244	Hearing aid, digitally programmable analog, monaural, CIC
V5245	Hearing aid, digitally programmable, analog, monaural, ITC
V5246	Hearing aid, digitally programmable analog, monaural, ITE (in the ear)
V5247	Hearing aid, digitally programmable analog, monaural, BTE (behind the ear)
V5248	Hearing aid, analog, binaural, CIC
V5249	Hearing aid, analog, binaural, ITC
V5250	Hearing aid, digitally programmable analog, binaural, CIC
V5251	Hearing aid, digitally programmable analog, binaural, ITC
V5252	Hearing aid, digitally programmable, binaural, ITE
V5253	Hearing aid, digitally programmable, binaural, BTE
V5254	Hearing aid, digital, monaural, CIC
V5255	Hearing aid, digital, monaural, ITC
V5256	Hearing aid, digital, monaural, ITE
V5257	Hearing aid, digital, monaural, BTE
V5258	Hearing aid, digital, binaural, CIC
V5259	Hearing aid, digital, binaural, ITC
V5260	Hearing aid, digital, binaural, ITE
V5261	Hearing aid, digital, binaural, BTE
V5262	Hearing aid, disposable, any type, monaural
V5263	Hearing aid, disposable, any type, binaural
V5264	Ear mold/insert, not disposable, any type
V5265	Ear mold/insert, disposable, any type
V5267	Hearing aid or assistive listening device/supplies/accessories, not otherwise specified
V5275	Ear impression, each
V5298	Hearing aid, not otherwise classified

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
09/05/2023	09/05/2023[MPC],	09/05/2023

[MPC] Medical Policy Committee

Revision History	Description
09/05/2023	MPC approved medical necessity coverage indications for Prescription Hearing Aids. Requires 60-day notice. Effective date 2/01/2024.

Back to Top

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Patient Referral Guidelines
Heart/Lung Transplant

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Heart Transplants (260.9)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Heart Transplant

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for Heart transplantation[1]. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral. As such, these should be applied together with careful clinical judgment.

1. **GENERAL PRINCIPLES**
   a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.
   b. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
   c. Uncontrollable active infection is a contraindication to transplant.
   d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low [2,3,4]. Exceptions may be made on a case-by- case basis.
   e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines and kidney) may require abstinence from tobacco products to be actively listed.
   f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
      1. Patient must have a care giver or care givers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
      2. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
   g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

Back to Top

Date Sent: 4/29/24

h. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
i. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

INDICATIONS FOR HEART TRANSPLANT

a. End-stage heart disease as evidenced by one or more of the following:
    i. Functional class III or IV
    ii. Not correctable by medical or other surgical therapies
    iii. A low VO2 maximum: [5]
        1. ≤14 ml/kg/min in patients not on a beta blocker
        2. ≤12 ml/kg/min in patients on a beta blocker [6]
        3. <19 ml/kg/min adjusted for lean body mass in patients with a BMI >30 kg/m^2
        4. Less than 50% of age predicted maximum.
    iv. A VE/VCO2 >35 in a patient with a sub-maximal cardiopulmonary exercise test (RER <1.05)[2]
    v. Cardiac index < 2 L/min/m^2
b. Unable to wean from mechanical or inotropic support.
c. Amyloid Cardiomyopathy
    i. TTR Amyloid
    ii. (AL) Amyloidosis without significant extra-cardiac involvement.
d. Refractory Life-Threatening Arrhythmias

3. The transplant should only be offered for conditions in which cardiac transplant has proven clinical benefits.
CONTRAINDICATIONS FOR HEART TRANSPLANT (In conjunction with the General Principles listed above in Section 1 of these guidelines):

a. Significant diseases such as:
    i. Severe uncontrolled or poorly controlled hypertension.
    ii. Clinically significant vascular disease not correctable by intervention.
    iii. Pulmonary hypertension not reversible by drug manipulation despite maximum tolerated medical management. [7]
        1. Adults: PVR > 4-6 Wood units or transpulmonary gradient > 15 mm Hg
        2. Children: PVR > 9 Wood units
    iv. Severe pulmonary disease after optimal treatment of severe heart failure.[8]
    v. Severe hepatic disease after optimal treatment of severe heart failure.[8]
    vi. Kidney disease with creatinine clearance <34 ml/kg/min or GFR < 30 ml/min after optimal treatment of heart failure. [8,9,10]
    vii. Active and/or progressive central nervous system disease excluding patients with embolic stroke who have recovered completely.
    viii. Evidence of cachexia or malnutrition (BMI < 19 kg/m^2 or < 80% ideal body weight).[10]
    ix. Obesity (BMI>35 kg/m^2 or > 140% ideal body weight) [11] has been associated with poor outcomes after cardiac transplant.
    x. Diabetes with complications resulting in severe end-organ damage.
    xi. Auto/acquired immune disease with multi-organ manifestation
    xii. Acute pulmonary embolus
    xiii. Active peptic ulcer disease
    xiv. Severe symptomatic osteoporosis
    xv. Age over 70 (Carefully selected patients over 70 years of age may be considered for cardiac transplantation)
    xvi. AL Amyloidosis with significant extra-cardiac manifestations
    xvii. Patients with viral hepatitis will require additional evaluation, including hepatology consultation.
    xviii. Any other co-morbid condition that would limit life expectancy or quality of life.

Footnotes

1. Note: All patients must be continuously re-evaluated for indications and contraindications. Candidates considered for re-transplantation must be evaluated using the same indications.
2. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
3. Liver Transplant Surg., 1997, Vol. 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.
4. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology.

Back to Top

5. Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant 2016; 35:1-23. 10.1016/j.healun.2015.10.023
6. Patients on Beta blockers should have a cut-off of ≤12 ml/kg/min, and patients intolerant to beta blockers a VO2 ≤14 ml/kg/min.
7. Circulation; 84 (3), 329 – 337. *Journal of Heart Transplantation* (1990): 526 – 537.
8. Selected patients for combined organ transplant will be evaluated on a case-by-case basis.
9. Must have 20mg per kilogram of creatinine in a 24-hour collection period. Creatinine clearance can also be calculated by the Cockcroft-Gault formula.
10. Mehra MR, Canter CE, Hannan MM, et al. The 2016 International Society for Heart Lung Transplantation listing criteria for heart transplantation: A 10-year update. J Heart Lung Transplant 2016; 35:1-23. 10.1016/j.healun.2015.10.023
11. Body Mass Index (BMI) = (weight [kg] / height2 [m^2]). Percent Ideal Body Weight (PIBW) was calculated as follows: Men IBW = 106 pounds for the first 5 feet of height, add 6 pounds for each additional inch. Women IBW = 100 pounds for the first 5 feet of height add 5 pounds for each additional inch. Journal of Heart and Lung Transplantation, Aug 1999, page 752.

LUNG TRANSPLANT:

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. The following are current, generally accepted, guidelines for lung & heart/lung transplantation. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral, rather should be applied together with careful clinical judgment.

1. GENERAL PRINCIPLES

a. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, early referral should be made.
b. Patients with a history of malignancy with moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.
c. Uncontrollable active infection is a contraindication to transplant.
d. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low. [4, 5, 6] Exceptions may be made on a case-by-case basis.
e. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.
f. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.
    i. Patients must have a care giver or care givers who are physically and cognitively able to assist the patient with self- care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.
    ii. Evidence of non-adherence may be failure to keep appointments, failure to make steady progress in completing pre- transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
g. Patients must be willing and able to travel within short notice to the KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.
h. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.
    i. Evidence of such non-adherence may be failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required for maintenance on the waiting list.
i. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Any disease state in which transplantation has become an accepted mode of treatment worldwide including

Back to Top

Date Sent: 4/29/24

i. Chronic obstructive pulmonary disease (COPD), which may include asthma, chronic bronchitis, emphysema and/or Alpha 1 antitrypsin deficiency
ii. Idiopathic pulmonary fibrosis
iii. Sarcoidosis
iv. Connective tissue disease-related pulmonary fibrosis
v. Eosinophilic granulomatosis
vi. Bronchiectasis
vii. Cystic fibrosis (CF)
viii. Pulmonary hypertension (both primary and secondary)
ix. Lymphangiomyomatosis (LAM)
x. Interstitial lung disease not otherwise defined.

c. Patients should be referred for transplant evaluation by a pulmonologist or a cardiologist who has accumulated data defining both the disease as potentially treatable by transplantation and progression is occurring despite maximal medical therapy.
d. Early referral is strongly encouraged for progressive lung disease with a poor prognosis[7]
e. Ideally, the patient should be ambulatory with rehabilitation potential.

3. CONTRAINDICATIONS FOR LUNG TRANSPLANT

a. Must meet all prerequisites listed in the General Principles section
b. Invasive mechanical ventilator support[8].
c. Unresolved infection (except in cystic fibrosis and bronchiectasis).
d. Uncontrolled chronic infection (i.e., HIV with detectable viral load)
e. Other systemic diseases including but not limited to:
i. Diabetes with end organ effects; i.e., renal, cardiac or uncorrectable peripheral vascular disease. Insulin use itself is not a contraindication.
ii. Uncontrolled hypertension.
iii. Significant neurologic disease impairing cognitive function.
iv. Malnutrition [9]
v. Obesity >140% ideal body weight or BMI >32 kg/m2 [10, 11](with an understanding that a BMI <30 may be necessary for transplantation).
1. May wish to consider initiating transplant workup if patient has pulmonary fibrosis and BMI >32 (but <34) if showing willingness to lose weight.
vi. Advanced hepatic dysfunction.
vii. Advanced renal dysfunction (creatinine clearance < 50 ml/min. after maximum therapy). However, patients with underlying cardiopulmonary causes of low creatinine clearance can be considered for transplant on a case-by-case basis.
viii. Evidence of clinically significant obstructive coronary artery disease and/or LVEF <40%. [12]
ix. Active or unresolved peptic ulcer disease.
x. Chronic opiate use: Patients should be seen by a pain management specialist for alternative forms of therapy.
xi. Uncorrectable bleeding diathesis or clotting disorder

4. RELATIVE CONTRAINDICATIONS

a. Patients with previous thoracotomy and/or sclerosing procedures should be considered on a case by case basis.
b. Systemic corticosteroid therapy >10 mgs prednisone daily.
c. Esophageal dysmotility and reflux. Surgical repair may be necessary.[13]
d. Age >70 for lung transplant referral.
e. Symptomatic osteoporosis.
f. Major mechanical chest deformity (such as kyphoscoliosis).
g. Short stature patients (in USA 4'11" for females and 5'4" for males) are significantly disadvantaged and early consideration of multiple listing is encouraged.

PATIENT PROFILE FOR COMMON DIAGNOSES LUNG TRANSPLANT REFERRAL GUIDELINES

Any or all of the listed guidelines for each disease entity should raise consideration for lung transplantation evaluation. Clinical correlation is always of primary importance.

1. GROUP A – Obstructive Lung Disease [14, 15] (See Table 1Below)

1.1. FEV1 < 25 %

Back to Top

Date Sent: 4/29/24

1.2. DLCO < 40%

1.3. Hypoxemia; PO2 < 55Hypercapnia; PCO2> 51[16]

1.4. Bode Index > 5

2. **GROUP B – Pulmonary Arterial Hypertension** (See Table 1 Below)[17, 18, 19]

2.1. Patients with clinically significant PAH should be evaluated by physicians experienced in treating pulmonary hypertension and have received maximum available pharmacological treatment.

2.2. Possible indications for referral include:

2.2.1. Pericardial Effusion[20]

2.2.2. World Health Organization (WHO) (New York Heart Association) class 3 or 4

2.2.3. Lack of improvement in WHO Class 3 or 4 and/or lack of improvement in 6-minute walk test of < 350 meters, despite maximum pharmacological therapy.

2.3. Definite indications, after maximum pharmacologic treatment for referral include: [21]

2.3.1. Mean RA > 15 mmHg

2.3.2. Cardiac Index < 2L per minute. Untreated, the mean survival for patients with these criteria is 10-11 months.

3. **GROUP C – Cystic Fibrosis** [22](See table 1 Below)

3.1. FEV1 < 40%

3.2. PO2 < 55

3.3. Clinical deterioration, especially in young female patients, as characterized by increasing number of hospitalizations, including recurrent pneumothoraxes, rapid fall of FEV1, recurrent major hemoptysis uncontrolled by embolization and/or increasing cachexia should prompt consideration for transplant referral.

3.4. PCO2 > 51

3.5. Patients with *Burkholderia cepacia* have a relative contraindication.

4. **GROUP D – Restrictive Lung Disease)** [22, 23](See Table 1 Below)

4.1. Force Vital Capacity < 80%[22]

4.2. Decline in Forced Vital Capacity of ≥10% and/or decline in DLCO ≥ 15% during 6 months of follow-up[22]

4.3. Diffusing Capacity (corrected for alveolar volume) < 60%

4.4. Evidence of interstitial lung disease on HRCT in conjunction with one or more of the above.

Referral to lung transplant program should be considered when a definitive diagnosis of usual interstitial pneumonitis (UIP) or idiopathic pulmonary fibrosis (IPF) is made and may be considered for the diagnosis of fibrotic nonspecific interstitial pneumonitis (NSIP).

OTHER CONDITIONS

Other conditions for which transplant may be appropriate include the Lung diseases described ~~in~~ in Table 1 below.[24]

Date Sent: 4/29/24

Table 1: Lung allocation score (LAS) primary diagnostic groupings for lung transplant candidates

LAS lung disease diagnosis grouping	
Group A (obstructive lung disease)	• Chronic obstructive pulmonary disease (COPD), with or without alpha-1-anti deficiency, due to chronic bronchitis and or emphysema • Lymphangioleiomyomatosis (LAM) • Bronchiectasis, including primary ciliary dyskinesia • Sarcoidosis with a mean pulmonary artery (PA) pressure ≤30 mmHg
Group B (pulmonary vascular disease)	• Idiopathic pulmonary arterial hypertension (iPAH, formerly known as primary hypertension [PPH]) • Eisenmenger's syndrome • Other pulmonary vascular diseases
Group C (cystic fibrosis or immunodeficiency disorders)	• Cystic fibrosis (CF) • Immunodeficiency disorders such as hypogammaglobulinemia
Group D (restrictive lung disease)	• Idiopathic pulmonary fibrosis (IPF) • Pulmonary fibrosis due to other causes • Sarcoidosis with mean PA pressure >30 mmHg • Obliterative bronchiolitis (nonretransplant)

Source: Revision to policy 3.7.6.1.

1

ADDENDUM

GUIDANCE FOR LUNG TRANSPLANT FOR IRREVERSIBLE PULMONARY FAILURE FROM COVID-19

Background: Transplant has been successful for other conditions, including infections, that lead to irreversible pulmonary failure, so this disease has some familiar aspects within the lung transplant community. Because of the specific conditions surrounding the effects of SARS-C0V-2, and because much of the mechanism underlying the development of lung injury and recovery are still unclear, the following elements are recommended for any consideration for referral of and authorizations for potential candidates for lung transplant. The below represent elements, *IN ADDITION TO THE USUAL CRITERIA PROVIDED IN THE CMS LUNG PATIENT REFERRAL GUIDELINES:*

1. Age under 65 if ECMO has been used as bridge to transplant
2. Disease has progressed in spite of maximal non-invasive ventilatory support
3. No other significant organ dysfunction exists
4. Sufficient time for recovery must be allowed: once on invasive mechanical support or ECMO, referral should not be considered fewer than 4-6 weeks after ventilator-dependent or ECMO-supported pulmonary failure
5. Patients on prolonged 0_2 therapy other than mechanical support or ECMO should be given sufficient time to determine irreversibility of the condition (usually three months) and should be ambulatory with good opportunity for rehabilitation.
6. Evidence of irreversible lung disease (bullae, fibrosis) must be present
7. The ability to gain patient, not surrogate, approval for transplant is an essential ethical concept in light of the relatively poor long-term outcomes from lung transplant
8. Ability to do adequate pulmonary rehabilitation while on support for respiratory failure
9. Have 2 negative SARS-COV-2 PCR tests at least 24 hours apart with one of the samples being a deep respiratory specimen.
10. Transplants should be performed only at lung transplant programs experienced in the highest risk lung transplants including familiarity with transplanting patients with ECMO bridging to transplant. Furthermore, they should have:
    a. Broad donor pool (represented by low time to transplant measures), and
    b. Low wait-list mortality

Reference: Cypel M, Keshavjee S. Comment When to consider lung transplantation for COVID-19. Lancet Respir Med. 2020;8:944–6. https://doi.org/10.1016/S2213-2600(20)30393-3 .

Back to Top

Footnotes

1. See Addendum 1, New system for lung allocation (enclosed)
2. Orens, JB, et al, 'International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation', *Journal of Heart and Lung Transplantation*, 25(7), July 2006, 745-755.
3. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
4. *Liver Transplantation* 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.
5. *Liver Transplant Surg,*. 1997, Vol 3, 304 – 310.The natural history of alcoholism and its relationship to liver transplantation.
6. 6. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), *TPMG New Medical Technology*
7. J Thorac Dis. 2019 Sep; 11(Suppl 14): S1708–S1720.
8. Under acceptable case-by-case circumstances, a patient who has been listed for a lung transplant and previously ambulatory, and now requires mechanical ventilation, may still be a potential candidate for lung transplantation. Patients who have been listed for lung transplant, and require invasive mechanical ventilation, can remain on the transplant list provided that there remains rehabilitation potential. On a carefully selected case-by-case basis, patients who are on invasive mechanical support, and are ambulatory with a potential for rehabilitation, can be listed for lung transplant. *Chest 2001; 119* (1) 224-227.
9. Any disorder of nutrition causing a lack of necessary or proper food substances in the body or improper absorption and distribution of them (Taber's Cyclopedic Medical Dictionary).
10. *Journal of Heart and Lung Transplantation Vol. 18 (8), August 1999, pg 750-761*
11. *The Journal of Heart and Lung Transplantation 2010*; 29 (9), 1026 – 1033. Impact of Recipient Body Mass Index on Survival after Lung Transplantation.
12. Potential candidate for Heart/Lung transplantation will be evaluated independently.
13. Annals of Surgery, 2006. Vol.244 (4) 491-497.
14. Lung Transplantation in Advanced COPD: Is it Worth it? Semin Respir Crit Care Med. 2010 June; 31(3): 365-372; Selecting lung transplant candidates: where do current guidelines fall short? Expert Rev Respir Med. 2012 February; 6(1): 51-61.
15. Amer *Rev Respir Dis* 140: S92 and S95 1989; Ann Int Med 99: 612: 1983; *New England Journal of Medicine*,1999 340(14), 1081-91
16. Celli BR, Cote CG, Marin JM et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. N Engl J Med 2004;350:1005-12.
17. Applicable to idiopathic pulmonary arterial hypertension, familial pulmonary arterial hypertension, collagen vascular disease limited to the lungs, pulmonary veno-occlusive disease, pulmonary capillary hemangiomatosis, and drug induced pulmonary hypertension. *CHEST, 2004*, Volume 126 (Supplement 1).
18. AJRCCM 201. 184: 159-171 - Thorough review of lung transplantation; J Heart Lung Transplant. 2006. 25(7): 745-55. - Consensus report from ISHLT Pulm Circ. 2011. April-June. 1(2): 182-191 - PH and lung transplant.
19. *Transplantation*. 2010 Aug 15. 90(3): 298-305. - Suggests that 6MWD </= 300 m and RAP >/= 14 mm Hg is better predictor of wait list mortality than LAS scoring system.
20. McGoon MD and Miller DP. Eur Respir Rev. 2012; 21(123):8-18.
21. *Ann Int Med* 115: 343 1991
22. Weill D, et al. A consensus document for the selection of lung transplant candidates: 2014 An update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant 2015; 34:1–15
23. Nathan, SD., Lung Transplantation- Disease-Specific Considerations for Referral', CHEST 2005; 127: 1006-1016.
24. OPTN Policy 10: Allocation of Lungs, 10.1.F.i Lung Disease Diagnosis Groups, Effective Date 9/1/2016

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

This service is covered when it is medically necessary and identified as a benefit in the consumer's coverage contract. Kaiser Permanente adopted the MCG Guideline for medical necessity decision making.

Evidence and Source Documents

The scientific literature is periodically reviewed, and patient selection criteria are updated when new efficacy data becomes available.

Back to Top

Kaiser Permanente Committee on Medically Emerging Technology
Transplant, Lung, Double - 7/12/91 - Double lung transplantation is efficacious for appropriately selected patients.
Transplant, Lung, Single - 7/12/91 Single lung transplantation is efficacious for appropriately selected patients.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33940	Donor cardiectomy (including cold preservation)
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/1996	09/07/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 03/05/2013 MDCRPC, 01/07/2014 MPC, 10/07/2014MPC, 11/04/2014 MPC, 09/01/2015MPC, 07/05/2016MPC, 05/02/2017MPC, 03/06/2018MPC, 03/05/2019MPC, 03/03/2020MPC, 03/02/2021MPC, 03/01/2022MPC, 03/07/2023MPC	01/10/2022

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
03/05/2019	MPC approved to adopt KP National Criteria for Heart and Lung Transplant
09/03/2019	MPC approved to change General Principles 1.3 to *Uncontrollable infection is a contraindication to transplant* as recommended by KP National Transplant Services.
03/03/2020	MPC approved the proposed changes from KP National Transplant Services
04/06/2021	Per National Transplant Guidelines: 1.3 added “active” for Heart Transplant and changes to Lung Transplant. *Lung Transplant Guideline requires 60-day notice, effective date September 1, 2021.
01/10/2022	MPC approved the proposed changes from KP National Transplant Services. 60-day notice is not required.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
High-Frequency Chest Wall Oscillation Devices (HFCWO)

- ABI Vest® for Cystic Fibrosis
- Vest® Airway Clearance System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	High Frequency Chest Wall Oscillation Devices (L33785)
Local Coverage Article (LCA)	High Frequency Chest Wall Oscillation Devices (A52494)

For Non-Medicare Members

A. The member must have **ONE of the following**:
   1. A diagnosis of cystic fibrosis.
   2. A diagnosis of bronchiectasis:
      a) Characterized by daily productive cough for at least 6 continuous, months or, frequent (i.e. more than 2/year) exacerbations requiring antibiotic therapy, and
      b) Confirmed by high resolution, spiral, or standard CT scan
   3. Neuromuscular Disorder
      a) Acid maltase deficiency
      b) Anterior horn cell diseases, including amyotrophic lateral sclerosis
      c) Hereditary muscular dystrophy
      d) Multiple sclerosis
      e) Myotonic disorders
      f) Other myopathies
      g) Paralysis of the diaphragm
      h) Post-polio
      i) Quadriplegia regardless of underlying etiology.

B. And meet **ALL of the following** criteria:
   1. Well-documented failure of standard treatments to adequately mobilize retained secretions with all of the following:
      a) Chest physical therapy and flutter device at least twice daily (when age appropriate)
      b) A pattern of hospitalizations at least annually or more
      c) Significantly deteriorating clinical condition
   2. Be under the care of a pulmonologist
   3. Had a rental trial to confirm compliance before purchase

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

Back to Top

Date Sent: 4/29/24

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Conventional chest physical therapy (CPT), also known as percussion and postural drainage (P/PD) has traditionally been the standard of care of secretion clearance methods for patients with excessive or retained lung secretions. Depending on the severity of the disease or the presence of infection, CPT is performed in 1-3 sessions per day, each lasting between 23-30 minutes. These are administered by a physical therapist or a trained caregiver. CPT is labor intensive and time consuming, which could lead to poor compliance.

A number of airway clearing devices have thus been developed for independent use with little or no assistance by others. These include the high-frequency chest wall oscillation (HFCWO), which is an external non-invasive respiratory modality that mobilizes airway secretions from the small peripheral airways. The technique typically produces compression of the chest wall via an inflatable vest linked to an air pulse generator. The generator delivers an intermittent flow to the vest which rapidly compresses and releases the chest wall at a variety of frequencies. Consequently, an oscillation of airflow within the airways is achieved. The researchers believe that the underlying mechanisms include increased airflow-mucous interaction causing a reduction in viscoelasticity, production of airflow bias that promotes a cephalad movement of the mucous, as well as the enhancement and stimulation of ciliary activity (Osman 2010).

HFCWO is most commonly used for assisting mucous secretion in patients with disorders associated with abnormally thick mucous hypersecretion but preserved muscle function such as cystic fibrosis. It has also been advocated as an adjunctive therapy to assist cough clearance in patients with neuromuscular disorders who have relatively normal mucus but weak respiratory muscles (Chaisson 2006, Osman 2010, Finder 2010).

The FDA has cleared several airway clearing systems for delivering high-frequency chest wall oscillation to promote airway clearance and improve bronchial drainage in situations where physicians recommend external manipulation of the thorax. These systems include the Vest™ Airway Clearance System (also known as the ABI Vest or the ThAIRapy Vest, or the ThAIRapy Bronchial Drainage System), Medpulse Respiratory Vest System, and the FREQUENCER which produces sound wave stimulation to oscillate and loosen mucous secretion in the chest.

HFCWO is most commonly used with cystic fibrosis patients who have abnormally thick secretions. It has also been used for other conditions such as bronchiectasis. Another proposed application is treating patients with neuromuscular disorders, who may have impaired cough and may not be able to clear their airways. An inadequate cough in these patients can lead to atelectasis or pneumonia. Other possible treatments for airway clearance in patients with neuromuscular disorders include percussion and postural drainage (P&PD), the traditional procedure, autogenic drainage, positive expiratory pressure therapy, flutter valve and intrapulmonary percussive ventilation (IPV) (Panitch et al., 2006; Langenderfer, 1998).

Neuromuscular diseases are a heterogeneous group of inherited or acquired disorders characterized by progressive irreversible weakness of functional groups of skeletal muscles including the respiratory muscles necessary for ventilation and cough. Depending on the severity of the disorder, ineffective cough and clearing of respiratory secretions can present as frequent respiratory infections, pneumonias, and atelectasis. As the disorder progresses, the patients may develop spinal deformities, gas exchange abnormalities, sleep disorders, and cardiac dysfunction. These and any concomitant pulmonary disorder can severely compromise the existent muscle weakness and precipitate respiratory failure (Chaisson 2006, Yuan 2010).

The Vest™ Airway Clearance System (Hill-Rom, ST Paul, Minnesota), consists of a 1. Non-stretching inflatable cloth-like vest that covers the entire thorax and provides high frequency chest wall oscillation; 2. Large-bore tubing connects the vest to the air-pulse generator; and 3. An air pulse generator that creates pressure to inflate and deflate the vest against the thorax. The vest is inflated to a constant pressure to maximize the surface area over which high frequency (5-20 Hertz), small volume pressure impulses are transmitted externally to the entire chest area. Pressure pulses are controlled by the patient and applied during expiration. A typical treatment may last for 20-30 minutes and consists of periods of compression separated by huff coughs (Chatburn 2007).

Back to Top

Date Sent: 4/29/24

Medical Technology Assessment Committee (MTAC)

ThAIRapy/ABI Vest®

12/13/2000: MTAC REVIEW

Evidence Conclusion: The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI Vest® on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI Vest® compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluft study included only 29 individuals, had a brief intervention (4 days total), no "wash-out" period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI Vest®.

Articles: The search yielded 20 articles. 11 articles were not directly relevant or were review articles. Of the remaining 9 articles, 5 were randomized controlled trials (RCTs). The two RCTs with the largest sample sizes were selected for critical appraisal (the remaining three RCTs all had sample sizes of less than 20 patients). In addition, an interrupted time-series analysis with longer-term follow-up of patients was reviewed. Arens R, Gozal D, Omlin KJ, Vega J, Boyd KP, Keens TG, Woo MS. Comparison of high frequency chest compression and conventional chest physiotherapy in hospitalized patients with cystic fibrosis. Am J Respir Crit Care Med 1994; 150: 1154-7. See Evidence Table Kluft J, Beker L, Castaginino M, Gaiser J, Chaney H, Fink RJ. A comparison of bronchial drainage treatments in cystic fibrosis. Pediatr Pulmonol 1996; 22: 271-74. See Evidence Table .Warwick WJ, Hansen LG. The long-term effect of high-frequency chest compression therapy on pulmonary complications of cystic fibrosis. Pediatr Pulmonol 1991; 11: 265-71. See Evidence Table.

The use of ThAIRapy/ABI Vest® for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

ThAIRapy/ABV Vest®

10/08/2003: MTAC REVIEW

Evidence Conclusion: There is no published empirical evidence on the use of the Vest™ Airway Clearance System for bronchiectasis. There is no new published evidence on the use of the Vest™ Airway Clearance System for cystic fibrosis. The summary of the evidence on the ABI vest from December 2000 is: "The scientific evidence does not permit conclusions about the effect of the ThAIRapy/ABI vest on health outcomes. The two randomized trials had small sample sizes and threats to validity that make their findings inconclusive. The Arens study did not find differences between patients (n=50) randomized to the ABI vest compared to chest physical therapy, but this may have been due to low statistical power (the authors did not discuss statistical power issues). The Kluft study included only 29 individuals, had a brief intervention (4 days total), no "wash-out" period between the ABI vest and chest physical therapy interventions (patients had a different intervention each day), gave nebulized saline to the ABI vest but not the physical therapy group, and examined sputum weight, an intermediate outcome measure. The Warwick and Hansen study, an interrupted time series design had the smallest sample size (n=16) and the validity was seriously threatened by possible selection bias. None of the available studies examined clinical outcomes such as pulmonary exacerbations or hospitalizations and no information was provided on short-term or long-term adverse health outcomes associated with the use of the ABI vest."

Articles: The search yielded 6 articles. There were no new empirical studies on the Vest™ Airway Clearance System for cystic fibrosis. There were no empirical studies on the Vest™ Airway Clearance System for bronchiectasis.

The use of ThAIRapy/ABI Vest® for treatment of cystic fibrosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

High Frequency Chest Wall Oscillation

02/04/2008: MTAC REVIEW

Evidence Conclusion: There is no empirical evidence on the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in patients with neuromuscular disease.

Articles: The search yielded 11 articles. When limited to English language publications and human populations, there were 7 articles. Only 2 of the 7 articles, both of them reviews/opinion pieces, specifically addressed the topic of interest, airway clearance for patients with neuromuscular weakness. The remaining articles were on different,

Back to Top

related topics. No empirical studies were identified. One of the review articles (Panitch, 2006) stated that HFCWO has not been studied in patients with neuromuscular disease.

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
High Frequency Chest Wall Oscillation
Evidence Conclusion: The evidence on the use of high-frequency chest wall oscillation (HFCWO) therapy in patients with neuromuscular disorders is very limited and insufficient to determine the safety and effectiveness of the Vest™ Airway Clearance System for improving health outcomes in these patients. The published studies to date have very small sample sizes and short follow-up durations. Those with a control group have several threats to their internal validity. Among these are unblinding, including heterogeneous groups of population, potential selection bias, insufficient power to detect significant differences between therapies, relatively high dropout rates, and/or analyses were not based on intention to treat. Additionally, the studies were funded by the manufacturer of the airway clearance systems used.
Articles: The majority of published literature on high-frequency chest wall oscillation (HFCWO) was on its use for patients with cystic fibrosis and other obstructive airway diseases. The literature search for studies published after the last MTAC review of the technology for patients with neuromuscular disorders revealed only one small RCT that compared the use of HFCWO to the standard chest physiotherapy among a small group of pediatric population with cerebral palsy or neuromuscular disease. Yuan N, Kane P, Shelton K, et al. Safety, tolerability, and efficacy of high-frequency chest wall oscillation in pediatric patients with cerebral palsy and neuromuscular diseases: an exploratory randomized controlled trial. *J Child Neurol*. 2010; 25:815-821**.** See Evidence Table

The use of High-frequency chest wall oscillation (HFCWO) for treatment of neuromuscular deficiency does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPC Codes	Description
A7025	High frequency chest wall oscillation system vest, replacement for use with patient-owned equipment, each
A7026	High frequency chest wall oscillation system hose, replacement for use with patient-owned equipment, each
E0480	Percussor, electric or pneumatic, home model
E0483	High frequency chest wall oscillation system, includes all accessories and supplies, each

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Dates Reviewed	Date Last Revised
12/13/2000	12/07/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] ,08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 02/13/2024[MPC]	01/19/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

Back to Top

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

01/19/2016	Defined conditions for neuromuscular disorder

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home Care Services Criteria

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual Chapter 7 Home Health Services.
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Home Care Guidelines for medical necessity determinations. ** For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

**note - Social Work is to be considered a secondary service and not a primary service

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The criteria for admission to home health services are based on the federal regulations for the Medicare home health benefit.

Evidence and Source Documents

Kaiser Permanente Home Care Services Policy HCS-06-1008.

Applicable Codes

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

CPT® or HCPC Codes	Description

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

No specific codes

Date Created	Date Reviewed	Date Last Revised
02/1996	01/05/2010[MDCRPC], 11/02/2010[MDCRPC], 09/06/2011[MDCRPC], 01/03/2012[MDCRPC], 11/06/2012[MDCRPC], 09/03/2013[MPC], 07/01/2014[MPC], 08/05/2014[MPC], 06/02/2015[MPC], 04/05/2016[MPC], 02/07/2017[MPC], 12/05/2017[MPC], 10/02/2018[MPC], 10/01/2019[MPC], 10/06/2020[MPC], 10/05/2021[MPC] , 10/04/2022[MPC] , 10/03/2023[MPC]	12/05/17

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
02/07/2016	MPC approved to adopt MCG guidelines for home health services

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
High Intensity Focused Ultrasound (HIFU) for the Treatment of Localized Prostate Cancer

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
KPWA Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, KPWA has elected to use ***MCG* High Intensity Focused Ultrasound (HIFU), Prostate (A-0271)*** for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* High Intensity Focused Ultrasound (HIFU), Prostate (A-0271) for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (oncologist, radiologist, primary care provider)
- Most recent imaging

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Prostate cancer is the second most frequently diagnosed cancer across the globe (Wolff et al., 2015). A 2008-2010 data estimated that 15% of men in the United States will be diagnosed with prostate cancer at some point in their lives (Wolff et al., 2015). However, the mortality rate is low because it is a slow growing cancer.

Back to Top

Date Sent: 4/29/24

Treatment is based on a number of factors including tumor stage, prostate specific antigen (PSA) value, Gleason score (GS), patient's age, concomitant diseases, life expectancy and patient's preference (Warmuth, Johansson, & Mad, 2010). A wide range of options are available for prostate cancer and these include active surveillance, watchful waiting, radical prostatectomy, hormone therapy, radiotherapy, external beam radiotherapy (EBRT), brachytherapy and chemotherapy (Wolff et al., 2015). High Intensity Focused Ultrasound (HIFU) and cryotherapy are being considered as treatment options.

HIFU is a procedure in which beams target localized tissue without destroying the surrounding tissue and the high energy produced by HIFU leads to coagulative necrosis (Dogra, Zhang, & Bhatt, 2009). Two mechanisms including hyperthermia and acoustic cavitation cause the destruction of the tissue (Kennedy, Ter Haar, & Cranston, 2014). First, high energy is produced and converted to heat as the ultrasound wave disseminates through the tissue. This high energy leads to extreme temperatures surpassing the threshold level of protein denaturation (>43-degree C) resulting in coagulative necrosis. In the surrounding areas of the target zone, temperatures decrease suddenly keeping the outside tissues unaffected. Second, the interaction between ultrasound and micro-bubbles of water in the sonicated tissue result in cavitation. Cavitation may lead to diffusion of energy reinforcing tissue destruction (Stride & Coussios, 2010).

For this procedure, a transducer, covered by a condom through which cooled water is circulated to cool the rectal wall, is inserted into the rectum and several images are taken. The transducers generate very precise small lesions destroying the prostate partially or completely (Cordeiro et al., 2012).

HIFU is non-invasive and non-ionizing technique that is believed to have some advantages over other thermal therapy such as cryotherapy, laser ablation, and photothermal therapy and radiofrequency interstitial tumor ablation (Cordeiro et al., 2012). Two types of systems have been approved by the Food and Drug Administration (FDA). These include the Sonablate 450 (developed by SonaCare Medical) and the Ablatherm HIFU (EDAP TMS SA) both of which received FDA approval in October and November 2015 respectively. HIFU is indicated for primary treatment and salvage treatment for localized prostate cancer.

Medical Technology Assessment Committee (MTAC)

High Intensity Focused Ultrasound (HIFU) for the treatment of localized Prostate Cancer

MTAC REVIEW: 06/21/2016

Evidence Conclusion: INTC reviewed the technology in 2008 and concludes that there is insufficient evidence to determine whether the technology is medically appropriate for any patient and that the existing evidence regarding how HIFU treats prostate cancer is of insufficient quantity and quality. In April 2016, INTC conducted another review of the technology and concludes that: "the body of evidence that is available from which to assess the efficacy and safety of HIFU for localized prostate cancer (as primary and salvage therapy) is very low quality. The risk of bias in existing studies is high. Across studies, there is variation and/or lack of information regarding patient selection criteria, how HIFU was delivered, how outcomes were measured, and how long patients were followed"

INTC review can be adopted.

HIFU for Primary and Salvage therapy

Systematic Review of the Efficacy and Safety of High-Intensity Focused Ultrasound for the Primary and Salvage Treatment (Warmuth, Johansson, & Mad, 2010) (evidence table 1) The aim of this study was to assess the efficacy and safety of HIFU in the primary and salvage treatment for prostate cancer. The primary outcomes were the biochemical disease-free survival rate, the negative biopsy rate, overall survival rates, prostate cancer–specific survival rates, adverse events, and QOL. The literature search was performed from 200 to 2010 and included 20 case series (with more than 50 participants) in which 93% of patients were treated with primary therapy and 7% for salvage HIFU. For all HIFU procedures, the biochemical disease-free survival rate was between 78% and 84%, 45%- 84%, and 69% at 1, 5, and 7 years, respectively. The negative biopsy rate was 86% at 3 months and 80% at 15 months. Overall survival rate and prostate-cancer specific survival rate were reported in 1 study and were 90% and 100% at 5 years and 83% and 98% at 8 years, respectively. Adverse events were mainly related to the urinary tract (1-58%), potency (1-77%) and rectum (0-15%).
The study has several limitations including the study design lacking control group, long term follow-up was not available and the quality of evidence of included studies was low, surrogate outcomes were used and the central question is whether surrogate outcomes corroborate with overall survival, QOL, and prostate cancer specific survival, and the possibility for publication bias. The evidence is of low quality; therefore, results should be interpreted with caution.

Back to Top

Ablative therapy for people with localized prostate cancer: a systematic review and economic evaluation (Ramsay et al., 2015) (evidence table 2) This systematic review indicates that the biochemical failure rate of HIFU was higher (statistically significant) than that of EBRT at 1 year but no statistically significant difference was observed at 5 years. The results also indicate statistically significant lower rate of disease free survival for HIFU compared to EBRT at 1 year. At 4 years, overall survival was better for HIFU compared to EBRT. Compared to RP, there was an increased risk of biochemical failure for HIFU at 1 and 5 years. But this difference was not significant. Also, in term of disease free survival, no statistical significant difference was noted when HIFU was compared to RP at 1 year. At 3 years, the difference was not statistically significant. For urinary incontinence, erectile dysfunction, or bowel problems (not in the table), data were insufficient to reach a conclusion. Results were not statistically significant for dysuria or urinary retention. Nonetheless, high proportion of urethral stricture was observed for HIFU. When comparing HIFU to active surveillance (AS) (not on the table), there was no difference in overall survival or erectile dysfunction. The results are mixed and due to the poor quality of case series included in the review, with the lack of long term findings, the result should be interpreted with caution.

HIFU for Salvage therapy

High intensity focused ultrasound (HIFU) for definitive treatment of prostate cancer (Cordeiro et al., 2012) The purpose of this review was to update the available literature on HFU as definitive treatment of prostate cancer and to describe the techniques extensively and give an overview of historical background. Searched was conducted from 200 to December 2011. The search included case series with more than 50 participants assessing efficacy and safety of HIFU. No RCTs were identified and only 33 uncontrolled studies were identified. HIFU as salvage therapy after EBRT was assessed in two case series. The mean age was 68 years with mean preoperative PSA ranged from 6.89 to 7.73 ng/mL and Gleason score (GS) was ≥ 8. Prostate volume preoperatively ranged from 18-21.4 mL; 34-56% received neoadjuvant androgen-deprivation therapy (NADT). Patients were followed for 15-18 months. The negative biopsy rate ranged from 73-80%; patients achieving PSA≤.5 ng/ml was 61% in one study; the mean PSA Nadir ranged from 1.97-2.38 ng/ml and disease-free survival ranged from 38-53% (30 mos-36mos). In terms of complications, urinary retention represented 7.8%, urinary tract infections (1.4- 3.5%), urinary incontinence (7-31.5%), bladder stenosis (17%), rectal urethral fistula 3 weeks after HIFU (3-6%) and erectile dysfunction was not assessed. The authors concluded that HIFU seems to control cancer on the short to medium term with less adverse events compared to established therapies.
There was heterogeneity among the studies; individual studies are case series resulting in low quality evidence. In addition, long term data was not available. Therefore, results should be interpreted with caution.

Additional studies

Subsequent studies (assessing HIFU as primary or salvage therapy) to the systematic reviews aforementioned were non-randomized controlled trial and did not compare HIFU to other treatment options. Accurate conclusions cannot be made from these studies. Summary of additional studies for HIFU as primary therapy: Nine non-RCTs (Aoun et al., 2015; Sebastien Crouzet et al., 2014; Dickinson et al., 2016; Feijoo et al., 2016; Ganzer et al., 2013; Liu & Chiang, 2016; Mearini et al., 2015; Uchida et al., 2015; van Velthoven et al., 2015) were examined and were for the most part observational studies. The sample size ranged from 50 to 1002; follow-up varied from 12 to 108 months. Of the nine studies, only two were comparative (Aoun et al., 2015; Liu & Chiang, 2016) and the findings from these two studies indicate: for Liu, 2016 (HIFU vs. cryoablation), no differences between biochemical recurrence rates were found; for Aoun, 2015 (HIFU vs. brachytherapy), similar survival outcomes were observed with greater biochemical recurrence free survival in the brachytherapy group. Summary of additional studies for HIFU as salvage therapy: Five observational studies (Baco et al., 2014; Sébastien Crouzet et al., 2012; Song et al., 2014; Uddin Ahmed et al., 2012; Yutkin et al., 2014) were examined; the sample size varied from 19 to 290; follow-up ranged from 19.8 months to 51.6 months and there was heterogeneity in the measures of outcomes. The survival rates varied as well.

Conclusion:

- No RCTs comparing HIFU to other treatment options were identified.
- The available evidence is of low quality since it is represented by non-comparative, case series/observational studies.
- The overall concerns are the lack of control group and long-term follow-up, the use of surrogate outcomes raising the question of consistency with overall survival and QOL, and the variations in patient populations and biochemical progression-free survival.
- Conclusion on efficacy and safety of HIFU for the treatment of localized prostate cancer or recurrent localized prostate cancer cannot be drawn at this time.

Back to Top

Articles: No RCTs were identified. The following articles are selected for critical appraisal: Systematic Review of the Efficacy and Safety of High-Intensity Focused Ultrasound for the Primary and Salvage Treatment (Warmuth et al., 2010) (evidence table 1) Ablative therapy for people with localized prostate cancer: a systematic review and economic evaluation (Ramsay et al., 2015) (evidence table 2) High intensity focused ultrasound (HIFU) for definitive treatment of prostate cancer (Cordeiro et al., 2012)

The use of High Intensity Focused Ultrasound (HIFU) for the treatment of localized Prostate Cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/05/2016	07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC]	01/07/2022

[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Adopted MCG A-0271
05/02/2017	Adopted Non-Medicare policy for Medicare members
03/16/2021	Added new CPT code 55880 effective 1/1/2021
01/07/2022	Removed diagnosis codes for HIFU

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
High-end imaging Site of Care Medical Policy

Criteria

For Medicare Members

This policy does not apply to Medicare members.

For Non-Medicare Members

A high-tech imaging service (i.e., MRI/MRA/CT/CTA) must meet applicable medical necessity criteria for coverage. When coverage criteria are met for the requested imaging procedure, this coverage policy is used to help determine the medical necessity of the requested site of care for ambulatory, non-emergent imaging.

A high-tech imaging procedure in a *hospital-based* imaging department or facility is considered medically necessary for an individual with **ANY** of the following indications:

- Less than 13 years of age
- Requires obstetrical observation
- Requires perinatology services
- Imaging related to transplantation services at an approved transplantation facility
- Patient is enrolled in an approved clinical trial and trial protocol requires imaging to be done at this site
- Known contrast allergy and use of that contrast agent is planned
- There are no other appropriate alternative sites for the individual to undergo the imaging procedure for **ANY** of the following reasons:
  - A covered surgery or procedure will be performed at a specific hospital and pre-operative or pre-procedure imaging must be done at the same hospital, as the image is an integral component of the procedure and the protocol is unique to the institution or image interpretation requires specialized Radiology expertise not routinely available outside the hospital setting. This is not common. Examples would include epilepsy surgery where ablation of specific areas is planned; or pre TAVR insertion in certain geographies; breast reconstruction involving deep flaps that require unique imaging protocols and specialized Radiology expertise to identify vascular supply. There must be documentation of a medically necessary reason the images cannot be performed at a freestanding facility and transmitted to the hospital and/or surgeon for pre op planning or in the OR.
  - To maintain continuity within an episode of care, hospital-based imaging is medically necessary when performed within 6 weeks of a hospital-based operation or procedure and non-hospital-based imaging is not available in the same care delivery system (e.g., drain management)
  - Moderate or deep sedation or general anesthesia is required for the imaging procedure and freestanding facility providing such sedation is not available
  - Equipment for the size of the individual is only available at a hospital-based imaging facility
  - Individual has a documented diagnosis of claustrophobia requiring open magnetic resonance imaging which is not available in a freestanding facility; or
  - Imaging outside the hospital-based imaging department or facility is expected to adversely impact or delay care.
  - The patient has a pacemaker that requires coordination, monitoring, and a code team onsite during the MRI, which are not available at a nearby freestanding site*

Back to Top

All other high-tech radiology (imaging) procedures at a hospital-based imaging department or facility are considered not medically necessary (including but not limited to pre-procedural planning for elective procedures, robotic assisted surgeries, etc.). In the absence of one of the above circumstances, it would be expected that non hospital-based locations would be used, such as a clinic or free-standing imaging centers. Hospital-based imaging departments may be authorized if there is no appropriate geographically accessible free-standing imaging center.

*Kaiser Permanente can provide this at multiple sites

If requesting these *services*, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Hospital-based advanced radiologic imaging procedures are generally more appropriate for individuals whose health status necessitates the availability of more supportive care for the minimization of the risks associated adverse health events.

Certain high-risk medical conditions can necessitate the need for an anesthesiologist to be present during the advanced radiologic imaging for individuals including neonates and children. Children can require specialized pediatric equipment including smaller anesthetic tools such as endotracheal tubes and monitoring equipment. Conversely, large individuals or those with claustrophobia may also require specialized equipment which could include an open magnetic resonance imaging (MRI) as opposed to a traditional MRI scanner.

Examples of advanced radiologic imaging include computed tomography, computed tomography angiography, magnetic resonance imaging, magnetic resonance angiography.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Computed Tomography (CT) and Computed Tomographic Angiography (CTA)

CPT® or HCPC Codes	Description
70450	Computed tomography, head or brain; without contrast material
70460	Computed tomography, head or brain; with contrast material(s)
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing
70480	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material
70481	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; with contrast material(s)
70482	Computed tomography, orbit, sella, or posterior fossa or outer, middle, or inner ear; without contrast material, followed by contrast material(s) and further sections
70486	Computed tomography, maxillofacial area; without contrast material
70487	Computed tomography, maxillofacial area; with contrast material(s)
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections
70490	Computed tomography, soft tissue neck; without contrast material
70491	Computed tomography, soft tissue neck; with contrast material(s)

Back to Top

70492	Computed tomography, soft tissue neck; without contrast material followed by contrast material(s) and further sections
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing
71250	Computed tomography, thorax, diagnostic; without contrast material
71260	Computed tomography, thorax, diagnostic; with contrast material(s)
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing
72125	Computed tomography, cervical spine; without contrast material
72126	Computed tomography, cervical spine; with contrast material
72127	Computed tomography, cervical spine; without contrast material, followed by contrast material(s) and further sections
72128	Computed tomography, thoracic spine; without contrast material
72129	Computed tomography, thoracic spine; with contrast material
72130	Computed tomography, thoracic spine; without contrast material, followed by contrast material(s) and further sections
72131	Computed tomography, lumbar spine; without contrast material
72132	Computed tomography, lumbar spine; with contrast material
72133	Computed tomography, lumbar spine; without contrast material, followed by contrast material(s) and further sections
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing
72192	Computed tomography, pelvis; without contrast material
72193	Computed tomography, pelvis; with contrast material(s)
72194	Computed tomography, pelvis; without contrast material, followed by contrast material(s) and further sections
73200	Computed tomography, upper extremity; without contrast material
73201	Computed tomography, upper extremity; with contrast material(s)
73202	Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections
73206	Computed tomographic angiography, upper extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing
73700	Computed tomography, lower extremity; without contrast material
73701	Computed tomography, lower extremity; with contrast material(s)
73702	Computed tomography, lower extremity; without contrast material, followed by contrast material(s) and further section
73706	Computed tomographic angiography, lower extremity, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74150	Computed tomography, abdomen; without contrast material
74160	Computed tomography, abdomen; with contrast material(s)
74170	Computed tomography, abdomen; without contrast material, followed by contrast material(s) and further sections
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing
74176	Computed tomography, abdomen and pelvis; without contrast material
74177	Computed tomography, abdomen and pelvis; with contrast material(s)
74178	Computed tomography, abdomen and pelvis; without contrast material in one or both body regions, followed by contrast material(s) and further sections in one or both body regions
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium

Back to Top

75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)
75574	Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)
75635	Computed tomographic angiography, abdominal aorta and bilateral iliofemoral lower extremity runoff, with contrast material(s), including noncontrast images, if performed, and image postprocessing
76380	Computed tomography, limited or localized follow-up study

Magnetic Resonance Angiography (MRA)

CPT® or HCPC Codes	Description
70544	Magnetic resonance angiography, head; without contrast material(s)
70545	Magnetic resonance angiography, head; with contrast material(s)
70546	Magnetic resonance angiography, head; without contrast material(s), followed by contrast material(s) and further sequences
70547	Magnetic resonance angiography, neck; without contrast material(s)
70548	Magnetic resonance angiography, neck; with contrast material(s)
70549	Magnetic resonance angiography, neck; without contrast material(s), followed by contrast material(s) and further sequences
72159	Magnetic resonance angiography, spinal canal and contents, with or without contrast material(s)
71555	Magnetic resonance angiography, chest (excluding myocardium), with or without contrast material(s)
74185	Magnetic resonance angiography, abdomen, with or without contrast material(s)
72198	Magnetic resonance angiography, pelvis, with or without contrast material(s)
73225	Magnetic resonance angiography, upper extremity, with or without contrast material(s)
73725	Magnetic resonance angiography, lower extremity, with or without contrast material(s)
C8900	Magnetic resonance angiography with contrast, abdomen
C8901	Magnetic resonance angiography without contrast, abdomen
C8902	Magnetic resonance angiography without contrast followed by with contrast, abdomen
C8909	Magnetic resonance angiography with contrast, chest (excluding myocardium)
C8910	Magnetic resonance angiography without contrast, chest (excluding myocardium)
C8911	Magnetic resonance angiography without contrast followed by with contrast, chest (excluding myocardium)
C8912	Magnetic resonance angiography with contrast, lower extremity
C8913	Magnetic resonance angiography without contrast, lower extremity
C8914	Magnetic resonance angiography without contrast followed by with contrast, lower extremity
C8918	Magnetic resonance angiography with contrast, pelvis
C8919	Magnetic resonance angiography without contrast, pelvis
C8920	Magnetic resonance angiography without contrast followed by with contrast, pelvis
C8931	Magnetic resonance angiography with contrast, spinal canal and contents
C8932	Magnetic resonance angiography without contrast, spinal canal and contents
C8933	Magnetic resonance angiography without contrast followed by with contrast, spinal canal and contents
C8934	Magnetic resonance angiography with contrast, upper extremity
C8935	Magnetic resonance angiography without contrast, upper extremity
C8936	Magnetic resonance angiography without contrast followed by with contrast, upper extremity

Magnetic Resonance Imaging (MRI)

Back to Top

CPT® or HCPC Codes	Description
70336	Magnetic resonance (eg, proton) imaging, temporomandibular joint(s)
70540	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s)
70542	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; with contrast material(s)
70543	Magnetic resonance (eg, proton) imaging, orbit, face, and/or neck; without contrast material(s), followed by contrast material(s) and further sequences
70551	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material
70552	Magnetic resonance (eg, proton) imaging, brain (including brain stem); with contrast material(s)
70553	Magnetic resonance (eg, proton) imaging, brain (including brain stem); without contrast material, followed by contrast material(s) and further sequences
70554	Magnetic resonance imaging, brain, functional MRI; including test selection and administration of repetitive body part movement and/or visual stimulation, not requiring physician or psychologist administration
70555	Magnetic resonance imaging, brain, functional MRI; requiring physician or psychologist administration of entire neurofunctional testing
71550	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s)
71551	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); with contrast material(s)
71552	Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences
72141	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; without contrast material
72142	Magnetic resonance (eg, proton) imaging, spinal canal and contents, cervical; with contrast material(s)
72146	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; without contrast material
72147	Magnetic resonance (eg, proton) imaging, spinal canal and contents, thoracic; with contrast material(s)
72148	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; without contrast material
72149	Magnetic resonance (eg, proton) imaging, spinal canal and contents, lumbar; with contrast material(s)
72156	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; cervical
72157	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; thoracic
72158	Magnetic resonance (eg, proton) imaging, spinal canal and contents, without contrast material, followed by contrast material(s) and further sequences; lumbar
72195	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)
72196	Magnetic resonance (eg, proton) imaging, pelvis; with contrast material(s)
72197	Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences
73218	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; without contrast material(s)
73219	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; with contrast material(s)
73220	Magnetic resonance (eg, proton) imaging, upper extremity, other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73221	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s)
73222	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; with contrast material(s)
73223	Magnetic resonance (eg, proton) imaging, any joint of upper extremity; without contrast material(s), followed by contrast material(s) and further sequences

Back to Top

73718	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s)
73719	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; with contrast material(s)
73720	Magnetic resonance (eg, proton) imaging, lower extremity other than joint; without contrast material(s), followed by contrast material(s) and further sequences
73721	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material
73722	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; with contrast material(s)
73723	Magnetic resonance (eg, proton) imaging, any joint of lower extremity; without contrast material(s), followed by contrast material(s) and further sequences
74181	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s)
74182	Magnetic resonance (eg, proton) imaging, abdomen; with contrast material(s)
74183	Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s), followed by with contrast material(s) and further sequences
76391	Magnetic resonance (eg, vibration) elastography
77046	Magnetic resonance imaging, breast, without contrast material; unilateral
77047	Magnetic resonance imaging, breast, without contrast material; bilateral
77048	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; unilateral
77049	Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD real-time lesion detection, characterization and pharmacokinetic analysis), when performed; bilateral
77084	Magnetic resonance (eg, proton) imaging, bone marrow blood supply
C8900	MRA with contrast, abdomen
C8901	MRA without contrast, abdomen
C8902	MRA without contrast followed by with contrast, abdomen
C8903	Magnetic resonance imaging with contrast, breast; unilateral
C8905	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral
C8906	Magnetic resonance imaging with contrast, breast; bilateral
C8908	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral
C8909	MRA with contrast, chest (excluding myocardium)
C8910	MRA without contrast, chest (excluding myocardium)
C8911	MRA without contrast followed by with contrast, chest (excluding myocardium)
C8912	MRA with contrast, lower extremity
C8913	MRA without contrast, lower extremity
C8914	MRA without contrast followed by with contrast, lower extremity
C8918	MRA with contrast, pelvis
C8919	MRA without contrast, pelvis
C8920	MRA without contrast followed by with contrast, pelvis
C8931	MRA with contrast, spinal canal and contents
C8932	MRA without contrast, spinal canal and contents
C8933	MRA without contrast followed by with contrast, spinal canal and contents
C8934	MRA with contrast, upper extremity
C8935	MRA without contrast, upper extremity
C8936	MRA without contrast followed by with contrast, upper extremity

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised

Back to Top

12/23/2020	01/05/2021[MPC], 01/03/2022[MPC], 01/10/2023[MPC]	07/11/2023

[MPC] Medical Policy Committee

Revision History	Description
03/26/2021	Clarifying language added to specify that the policy applies to non-emergent, ambulatory high-tech imaging requests.
05/20/2021	Updated policy effective date to 08/01/2021.
07/08/2021	Updated policy effective date to 09/01/2021.
04/25/2022	Updated applicable codes to include related HCPCS codes. Requires a 60-day notice, effective date 09/01/2022.
06/07/2022	MPC approved the updates to the alternative sites section of the criteria; updated MRI codes
07/14/2022	Added clarifying language for pre TAVR insertion in certain geographies
07/11/2023	MPC approved the modifications to the existing HEI Imaging Site of Care criteria to allow continuity of care for patients who have already started treatment at a higher level of care and require imaging within the same healthcare system. Requires 60-day notice. Effective date 12/01/2023.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Prometheus Lab Testing

- Anser ™ ADA for Adalimumab (Humira) Antibodies
- Anser TM IFX test for Infliximab (Remicade) Antibodies
- Anser VDZ (Vedolizumab)
- IBD SGI Diagnostic Test

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	MolDX: Prometheus IBD sgi Diagnostic Policy (L37313) This service is not covered per Noridian LCD.
Local Coverage Article	Billing and Coding: MolDX: Prometheus IBD sgi Diagnostic Policy (A57517)
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance specific to Anser antibody levels for infliximab or adalimumab, Kaiser Permanente has chosen to use their own Clinical Review Criteria, “Prometheus Testing,” for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Anser antibody levels for infliximab or adalimumab can be approved under **ALL of the following** conditions:

1. Ordered by a gastroenterologist
2. Is being ordered as a consideration of changing to alternate therapy in the setting of a concern for loss of response

Service	Criteria
Homogenous Mobility Shift Assay (HMSA) Anser VDZ (Vedolizumab) Prometheus IBD sgi Diagnostic Test	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

Many chronic inflammatory diseases are mediated by up-regulation of the pro-inflammatory cytokine tumor necrosis factor-alpha ((TNF)-α. Protein-based drugs that block TNF-α such as Infliximab (IFX), are effective in reducing the disease activity of these inflammatory disorders. IFX is a chimeric mouse-human monoclonal antibody approved by the FDA for the treatment of patients with Crohn’s disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and chronic severe plaque psoriasis. IFX is highly effective in

Back to Top

inducing and maintaining remission in a large proportion of these patients. However, more than 30% of cases fail to respond to anti-TNF-α therapy, and 20-60% of those who initially respond, lose their clinical response over time despite maintenance treatment. This loss of response (LOR) usually requires escalation of the dose, shortening the interval between doses, change in the anti-TNF agent to regain the clinical remission, or switching to a non-anti-TNF therapy (Wang 2012, Nanda 2013, Wang 2013, FDA web page accessed August 26, 2013).

The reason for loss of response to IFX is still debatable, but the anti-drug antibody formation is believed to play an important role. IFX is a chimeric mouse/human IgG1 molecule and thus the antibodies are primarily directed against the murine fragment. Antibodies to IFX (ATI), also frequently called human antichimeric antibodies (HACAs), are reported to develop in up to approximately 60% of patients depending on the dosing schedule, administration of concurrent steroids or immunomodulators, and the method of measuring the antibodies in the blood. The antibodies can appear as soon as after the first IFX dose and can persist in the blood for up to 4.5 years even after discontinuation of the therapy. ATI may increase the drug clearance in treated patients and/or neutralize its effect. Researchers found that a lower serum IFX levels is associated with a significantly higher risk of loss of clinical response to the drug. This loss of clinical response and remission due to immunogenicity is a potential major limitation to IFX leading to clinical relapse, impaired quality of life, and increased cost of care. Anti-drug antibodies may also cause serum sickness and hypersensitivity reactions. Despite these observed associations, some researchers dispute the clinical relevance of anti-infliximab antibodies and question whether the presence of antibodies to TNF agents is directly correlated to the decreased efficacy. To date, there is insufficient knowledge about the factors influencing the formation of the antibodies, and on whether the immune reaction to IFX can be transient. It is assumed however, that once the antibody is initiated, it cannot be overcome (Afif 2010, Kopylov 2012, Vande Casteele 2013, Nanda 2013, Wang 2013).

It is suggested that accurate monitoring of the serum drug and anti-drug antibody levels should be an important part of therapy in patients receiving anti TNF-α drugs. However, there is no gold standard technique or test for the detection and quantitative measurement of anti-infliximab antibodies (ATI). Anti-drug antibodies and drug levels in the serum are assessed by the bridging ELISA method, or less commonly by the radioimmunoassay (RIA) method. Each of these two methods has its limitations; the main limitation of the bridge ELISA method is its inability to accurately detect the antibodies in the presence of the drug in the circulation due to cross interference between the drug and the assay. This lowers the sensitivity of the test in detecting antibodies in the presence of IFX. Thus, ELISA can accurately measure the anti-drug antibodies only when there is no drug in the circulation, which limits its clinical utility. RIA method is limited by its complexity, safety concerns of handling radioactive material, and prolonged time needed to reach equilibrium for proper management (Wang 2012).

A novel Homogenous Mobility Shift Assay (HMSA) was recently developed and validated by group of researchers In San Diego (Wang and colleagues 2012) to quantitatively measure the induced ATI and IFX levels in serum samples of patients treated with infliximab. The Anser ™IFX test is not ELISA-based and is believed to be able to measure both the serum concentrations of infliximab and infliximab antibodies in the presence of serum infliximab. In the HMSA, serum samples are acidified during sample preparation to dissociate drug-anti-drug-antibody (IFX-ATI) complexes, thereby allowing the detection of ATI in the presence of IFX and overcoming the limitation of bridge ELISA (Casteele 2013).

Medical Technology Assessment Committee (MTAC)

Homogenous Mobility Shift Assay (HMSA)

10/21/2013: MTAC REVIEW

Evidence Conclusion: ***Analytic validity*** There is insufficient evidence to determine the analytic validity of the existing tests for measuring the antibodies to IFX. There is no gold standard technique for anti-infliximab antibodies (ATI) measurement and comparing the technical performance and accuracy of ATI assays in detecting ATI in the presence of IFX may be problematic. As indicated in the introduction the ELISA and RIA have their limitations, and there are no standards available for comparison. Several confounding factors can influence the measurement of these antibodies, and in turn the accuracy and reproducibility of the test. ***Clinical validity*** The results of studies that examined the association between ATI and clinical efficacy of IFX are inconsistent. While some studies showed that detectable levels of ATI using different ELISA methods or RIA were correlated with low concentrations or undetectable trough levels of IFX and higher rates of loss of response to IFX treatment, others showed no significant effect of ATI on loss of response. Two published meta-analyses (Lee et al, 2012 and Nanda et al, 2013) had conflicting results. Both had their limitations and pooled the results of randomized trials together with observational studies. In these studies, ATI was measured at one time point which may not capture its possible fluctuating, transient, or latent occurrence; different methods and assays, mainly ELISA, were used to measure ATI with no standardization; patients were on different IFX regimes (episodic or maintenance); and immunosuppressants were used among some, but not all patients. Lee et al' (2012), meta-analysis pooled the

Back to Top

results of 18 studies to determine the prevalence of ATI, its effect on perfusion reactions and on disease remission rates among IBD patients treated with infliximab. The analysis included 9 RCTs, 5 cohort studies, and 4 retrospective studies with a total of 3,326 patients. The pooled results showed that patients who tested positive for ATI (using ELISA) were at increased risk of infusion reactions (RR= 2.07 [95% CI, 1.61-2.67]), but with no significant difference in the rates of remission compared to those who tested negative for ATI (RR=0.90, 95% CI 0.79-1.02). On the other hand, the pooled results of the more recent meta-analysis (Nanda et al, 2013) of 13 studies involving 1,378 patients with IBD showed that the presence of ATI was associated with lower IFX serum levels and significantly higher risk of loss of clinical response (LOR) to IFX with a pooled risk ratio for LOR = 3.2 (2.0-4.9). The ATI was measured by different methods including double antigen ELISA, antihuman chain ELISA, immunochromatography-based ELISA, fluid-phase RIA, and western blot. The results of the meta-analysis, however, have to be interpreted with caution due to the high risk of bias in the studies included, significant heterogeneity between studies, publication bias, and combining the results of randomized studies together with of observational studies. In addition, there were differences between studies in the method of assessing ATI, IFX dosing regimens, immunosuppressants use, and assessment of clinical response. The Anser IFX (HMSA) Wang and colleagues (2012) developed and validated a homogenous mobility shift assay (HMSA) to measure the serum levels of infliximab (IFX) and antibodies to IFX (ATI). They compared the performance of the newly developed IFX-HMSA to bridge ELISA and measured the ATI levels with the new test in 100 patients with ELISA positive ATI and found a high correlation between the two methods. HMSA identified five false-positive samples from the bridging ELISA method. Intra-and inter-assay precision rates for ATI were <4% and <15% respectively which, are considered high. The cutoff point of the assay was determined using sera of 100 healthy subjects who were naïve to IFX. The mean values of ATI in patient serum samples were significantly higher than those in the drug naïve health controls (mean ±SD=9.57+11.43, vs. 0.73 ± 0.29, p<0.0001). The area under the curve (AUC) was 0.986, the sensitivity was 95% (95% CI, 88.72-98.36%) The authors concluded that the HMSA-IFX method showed a high assay sensitivity, precision and accuracy. However, validation was performed by using bridging ELISA methodology which can only accurately measure the anti-drug antibodies when there is no drug in the circulation.

Clinical utility- In a retrospective study, Afif and colleagues (2010) evaluated the clinical utility of measuring Human Anti-Chimeric Antibody (HACA) concentration in patients with IBD treated with infliximab. They used recorded data for 155 patients treated in one center (from 2003-2008) who had ATI and IFX concentrations measured. Testing for IFX and ATI levels was performed by ELISA at the discretion of the treating physician with no systematic strategy and was not done for all patients receiving IFX. 72% of the initial tests were ordered by a single physician, and the assay(s) used were not defined. Indications for testing were mainly due to loss of response (49%), partial response (22%) and autoimmune or delayed hypersensitivity reaction (10%). There was no control or comparison group and according to the authors, the study population represented only a subset of the total population receiving IFX at the clinic, and the clinical response was abstracted through review of patients' charts using predefined clinical criteria. The use of validated instruments as Crohn's disease Activity Index, Harvey-Bradshaw Index and endoscopic improvement could not be obtained retrospectively. 47% of the patients were on immunosuppressives, and 43 patients (29%) had the dose or frequency of IFX increased before testing. 35 patients had positive ATI based on which, the dose was increased in 6 patients, and 12 were put on a different anti-TNF. The overall results suggest that change to another anti-TNF in these ATI positive patients was associated with a significantly higher complete or partial response than those who received a dose escalation (92% vs. 17%). The authors concluded that measurement of ATI and IFX concentrations had an impact on management and was clinically useful. These results have to be interpreted with caution due to the study design and its imitations. In addition, there was no control group to determine whether any change in management in the absence of ATI measurement would have a similar or different clinical outcome. It also to be noted that 29% of the patients had the dose or frequency of IFX increased before testing. A more recent study (Vande Casteele and colleagues, 2013), used the new HMSA to retrospectively measure 1,232 consecutive frozen serum samples of 90 patients with IBD treated in one center from 1999-2011. The HMSA confirmed ATI in 59% of the patients, this was transient (disappeared by time) in 28% and was sustained in 72% of the patients. All treatment decisions to optimize and to stop therapy were based on clinical grounds and C-reactive protein level without knowledge of infliximab trough levels (TLI) or ATI status. The results of the analysis show that 68% of the patients with sustained ATI needed to discontinue IFX treatment vs. 13% with transient ATI (RR 5.1, 95% CI, 1.4-19.0). The overall results suggest, but do not provide good evidence that ATI may be transient, and that optimizing the IFX dose in patients with low-level ATI may be useful. It also indicates that sustained ATI increases the risk of loss of response to IFX. Based on these results, the authors recommended measuring IFX trough levels at week 14 and at time of loss of treatment response, and only measure ATI at consecutive time points when the trough levels of IFX are undetectable or low. These results have to be interpreted with caution due to the nature of the study and its limitations. In conclusion there is insufficient evidence to determine analytic and clinical validity of HMSA in detecting ATI to IFX. There is also inconclusive evidence to determine that ATI measurement has a significant impact on management of patients treated with infliximab or significant effect on clinical outcomes.

Back to Top

Articles: The published literature on the validity and clinical utility of measuring the antibodies to infliximab (ATI) levels among patients treated with IFX agent is limited. The therapeutic effect of IFX and measuring of the drug and antibody levels were mainly studied for patients with inflammatory bowel disease (IBD). The search revealed one study on the development and validation of a HMSA test, two meta-analyses on the impact of anti-IFX among IBD patients, two observational retrospective studies on clinical utility of measuring the anti-chimeric antibody concentration (ACAC), as well two studies that compared different ELISA methods in their ability to detect ATI.The meta-analysis with more valid methodology, the validation study on the new Anser IFX (HMSA) test, and the larger observational study on the clinical utility of detecting ATI were selected for critical appraisal, Afif W, Loftus EV, Faubion WA, et al. Clinical utility of measuring infliximab and human anti-chimeric antibody concentrations in patients with inflammatory bowel disease. *Am J Gastroenterol*. 2010; 105: 1133-1139. See Evidence Table. Vande Casteele N, Gils A, Singh S, et al. Antibody response to infliximab and its impact on pharmacokinetics can be transient. *Am J Gastroenterol*. 2013; 108:962-971. See Evidence Table. Lee LY, Sanderson JD, Irving PM. Anti-infliximab antibodies in inflammatory bowel disease: prevalence, infusion reactions, immunosuppression and response, a meta-analysis. *Eur J Gastroenterol Hepatol*. 2012; 24:1078-1085. Nanda KS, Cheifetz AS, Moss AC. Impact of antibodies to infliximab on clinical outcomes and serum infliximab levels in patients with inflammatory bowel disease (IBD): a meta-analysis. *Am J Gastroenterol.* 2013; 108:40-47. See Evidence Table. Wang SL, Ohrmund L, Hauenstein S, et al. Development and validation of a homogeneous mobility shift assay for the measurement of infliximab and antibodies-to-infliximab levels in patient serum. *J Immunol Methods*. 2012; 382:177-188.

The use of Homogenous Mobility Shift Assay (HMSA) (Anser TM IFX test) for Infliximaub Antibodies does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Prometheus IBD sgi Diagnostic

10/17/2017: MTAC REVIEW

Evidence Conclusion: Analytic validity: No studies were identified **Clinical validity:** One study (Lawrence et al., 2015) with low evidence was reviewed. Fifty patients with symptoms of IBD and glycogen storage disease (GSD) type Ib were enrolled consecutively. Of 50 patients who were screened using Prometheus IBD, 11 (22%) tested positive for IBD. Of 11 patients who tested positive, 5 were Crohn's Disease, 5 were ulcerative colitis, and one was non-IBD. However, the major limitations included the sample size, lack of reference test (no test had been performed to confirm the diagnosis of IBD), non-randomized design of the study. **Clinical utility:** No studies were identified.

Conclusion:

- No studies assessing analytic validity or clinical utility were identified
- Only one study with non-randomized design and small sample size assessed clinical validity
- There is insufficient evidence to support for or against the use of Prometheus IBD sgi Diagnostic test for patients who present with symptoms of IBD

Articles: The search yielded 18 articles, none of which were relevant except one study (Lawrence, Chengsupanimit, Brown, & Weinstein, 2015) with low evidence.

The use of Prometheus IBD sgi Diagnostic does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met (Anser antibody levels for infliximab or adalimumab):

CPT® or HCPC Codes	Description
84999	Unlisted chemistry procedure

Considered Not Medically Necessary when requested/submitted as a panel (IBD sgi Diagnostic Test):

CPT® or HCPC Codes	Description
83520	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified
82397	Chemiluminescent assay

Back to Top

86140	C-reactive protein;
88346	Immunofluorescence, per specimen; initial single antibody stain procedure
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)
81479	Unlisted molecular pathology procedure

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Date Reviewed	Date Last Revised
12/03/2013	12/03/2013[MPC],1/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC]	02/02/2021

[MPC] Medical Policy Committee

Revision History	Description
05/02/2017	Adopted KPWA medical policy for Medicare members
06/06/2017	MPC approved medical necessity criteria for Anser Antibody testing
02/06/2018	Added MTAC review for Prometheus IBD sgi Diagnostic
02/02/2021	Added Medicare/Noridian LCD and LCA for IBD sgi Diagnostic Test

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home INR Monitoring

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11).
Local Coverage Determinations (LCD)	None
Local Coverage Article	Home PT/INR Monitoring (G0249) Billing and Coding (A55756)

For Non-Medicare Members

Kaiser Permanente has elected to use the Prothrombin Time (INR) Home Monitoring Device (A-0650) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Documentation of initial start date for warfarin
- Last 6 months of clinical notes from requesting provider &/or specialist (orthopedics, cardiology)

Home testing is usually not recommended for a frequency of more than once a week.

Additional software or hardware required for downloading data from home prothrombin time testing systems to computers for the management of anticoagulation will not be covered because each is considered a convenience item and not medically necessary.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Oral anticoagulation (OAC) therapy is used for the prophylaxis and /or treatment of thromboembolic complications of deep vein thrombosis, embolic stroke, pulmonary embolism, cardiac valve replacement, and atrial fibrillation, as well as postmyocardial infarction. The aim of the therapy is to maintain a level of anticoagulation that will prevent thromboembolic events without increasing the risk of hemorrhagic complications. Warfarin is an oral anticoagulant that interferes with the cyclic interconversion of vitamin K which in turn leads to depletion its dependant coagulation factors including prothrombin. It is estimated that more than a million patients are treated annually with warfarin in the USA (Koerner 1998).

Back to Top

Date Sent: 4/29/24

In the USA, almost 40,000 mechanical heart valves are implanted annually. Mechanical valves are associated with a risk of thrombus formation and emboli. This risk is reduced by lifetime treatment with oral anticoagulants. Biologic implants on the other hand, have a lower thrombogeneity and do not require long-term anticoagulation. Thromboembolism, together with anticoagulant-induced hemorrhage, account for three fourths of all complications after mechanical heart valve replacement. These events were found to be associated with the intensity of oral anticoagulation therapy and fluctuation of international normalized ratio (INR) values. (Edmunds 1987).

Atrial fibrillation (AF), a common arrhythmia, is a leading cause of thromboembolism. It is common among the elderly, and its prevalence increases with age (1% among 60-year-old population, 5% among those aged 70-75 and >10% for 80+ years patients. (Ezekowitz 1999). The incidence of ischemic stroke among these patients may be as much as six times higher than among others with no AF. Studies show that oral anticoagulants significantly reduce the rate of stroke among AF patients (Eldor 2002). However, older patients treated with OAC have a higher rate of bleeding mainly due to the slower metabolization of the drug, and its interaction with other underlying chronic health problems. These patients should thus have better monitoring, and more rigorous regulation of the OAC to optimize their therapy, and prevent intracerebral hemorrhages, and other bleeding complications.

The intensity of anticoagulation treatment also needs to be controlled closely due to the narrow therapeutic range of warfarin, the potentially life-threatening effects of both over, and under-dosing, and its interaction with other drugs or foods like leafy green vegetables. Several other factors may affect the patients' response to warfarin control including compliance to therapy, underlying liver or kidney diseases, infections, diet, and others.

Oral anticoagulation therapy has been monitored for almost 50 years with the prothrombin time (PT) test. The test is easy to perform but its results may widely vary between institutions, and even within the same institution. In 1983 the WHO proposed the international normalized ratio (INR) in attempt to standardize PT measurements. The proposal was supported by the International Committee for Standardization in Hematology in 1985, and INR is the current standard for monitoring anticoagulation therapy. It is calculated as: INR= patient PT/mean normal PT). The recommended therapeutic INR range for oral anticoagulant therapy is 2.0-3.0 for the majority of indications. A higher range of 2.5-3.5 is recommended for patients with mechanical heart valves, and when therapy is recommended to prevent recurrent MI (Koerner 1998). Monitoring patients on OAC requires frequent testing, which in turn requires frequent venous punctures, and regular visits to a physicians' office or lab, as well as lab standardization. Patients on a stable OAC are seen every 4-6 weeks. It was found that at this rate of testing, 40-60% of the PT measurements fall in the desired therapeutic range (Hortskotte, 1998).

Patients using long-term OAC usually worry about complications, regular visits to the physician or lab, frequent venous punctures that may be difficult at times, dietary limitations, freedom at traveling, and other concerns that may affect their quality of life. There has always been an interest in developing an accurate faster and easier way to measure PT. Currently several monitors for finger stick testing of PT are available. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, and Harmony INR Monitoring System. These monitors require only a finger stick whole blood rather than the citrated venous blood, and the patients can perform it at home. Among the other advantages of these systems is the immediate INR results, and convenience. In theory patient self-testing at home increases the duration when the patient is within the therapeutic INR range, increases compliance, and patient interaction with his physician, and allows better control of OAC, which in turn reduces morbidity and mortality.

Self-management or personal-self testing however is not suitable for everyone. Patients need to operate the machine, and self-sample blood, they have to be free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing, they also have to be reliable and complying with the dosage algorithm.

After Joint Replacement Patients undergoing major orthopedic surgery; hip or knee arthroplasty, or hip fracture repair are in the highest risk category for venous thromboembolism (VTE) solely on the basis of the orthopedic procedure itself. Without prophylaxis, the rate of deep vein thrombosis or pulmonary embolism in these patients range from 40% to 84% and is the most common cause of death. It is thus recommended to use some type of prophylaxis for total knee replacement (TKR), total hip replacement (THR), and hip fracture surgery. The currently available methods of thromboprophylaxis include intermittent pneumatic calf compression, elastic compression stockings, or the use of pharmacological agents.

Back to Top

Date Sent: 4/29/24

Warfarin is the most commonly used pharmacological agent followed by low molecular weight heparin (LMWH). The American College of Chest Physicians (ACCP) recommends either adjusted-dose warfarin (INR range 2.0 to 3.0); started preoperatively or immediately after the hip or knee replacement, or SC LMWH therapy. The duration of thromboprophylaxis is controversial and varies widely between practices, ranging from 1-12 weeks postoperatively. Studies have shown a peak incidence of postoperative DVT two to three weeks after total hip arthroplasty. This, together with the shorter durations of hospitalization, extending the use of antithrombotic prophylaxis for up to 5 weeks is becoming more common (Schuringa 1999, Geerts 2001, Frederick 2003, He Xing 2008).

The intensity of anticoagulation treatment needs to be controlled closely due to the narrow therapeutic range of warfarin, its interaction with several other drugs and foods, and the potentially life-threatening effects of both over- and under-dosing of the drug. Monitoring patients on oral anticoagulation (OAC) therapy requires frequent testing, which in turn requires frequent venous punctures, laboratory standardization, and regular clinical visits.

There in an ongoing interest in developing a faster and easier way to accurately measure prothrombin time (PT). Currently several home testing systems have received FDA approval for use. These include CoaguChek, CoaguChek plus, ProTime Microcoagulation System, INRatio Prothrombin Time Monitoring System, Harmony INR Monitoring System, AcuSure, and Rubicon. These monitors may be used at home and only require a fingerstick whole blood rather than the citrated venous blood. They also give immediate INR results. In theory, patient self-testing at home increases the duration within the therapeutic INR range, increases compliance, patient interaction with his physician, and allows better control of OAC which reduces morbidity and mortality. Personal self-testing with or without self-management is however is not suitable for everyone. Patients have to be reliable and free from any major visual problems, tactile dysfunction, or severe tremors to be able to mechanically handle self-testing. They also have to comply with the dosage algorithm.

Medical Technology Assessment Committee (MTAC)

Home INR Monitoring

08/13/2003: MTAC REVIEW

Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Two important health outcomes, bleeding and thromboembolism, were only studied in ESCAT (Kortke 2001), and time in the therapeutic range, an intermediate outcome, was used in all other studies. Kortke et al, in the ESCAT randomized controlled trial, followed 600 patients with mechanical heart valves for at least 2 years (25-51 months). They evaluated the event rates, as well as time in the therapeutic range. Less than 10% of the randomized sample took part in the 25-30-month follow-up. Patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. The trial also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. Sawicki's RCT in which 84% of the participants had heart valve replacement, also showed that a higher proportion of patients in the self-management group were within the INR target range compared to those in the routine care group. This difference was only statistically significant at three months of follow-up but not after six months. In Watzke's trial, 57% of the patients had mechanical heart replacement, and 24.5 % had atrial fibrillation. It also showed that a higher proportion of measurements among patients in the self-management group were in the therapeutic range vs. those in the standard care group, however the P value was not provided. Eldor's study on elderly patients with atrial fibrillation was too small, nonrandomized and had insufficient power to detect any difference between the groups. In conclusion there is some evidence that selected patients with mechanical heart valve replacement, who self-monitor their PT, and self manage their OAC therapy, have better control of their INR values, than those receiving a standard care. Only one trial with several limitations, showed some benefit in reducing the severe complications associated with OAC treatment. The other studies had insufficient sample sizes, and follow-up durations to study that outcome. It is worth noting that the studies were conducted among selected groups of patients and cannot be generalized to all patients with mechanical heart replacement. There is insufficient evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.

Articles: The search yielded 28 articles. Many were reviews and tutorials. Abstracts, and studies conducted to evaluate the accuracy of the portable PT monitoring systems were not reviewed. The purpose of this review is assessing the home use of the monitors for patients with mechanical heart valves, or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were three randomized controlled trials, and three non-randomized controlled studies on self-testing/home INR monitoring. Trials conducted among patients with mechanical heart valves, or atrial fibrillation were selected. *The following articles was critically appraised:* Kortke H, and Korfer R. International Normalized Ratio self-management after mechanical heart valve replacement: is an early start advantageous? *Ann Thorac Surg* 2001; 72:44-48. See

Back to Top

Evidence Table Sawicki PT. A structured teaching and self-management program for patients receiving oral anticoagulation. A randomized controlled trial. *JAMA* 1999; 281:145-150. See Evidence Table Watzke H.H, Forberg E, Svolba G, et al. A Prospective Controlled Trial Comparing Weekly Self-Testing and Self-dosing with the Standard Management of Patients on Stable Oral Anticoagulation. *Thromb Haemost* 2000; 83: 661-665. See Evidence Table Eldor A, and Schwartz J. Self-management of oral anticoagulants with a whole blood prothrombin-time monitor in elderly patients with atrial fibrillation. *Pathophysiol Haemost Thromb* 2002; 99-106. See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/01/2005: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: Ideally the outcomes of randomized controlled studies for the effectiveness of a test should demonstrate its effect in altering treatment and improving the health outcomes. Clinical endpoints for studies on self-management of anticoagulation therapy would be bleeding and thromboembolic complications. However, time within therapeutic INR range was used by some studies as a surrogate outcome to assess the quality of treatment based on self-management. In ESCAT I study (Koertke 2001) previously reviewed, 1,200 patients 6-11 days after a mechanical heart replacement were randomly divided into two groups: one monitored by family physicians, and the other controlling INR values at home. Patients were followed for at least 2 years (25-51 months) and the primary outcome was the rate of thromboembolic events and hemorrhage, and stability of INR values. Six hundred patients (50% of the randomized sample) were included in the analysis, dropouts and deaths were not included, and analysis was not based on intention to treat. The results of the trial showed that patients in the self-management group had significantly less overall grade III complications (severe hemorrhage or thromboembolism) compared to those in the standard care group. It also showed that significantly more measurements were in the therapeutic range among patients in the self-management group. ESCAT II study (Koertke 2003) was a large (N=3,300), multicenter RCT that randomized patients to two INR targets for self-management. The primary outcomes were the rate of thromboembolic events and hemorrhage, and the stability of INR values. It is an ongoing trial and the published articles only present the interim analysis with data on 55% of the total sample size. The investigators compared the results of the two INR targets for self-management in this trial and included data on thromboembolism and bleeding for the group controlled by general practitioner from ESCAT I study, which is not a valid comparison. ESCAT I was conducted years earlier, in a single center, and on a different group of patients. In this latter study, patients in the self-managed group had a higher mean INR value (3.0) compared ESCAT II study (2.8 for the conventional-dose INR, and 2.4 in the low-dose INR patients with aortic valve replacement). Overall, the interim results of ESCAT II study show that 72% to 74% of the patients in the low and conventional INR range, respectively, were within target range. The bleeding and thromboembolic rates were <1% in each of the two groups. There was no difference between them the in thromboembolic rates, and the difference in the bleeding rates did not reach statistical difference. There is no new evidence to determine the effect of home INR monitoring on patients with atrial fibrillation.
Articles: The search yielded 20 newer articles many of which were reviews and editorials. Studies conducted to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients with mechanical heart valves or atrial fibrillation, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). There were two publications on one large randomized controlled trial (ESCAT II) that compared two INR targets for self-management of anticoagulants after mechanical valve replacement, a small RCT that included patients with different indications for anticoagulation, and small case series with intermediate outcomes. SMART, a large ongoing trial on self-management of anticoagulation was also identified but no results were published to date. The ESCAT II trial was critically appraised: Kortke H, Minami K, Boethig, et al. INR self-management permits lower anticoagulation levels after mechanical heart valve replacement. *Circulation* 2003;108 II:75-78. Kortke H, Zittermann A, Minami K, et al. Low-dose International normalized ratio self-management: A promising tool to achieve low complication rates after mechanical heart valve replacement. *Ann Thorac Surg* 2005; 79:1909-1914.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/07/2006: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: The previous MTAC reviews of home INR monitoring showed some evidence that selected patients with mechanical heart valve replacement who self-monitor and manage their OAC therapy, may have better control of their INR values, than those receiving standard care. All studies were conducted among selected groups of patients and the results might not be generalized to all patients with mechanical heart

Back to Top

replacement. There was insufficient evidence to determine the safety and efficacy of home INR monitoring on clinically important outcomes as thromboembolic events, major hemorrhage, and death. There was also insufficient evidence to determine the benefit of home INR monitoring in patients with atrial fibrillation. Heneghan et al's recent meta-analysis (2006) assessed the effects of self-monitoring with/ or without or self-management of anticoagulation compared with standard monitoring. The meta-analysis had valid methodology, was well-conducted, and 10 out of the 14 studies it included were judged to be of good quality. The authors also performed a sensitivity analysis by excluding the studies with the lowest quality. However, the control groups in the trials received their routine care in different settings. The results of a recent meta-analysis (van Walraven, 2006) showed that the study setting has a major influence on anticoagulation control. Moreover, the majority of the trials included in Heneghan's meta-analysis, provided education and training sessions only to the patients randomized to self-testing, not to the entire study population. Education increases awareness, motivation, and may modify the patient's attitude and behavior. The education and training were given after randomization, and those who could not complete the training sessions or were incapable of self testing and/or self-management either left the study or were transferred to the routine care group. This resulted in a high dropout rate (20% to > 30%) in the intervention groups, and intention to treat analysis was not conducted in all the trials, which could overestimate the observed results. Ideally, training would be performed prior to randomization to eliminate those who are unable to complete it, and/or are incapable of self testing or self-management, from participating in the trial. The results of this meta-analysis indicate that the thromboembolic events, major bleeds, and death rates were significantly lower in the self-monitoring groups versus the controls who were managed by their personal physicians, anticoagulation management clinics, or managed service. Those who both self-tested and self-adjusted their therapy dose had significantly lower thromboembolic events and mortality rates but a non-significant reduction the rate of hemorrhage. The difference in thromboembolic event rates was not significant between the intervention and control groups in the pooled results of the 3 trials conducted among patients with mechanical heart valves. The authors did not report on the difference in major hemorrhage or death rate among these patients, and no subgroup analysis was provided for patients with atrial fibrillation. Kaiser Permanente INTC recalculated some of the results of Heneghan's meta-analysis using ITT analysis, and found no significant differences between the intervention and routine care group in the percent of subjects with a mean INR in the therapeutic range, and in the major hemorrhagic events in the self-management vs. those receiving care in AMS (anticoagulation management services). Fitzmaurice, et al's (2005) study was a relatively large, multicenter, randomized, and controlled trial. However, it had several limitations and potential biases. Less than 25% of the eligible patient agreed to participate in the trial and were actually randomized to the study groups. Training on self-testing was given after randomization and only to the intervention group not to the entire population, which resulted in a higher dropout rate (43%) in the self-management group compared to 11% of those in the routine care group. Those who were considered incapable of self managing withdrew from the trial or were returned to the routine care group. The study population who self-selected to enroll was younger and included more men than the eligible population. Moreover, participants in the intervention group tested their INR more frequently than those in the routine care group (mean every 12 days vs.38 days) group, and apparently received more care, which is another potential source of bias. Patients in the routine care group were managed in a variety of models including anticoagulation clinics, hospital outpatient clinics, and primary care clinics which may have an influence on their anticoagulation control, and outcomes. Overall the results of this RCT show no significant differences between the intervention and routine care groups in the percent of time spent within therapeutic INR range (primary outcome) or in the rates of serious bleeding, or serious thrombosis. Patients in a target INR of 3.5 had poorer control before and during the study compared to those with target INR of 2.5. However, patients in the intervention group with a 3.5 target INR showed a significant improvement between the pre-study and study periods. No such improvement was observed for those with a 2.5 INR target in either group, or those with a 3.5, target in the routine care group. These results of the Heneghan's meta-analysis and Fitzmaurice's RCT may not be generalizable to all patients treated with long-term oral anticoagulants. The study participants were highly motivated, mainly younger, willing to take and complete a structured training course on self-management, and capable of performing self-testing correctly and reliably.

Articles: The search revealed 7 newer randomized trials that were published after the last review, as well as a meta-analysis of RCTs that assessed the effects of self-monitoring or self-management of anticoagulation compared with standard monitoring. Only three of the recent RCTs were relevant (Fitzmaurice 2005, Voler 2005, and Menedez-Jandula 2005). The latter two were included in the meta-analysis. Studies conducted to compare two home INR monitors, or to evaluate the accuracy of the portable PT monitoring systems were excluded. The purpose of this review is to assess the home use of the monitors for patients receiving long-term anticoagulation treatment, and not for evaluating the portable systems that have been in use since 1987 (known as point of service). Two ongoing trials were also identified: 1. Self-Management of Anticoagulation, a Randomized Trial (SMART) which is a large multicenter trial on self-management of anticoagulation and, 2. The Home INR Study (THINRS) with more than 400 patients from VA Medical Centers with atrial fibrillation and/or mechanical heart valve who are expected to be anticoagulated indefinitely. The trial compares anticoagulation (AC) management using home monitoring devices to high quality management implemented by an AC service. It will have a

Back to Top

minimum of 2 years of follow-up, and the primary outcome is event rates (stroke, bleeding or death). Heneghan's (2006) meta-analysis and the RCT that was not included in the meta-analysis were critically appraised. Heneghan C, Alanzo-Coello P, Garcia-Alamino JM et al. Self-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006; 367:404-11.See Evidence Table Fitzmaurice DA, Murray ET, McCahon D, et al. Self-management of oral anticoagulation: randomized trial. BMJ 2005;331:1057- See Evidence Table

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/01/2008: MTAC REVIEW
Home INR Monitoring
Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of home INR monitoring for thromboprophylaxis warfarin therapy post knee or hip replacement surgery. An ideal study would be a randomized controlled trial that compares health outcomes of home INR monitoring of the warfarin dose to routine monitoring in hospital or anticoagulation management services. The trial should address the effect of INR home monitoring on altering treatment and preventing thromboembolism without increasing bleeding risks. The only published study on home thromboprophylaxis with warfarin anticoagulation therapy after hip and knee replacement surgery was a case series that studied the efficacy of a program designed to maintain the prophylactic anticoagulant oral therapy within the target range. The patients did not monitor their own INR or adjust their own therapy. Instead it was coordinated between Home Care and community laboratory, and dose adjustments were made by the patient's family physician. Yet the program failed to achieve the target INR in almost 60% of cases during the six weeks postoperatively. Conclusion There is insufficient evidence to determine that: Home INR monitoring after joint replacement surgery increases the percentage of time spent within the therapeutic INR range, compared to routine care. Home INR monitoring, vs. routine care, after joint replacement surgery is effective in reducing the deep vein thrombosis and pulmonary embolic events rates, without increasing hemorrhagic events.
Articles: The search did not reveal any RCT that compared outcomes of monitoring of INR post joint replacement at home vs. in the hospital or anticoagulation management centers. There was only one published empirical study on the home prophylaxis with warfarin after hip and knee arthroplasty. Schuringa P, Yen D. Home prophylactic warfarin anticoagulation program after hip and knee arthroplasty. Can J Surg. 1999; 42:360-362. See Evidence Table.

The use of Home INR Monitoring in the treatment of anticoagulation for mechanical valves does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT or HCPC® Codes	Description
G0248	Demonstration, prior to initiation of home INR monitoring, for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient's ability to perform testing and report results
G0249	Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes: provision of materials for use in the home and reporting of test results to physician; testing not occurring more frequently than once a week; testing materials, billing units of service include four tests
G0250	Physician review, interpretation, and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include four tests

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

Back to Top

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Date Created	Date Reviewed	Date Last Revised
12/10/2002	01/05/2010 MDCRPC, 05/04/2010 MDCRPC, 03/01/2011 MDCRPC, 01/03/2012 MDCRPC, 11/06/2012 MDCRPC, 09/03/2013 MPC, 07/01/2014 MPC, 05/05/2015MPC, 03/01/2016MPC, 01/03/2017MPC, 11/07/2017MPC, 09/04/2018MPC, 09/03/2019MPC, 09/01/2020MPC, 09/07/2021MPC , 09/06/2022MPC , 09/05/2023MPC, 02/13/2024MPC	09/01/2020

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/01/2020	Added Medicare LCA A55756

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home Pulse Oximetry – Rental for Home Use

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Oxygen and Oxygen Equipment (L33797) "Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment."
Local Coverage Article	Oxygen and Oxygen Equipment – Policy Article (A52514) "Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the beneficiary's treatment."

For Non-Medicare Members

Medical necessity review no longer required.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

The pulse oximeter is a completely noninvasive device that provides a means of continuous and quick real-time estimates of arterial oxygen saturation (SaO_2). It has been validated relative to transcutaneous oxygen tension, and arterial blood gas measurement. (Fanconi, 1985). The device estimates arterial hemoglobin saturation by measuring the light absorbance of pulsating vascular tissue at two wavelengths. It is easy to use and interpret and does not need any special training or new skills on the part of the user. It also requires a little setup time and adds no risk to the patient.

Pulse oximetry is becoming a standard of practice during general anesthesia in the United States (Eichhorn, 1986). It is also used as an independent monitor in emergency rooms and intensive care units. Other clinical applications of the device include monitoring patients during transport, respiratory monitoring during narcotic administration, and the evaluation of home-oxygen therapy.
The pulse oximeter, however, has some limitations; it does not provide an early warning of decreasing arterial oxygen tension (PaO_2) and may fail to detect an inadvertent endobronchial intubation in the operating room. It also cannot distinguish more than two hemoglobin species in the blood; thus methemoglobin and carboxyhemoglobin will cause errors in the pulse oximeter saturation (SpO_2) if present in large amounts. Artifactual signals created by patient motion or external light may also create a technical problem and interfere with the device in estimating the oxygen saturation. It was also reported that circumstances that reduce the amplitude of finger pulsation e.g. hypothermia, hypotension, or the administration of a vasoconstrictive drug would adversely affect the accuracy of the device (Yelderman,1983).

Back to Top

The home pulse oximeter is being reviewed due to several requests received by Clinical Review for coverage for adult patients with progressive pulmonary disease, pediatric patients with RVS, or patients being discharged home but requiring continued monitoring to ensure stability in the home.

Medical Technology Assessment Committee (MTAC)

Home Pulse Oximetry

10/08/2003: MTAC REVIEW

Evidence Conclusion: There are insufficient published studies to provide evidence on the home use of pulse oximeters among adults or children with respiratory failure or chronic pulmonary disease.

Articles: The search yielded 46 articles. A large number was not related to home monitoring of oxygen saturation, and a few addressed the home use of pulse oximetry for the diagnosis of sleep apnea. The search did not reveal any empirical study conducted among adults with chronic obstructive lung disease using a home pulse oximeter to monitor their oxygen saturation. The search revealed three small case series conducted among either healthy infants to assess their oxygen saturation during the first six months or among infants with bronchopulmonary dysplasia receiving home oxygen therapy. None of the studies was critically appraised.

The use of home pulse oximetry in the management of oxygen levels for adults or children with respiratory failure or chronic pulmonary disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Please refer to Kaiser Permanente payment policy Durable Medical Equipment for reimbursement clarification

Effective until May 1, 2024

Medicare: considered not medically necessary

Non-Medicare: medical necessity review no longer required

CPT® or HCPC Codes	Description
E0445	Oximeter device for measuring blood oxygen levels noninvasively
A4606	Oxygen probe for use with oximeter device, replacement

Effective May 1, 2024

Considered non-covered personal convenience item/not separately reimbursable in the home setting (except for use for an approved advanced care at home episode):

CPT® or HCPC Codes	Description
E0445	Oximeter device for measuring blood oxygen levels noninvasively
A4606	Oxygen probe for use with oximeter device, replacement

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/08/2003	09/07/2010[MDCRPC], 07/05/2011[MDCRPC], 05/01/2012[MDCRPC], 03/05/2013[MDCRPC], 01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/01/2022[MPC] , 03/07/2023[MPC], 02/13/2024[MPC]	12/09/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee

Back to Top

MPC Medical Director Clinical Review and Policy Committee

Revision History	Description
02/01/2017	Medical necessity review no longer required for non-Medicare members.
12/09/2023	MPC approved to endorse a position of non-coverage in the ambulatory setting, aligning with CMS payment methodology. Requires 60-day notice, effective date May 1, 2024.

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Home Oxygen Therapy for Chronic Use

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Claims Processing Manual Chapter 20, Section 30.6, Oxygen and Oxygen Equipment
National Coverage Determinations (NCD)	Home Use of Oxygen (240.2) Home Use of Oxygen in Approved Clinical Trials (240.2.1)
National Coverage Analysis (NCA) – Decision Memo	Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2)
Local Coverage Determinations (LCD)	Home Use of Oxygen and Oxygen Equipment (L33797)
Local Coverage Article	Oxygen and Oxygen Equipment – Policy Article (A52514)

For Non-Medicare Members

Kaiser Permanente has elected to use the Home Oxygen (KP-0343) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider and/or specialist (palliative care, primary care, pulmonary care)
- Most recent Pulse Oximetry documentation and/or most recent at rest &/or activity log

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In 1986, Kaiser Foundation Health Plan of Washington experienced an increased use of home oxygen and could find no clinical evidence in patient charts that would support the use of oxygen. In addition, once a patient was placed on home oxygen, they were never re-tested to verify continued need of the treatment. In 1989, a task force was initiated to review use and develop clinical indications for use at Kaiser Permanente. The task force reviewed the current literature and adopted the Medicare home oxygen criteria. In addition, they defined several situations where exceptions would be appropriate. The program was initiated for review of all home oxygen requests, and to set up testing and re-testing programs. The program was submitted to Medicare for approval. Medicare not only approved it, but also adopted several of its most critical features such as the re-testing program.

Applicable Codes

Back to Top

Date Sent: 4/29/24

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E0447	Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (LPM)
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, rental
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
12/15/1985	09/07/2010 MDCRPC, 07/05/2011 MDCRPC, 05/01/2012 MDCRPC, 01/08/2013MDCRPC, 11/05/2013 MPC, 09/02/2014 MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 11/06/2018MPC, 11/05/2019MPC, 11/03/2020MPC, 11/02/2021MPC, 11/01/2022MPC, 11/07/2023MPC, 02/13/2024MPC	03/01/2022

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
03/01/2022	Updated applicable codes

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.

Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Hyperbaric Oxygen Therapy

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Hyperbaric Oxygen Therapy (20.29)
Local Coverage Determinations (LCD)	Oxygen and Oxygen Equipment (L33797)
Local Coverage Article	Oxygen and Oxygen Equipment (A52514)

*Note: It is clinically rare for a patient to require more than 40 hyperbaric treatments for any diagnosis. Requests for more than 40 treatments should be sent to the Medical Director for closer review.

For Non-Medicare Members

Hyperbaric oxygen may be indicated with a confirmed diagnosis of **ONE or more of the following**:

1. Chronic severe diabetic ulcer, and need for initial treatment, as indicted by **ALL of the following**:
   a. Severe wound defined by Wagner grading system, as indicated by **one or more of the following**:
      - Grade 3 Wagner ulcers are deep and involve abscess(es), osteomyelitis (bone infection) and/or joint sepsis
      - Grade 4 Wagner ulcers include gangrene (decay of body tissues) in the forefoot (anterior third of the foot) or heel region(s)
      - Grade 5 Wagner ulcers involve extensive gangrene **AND**

   b. There is a document plan for initial treatment, which includes **ALL of the following**:
      - Must have complete evaluation and treatment for any underlying peripheral vascular or neuropathic disease. To assess vascular status there must be a documented exam of femoral, popliteal, dorsalis pedis and posterior tibial pulses. If absent or reduced, must have documented ABI Scores. If questionable accuracy of ABI score, due to diabetes, a vascular surgeon consult is needed.

   c. Minimal to no healing present despite conventional wound treatment for minimum of 30 days, including **ALL of the following**:
      - Documentation of adequate diabetic control and most recent HbA1C
      - Pressure reduction or offloading for at least 8 weeks. (Must have documentation at each visit of the use (or of noncompliance) of walker boot, knee, scooter, or wheelchair)
      - Topical wound treatment. Need documentation regarding what specific products have been used, duration, and effectiveness (i.e., Apligraf, dermagraph, saline, hydrogels, hydrocolloids, alginates, or wound vac)
      - Appropriate wound debridement (practitioner must have appropriate training to perform) and

   d. Must have formal Infectious Disease consult and treatment for a minimum of 6 weeks for severe wound/bone infection

   e. Transcutaneous tissue oxygenation (PtcO2) levels of **one or more of the following**:
      1. PtcO2 of 25 mm Hg (3.3 kPa) or greater on room air
      2. PtcO2 value less than 25 mm Hg (3.3 kPa) on room air that meets **one or more of the following:**

Back to Top

   a. PtcO2 increase of more than 20 mm Hg (2.7 kPa) while breathing 100% oxygen via face mask at normal atmospheric pressure or
   b. PtcO2 increase of greater than 200 mm Hg (26.6 kPa) in chamber during hyperbaric oxygen therapy
2. Chronic severe diabetic ulcer, and need for continued treatment, as indicated by **ALL of the following**:
   a. Adherent to hyperbaric oxygen therapy
   b. Documented evidence of improvement after 24 visits and need for continuing improvement after that point
   c. Plan for no more than 40 total treatments
3. Decompression illness or suspected intravascular gas embolism
4. Anemia, as indicated by **ALL** of the following
   a. Emergent anemia, as indicated by **1 or more** of the following
      - Active hemolysis with rapidly progressive anemia
      - Active massive hemorrhage
      - Severe signs or symptoms unresponsive to volume replacement (eg, tachycardia, hypotension, chest pain, cognitive impairment)
   b. Patient unable or unwilling to receive red blood cell transfusions
5. Carbon monoxide (CO) poisoning is unconscious and has a carboxyhemoglobin level over 40%
6. Cyanide poisoning, acute
7. Intracranial abscess
8. Central retinal artery occlusion
9. Gas gangrene (inpatient only)
10. Idiopathic sudden sensorineural hearing loss (will need 20 visits maximum)

KP SSNHL GUIDELINES

A. Patients presenting with mild to moderate HL:
   - Oral and IT steroid should be discussed with all patients.
   - Treatment should be initiated, if possible, within 2 weeks of onset.
   - Oral steroid alone should be recommended as initial therapy for mild to moderate HL within 2 weeks of onset but can be offered up to 6 weeks after onset.
   - IT steroid should be strongly recommended for salvage for oral steroid failure within 6 weeks of onset
   - Combo therapy (oral and IT steroid) should be recommended for those presenting more than 2 weeks after onset and within 6 weeks of onset.
   - HBO should not be offered unless there are medical contraindications to oral or IT steroid therapy or special situations ie only hearing ear.
   - Patients with > 25% drop in discrimination regardless of the severity of their pure tone loss should be treated as presenting with severe to profound HL patients

B. Patients presenting with severe to profound HL:
   - HBO therapy combined with steroid treatment should be initiated within 2 weeks of onset if possible.
   - Combo therapy (oral and IT steroid) should be “strongly” considered within 6 weeks of onset.
   - IT steroid should be strongly recommended for salvage for oral steroid failure within 6 weeks of onset
   - HBO should not be considered routinely as isolated adjuvant initial or salvage therapy without steroid therapy unless there are medical contraindications to oral or IT steroid therapy or special situations ie only has one hearing ear and that is the ear which is affected by sudden hearing loss.

C. Treatment:
   - Oral Prednisone should be 60mg for at least 7 days.
   - IT steroids should be Dexamethasone 10mg/ml up to 3 injections as needed. Treatment intervals – “weekly”
   - HBO: 100% at 2-2.5 ATA 10-20 Dives lasting 90 or 60 minutes.

D. Audiogram:
   - Initial, after treatment start consider audiograms prior to additional interventions or if patient reports significant improvement, 6 months after last intervention.

E. Ruling out Retro-cochlear Lesion:
   - MRI (or CT with contrast if MRI contraindicated) required to rule out retro cochlear lesion

F. Routine Laboratory Testing:
   Not recommended

11. Clostridial and non-clostridial myonecrosis: Plan of care indicates use will be in conjunction with other medical/surgical therapies and will not interfere with or delay surgical debridement. (Provided for hospital inpatient only)

Back to Top

12. Necrotizing soft tissue infections (provided for hospital inpatient only)
13. Osteoradionecrosis as indicated by **ONE or more of the following**:
    a. Mandibular/maxillary osteoradionecrosis (diagnosis is typically made by a clinical exam with exposed bone, and/or by imaging). History of previous radiation therapy to the mandible or maxilla of at least 5,000-7,000 rads
    b. Osteoradionecrosis in other sites, as an adjunct to conventional treatment. Osteoradionecrosis presents some months/years after radiation (sternum, long bones)
    c. 30 pre/10 post treatments
14. Open or closed crush injury, compartment syndrome, or acute traumatic ischemias (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
15. Femoral necrosis (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
16. Skin grafts and flaps (compromised) (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6147240/)
17. Soft tissue radionecrosis as an adjunct to conventional treatment: Typically, bowel, bladder, larynx or wounds in area of prior radiation therapy. Must wait 6 months post completion of radiation therapy. Requires visualization of the damaged area with serial exams to monitor progress (e.g., cystoscopy, laryngoscopy, sigmoidoscopy). Additional health plan review if 30 treatments are exceeded. (40 max). Total radiation dose and field must be documented. Must have **ONE of the following**:
    a. Radiation-induced proctitis diagnosed by sigmoidoscopy
    b. Radiation-induced hemorrhagic cystitis diagnosed by cystoscopy
    c. Radiation-induced head and neck soft tissue injury – soft tissue radionecrosis, typically of the larynx, or in a radiated field.
18. Dental extractions must meet **ALL of the following**:
    a. Clinical plan on file from the dentist/oral surgeon detailing planned extractions timeline
    b. History of at least 5,000-7,000 rads received to the teeth planned for the extraction
    c. Initial Request is for 20 treatments prior and 10 after the extractions. If the initial treatment of 20/10 was delivered within prior 5 years, then only 10 more treatments post extractions are required for any additional extractions done within 5 years but not pre-extraction)
19. Chronic refractory osteomyelitis, unresponsive to both conventional medical and surgical treatment. Must have a prior infectious disease consultation and at least 6 weeks of medical management and a surgical consultation regarding debridement. Any hardware should be removed if feasible. Not indicated for acute osteomyelitis. If involves a distal toe, requires physician consultation prior to auth. Any treatments beyond 30 should have physician consultation. Pelvic bone osteomyelitis from decubiti requires debridement and flap surgery and does not respond well to hyperbaric. For osteomyelitis associated with a diabetic foot ulcer, see I. above.

Hyperbaric oxygen pressurization is considered investigational in all other situations.

***Note: Topical application of oxygen (CPT A4575) does not meet the definition of HBO therapy and is considered investigational/not medically necessary in all cases. Also, its clinical efficacy has not been established.**

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or consulting specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multi-place chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999).

Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as

Back to Top

decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999).

Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation).

Evidence and Source Documents

Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis
Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible
Hyperbaric Oxygen Therapy for Prophylaxis before Breast Surgery
Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis

Medical Technology Assessment Committee (MTAC)

Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis

BACKGROUND

Many types of cerebral cancer are treated with external beam, stereo tactically focused or implanted radiation. One of the most common and debilitating sequelae of high dose radiation is tissue destruction and necrosis. Radiation-induced necrosis (RIN) manifests itself as headache, ataxia, cranial nerve palsy, seizures, and visual loss. Necrotic tissue had historically been surgically re-sected when anatomically feasible or left untreated. One proposed method of treatment is the use of hyperbaric oxygen therapy (HBOT) which increases tissue oxygen concentration and may stimulate angiogenesis and establish a new blood supply to healthy cerebral tissue. Typically, hyperbaric oxygen is administered by placing patients into a whole-body hyperbaric chamber and exposing them to oxygen concentrations of 2 times normal atmospheric pressure for a period of 2-4 hours, once a day. Treatments are usually repeated usually 20-40 times with symptomatic improvement used as the measure of treatment success.

08/11/1999: MTAC REVIEW
Hyperbaric Oxygen for Treatment of Radiation Induced Cerebral Necrosis
Evidence Conclusion: Evidence identification was conducted by searching MEDLINE from 1996-1999 using terms radiation necrosis, radiation injuries, cerebral necrosis and hyperbaric oxygenation. Dr. Kindwall, the author of a recent review, identified 2 case series (n=10, n=2) as the only published data on hyperbaric oxygen for treating **cerebral** radiation-induced necrosis. The Kaiser Permanente New Technology hotline staff was also unable to identify any additional literature reporting original data. Data from the case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone. The best published scientific evidence on treating radiation induced cerebral necrosis with hyperbaric consists of a case series of 10 patients, 8 of whom had biopsy-proven RIN, demonstrated that, with a median follow up of 7 months post HBOT, symptoms completely resolved in 1 patient, improved in 4 patients, did not get worse in 1 patient, and ended up worse in 4 patients. One patient developed ear pain from HBOT and had ear tubes placed and one developed sinusitis and discontinued treatment. Because this study was a case series rather than a randomized trial, it is not possible to determine whether hyperbaric oxygen therapy improves the clinical outcome of patients with radiation-induced cerebral necrosis beyond what would be expected with corticosteroid therapy alone.
Articles: Chuba, PJ, et al, Cancer 1997;80:2005-2012

The use of hyperbaric oxygen does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible

BACKGROUND

Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment

 Back to Top

sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum that can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). Osteoradionecrosis (ORN) of the mandible is a potential complication of head and neck irradiation. It is defined as a nonhealing, nonseptic lesion of bone (Clayman, 1997). The underlying cause of ORN is believed to be progressive vascular occlusion and tissue hypoxia after radiation treatment (Porter & Brian, 1999). Three types of ORN have been described. Type 1 occurs when a patient receives radiation therapy within 21 days of tooth extraction or mandibulotomy. Type 2 is induced by trauma. It generally occurs 3-6 years after radiation therapy, usually following a tooth extraction. Type 3 occurs spontaneously 6 months to 2 years after radiation therapy and is associated with higher radiation doses, neutron beam therapy and brachytherapy (Cronje, 1998). Hyperbaric oxygen therapy is generally accepted as a treatment for patients who have ORN. The use of hyperbaric oxygen therapy is also proposed as a prophylactic treatment before dental work to prevent ORN in patients who have had irradiation of the head and neck.

04/09/2003: MTAC REVIEW
Hyperbaric Oxygen Therapy for Prophylactic Treatment after Head and Neck Radiation to Prevent Osteoradionecrosis (ORN) of the Mandible
Evidence Conclusion: There is weak evidence from one randomized controlled trial (Marx), published in 1985, that prophylactic hyperbaric oxygen treatment of patients with previous head and neck irradiation before tooth removal lowers the incidence of osteoradionecrosis of the mandible compared to patients treated prophylactically with penicillin. The Marx study had a small sample size (n=74) and the methodology was not well described, leaving open the possibility of threats to validity such as selection bias, inadequate randomization and biased assessment of outcomes. The results of the Marx study have not been replicated. Many factors may have changed since 1985 making the findings less relevant including different radiation protocols that alter the likelihood of developing ORN, better alternative prophylactic treatments and better treatments for patients with ORN. Recent authors have questioned the need for prophylactic hyperbaric oxygen treatment before dental surgery for all patients who have received head and neck radiation before dental surgery because the incidence of post-extraction ORN is relatively low and over half of the patients who do develop ORN heal after conservative treatment. The Marx study has also been criticized as including a particularly high-risk group of patients. The incidence of ORN in the Marx study was 30% in the penicillin-treated group compared to a 5.8% incidence in the general population of post-radiation tooth extraction patients and a lower incidence, 2.1% in studies conducted in the 1990s (Clayman, 1997).
Articles: The search yielded 35 articles. Many of the articles were reviews or opinion pieces, dealt with technical aspects of the intervention or addressed the treatment of osteoradionecrosis with hyperbaric oxygen rather than prophylaxis. No randomized controlled trials on prophylactic use of hyperbaric oxygen to prevent osteoradionecrosis were included in the search findings. However, an RCT published in 1985 was identified from the reference list of a review article. In addition to the RCT, there were several case reports and small case series (n<30 patients). The RCT was critically appraised: Marx RE, Johnson RP, Kline SN. Prevention of osteoradionecrosis: a randomized prospective clinical trial of hyperbaric oxygen versus penicillin. JADA 1985; 111: 49-54. See Evidence Table.

The use of hyperbaric oxygen in the prevention of osteoradionecrosis of the mandible does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery
BACKGROUND
Breast cancer is the most common cancer in women, other than skin cancer, and the second leading cause of cancer death among them. According to the American cancer society, a woman has a 1 in 7 chance of having invasive breast cancer some time during her life. As of the 2004, there are slightly over 2 million women living in the USA who have been treated for breast cancer. Conservative therapy with lumpectomy, axillary dissection, and irradiation, is a frequently used option for treating early breast cancer. This allows the patient to keep her breast and reduce the physical and psychological trauma associated with the modified radical mastectomy. Radiation therapy is also indicated with mastectomy under certain conditions. In both cases, radiotherapy is given in a moderate to high dose and may be associated with mild to severe complications that might have negative
 Back to Top

influence on the health and quality of life. Among these complications are arm lymphedema, subcutaneous fibrosis, painful hardening of the breast, shoulder pain rib fracture, damage to the lungs and heart and others (Gothard 2003, Feldmeier 1995). These complications may be due to early reactions to radiation, or late effects that occur after at least 90 days after the start of treatment (Pasquier, 2004). Late injuries are irreversible and progressive in the majority of cases. These may cause cellular depletion, reduction in vascular density, fibrosis and atrophy all of which may result in hypoxia, and in turn delayed healing of the wounds. Conservative measures may be adequate for managing moderate cases with minimal necrosis, but cases of extensive necrosis are more challenging. Hyperbaric oxygen (HBO) was first used for the treatment of radiotherapy patients in the 1950s (Pasquier, 2004). It is defined as the breathing of pure oxygen at pressure exceeding the normal atmospheric pressure of 100 kPa that increases the solubility of oxygen in the blood. HBO treatment is administered within hyperbaric chambers, which are compressed by air (Plafki, 1998) Researchers indicate that hyperbaric oxygen therapy stimulates angiogenesis, osteogenesis, fibroblast activity, and collagen formation in irradiated tissues, which would increase the cellular level of oxygen. It has been reported that HBO therapy is associated with a low complication rate, but that there is uncertainty about the best time to start the treatment, and the number of sessions needed (Plafki, 1998). There is also uncertainty on the efficacy of the treatment for the different complications, what are its side effects, who would respond to treatment, and for which symptoms**.**

12/08/2004: MTAC REVIEW
Hyperbaric Oxygen Therapy for Prophylaxis Before Breast Surgery
Evidence Conclusion: There is no evidence to date on the prophylactic use of hyperbaric oxygen therapy before breast surgery in patients with prior radiation therapy. There is also insufficient evidence on the efficacy of HBO therapy in the treatment of late sequelae in women receiving radiation after breast-conserving surgery. The study reviewed was a case series that provide the least grade of evidence. It was small nonrandomized, and with potential selection and observation bias. The results of the study show that patients who received a hyperbaric oxygen therapy had a significant reduction of pain, edema, and erythema compared to those who refused the therapy. There was no significant difference between the groups in the improvement of fibrosis or telangiectasia.
Articles: The search yielded 35 articles. Many were review articles, dealt with technical aspects of the therapy, or the use of hyperbaric oxygen for the treatment of radio-induced lesions in different tissues and organs other than the breast. The search did not reveal any study on the use of Hyperbaric Oxygen Therapy for prophylaxis in breast surgery in patients with prior radiation therapy. There was one prospective case series with a control group on the use of hyperbaric oxygen for the treatment of late sequelae of radiation therapy after breast surgery, a smaller series of 21 patients and control group, and a retrospective review of 23 cases.
The case series with a control group was selected for critical appraisal. Carl UM, Feldmeier JJ, Schmitt, et al. Hyperbaric oxygen therapy for late sequelae in women receiving radiation after breast-conserving surgery. *Int J Radiat Oncol Biol Phys.* 2001; 49:1029-31. See Evidence Table.

The use of hyperbaric oxygen for prophylaxis before breast surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis
BACKGROUND
Hyperbaric oxygen therapy consists of placing a patient inside a pressurized chamber in which the patient breathes 100% oxygen under a pressure of greater than one atmosphere. Generally, there is a gradual increase to approximately two-and-a-half times the normal atmospheric pressure. Patients receive up to 40 treatment sessions lasting between 45 and 300 minutes. There are monoplace chambers for one person and multiplace chambers that can accommodate two or more patients. (Leach et al, 1998; Porter & Brian, 1999). Hyperbaric oxygen therapy has both a mechanical (pressure) and physiological (oxygen) component. The increased pressure causes compression of gas bubbles in the body and is useful for conditions such as decompression illness. Breathing 100% oxygen at increased pressure allows more oxygen to reach non-healing tissue and helps to prevent tissue from dying to a lack of oxygen and blood (Porter & Brian, 1999). Potential adverse events of hyperbaric oxygen therapy include myopia lasting for weeks or months, ruptured middle ear, seizures, lung damage and oxygen toxicity. The most common complication is a lack of pressure equalization on both sides of the eardrum which can cause pain and bleeding into the middle ear. The high concentration of oxygen also presents a fire hazard (Porter & Brian, 1999; oral cancer foundation). The treatment of gastrointestinal bleeding related to radiation enteritis is one possible application of hyperbaric oxygen therapy.

04/09/2003: MTAC REVIEW
Hyperbaric Oxygen Therapy for Treatment of Gastrointestinal Bleeding Related to Radiation Enteritis
Evidence Conclusion*:* There is no published evidence on the effectiveness of hyperbaric oxygen therapy for the treatment of gastrointestinal bleeding related to radiation enteritis.
 Back to Top

Articles: There were no published empirical studies. An abstract of a small case series (n=19) was identified in a review article. The abstract was presented at a professional meeting in 1998 and the study was not subsequently published.

The use of hyperbaric oxygen in the treatment of gastrointestinal bleeding related to radiation enteritis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session
HCPC Codes	**Description**
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval

Considered Not Medically Necessary - experimental, investigational or unproven:

HCPC Codes	Description
A4575	Topical hyperbaric oxygen chamber, disposable

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
09/1998	01/05/2010[MDCRPC], 11/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012 [MDCRPC], 06/04/2013 [MDCRPC], 04/01/2014[MPC], 09/02/2014[MPC], 02/03/2015[MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 01/09/2018[MPC], 07/10/2018[MPC], 11/06/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC] , 03/12/2024[MPC]	03/08/2021

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Director Clinical Review and Policy Committee

Revision History	Description
12/01/2015	Added one additional indication: treatment of central retinal artery occlusion
03/07/2017	Revised indication to dental extractions (part c)
08/06/2019	Revised criteria to include indications for open or closed crush injury, compartment syndrome, or acute traumatic ischemia's; femoral necrosis; skin grafts and flaps and added indication for dental extractions: Initial Request is for 20 treatments prior and 10 after the extractions. If the initial treatment of 20/10 was delivered within prior 5 years, then only 10 more treatments post extractions are required for any additional extractions done within 5 yrs. but not pre extraction
09/03/2019	MPC approved to adopt clinical indications for sudden hearing loss
07/07/2020	Removed Revenue code 413; Added Infectious Disease consult and treatment and medical management 6-week requirements
08/04/2020	MPC approved to adopt updates to clinical criteria for Non-Medicare-additional indications for anemia, cyanide poisoning and intracranial abscess. Requires 60-day notice, effective date 01/01/2021. Added Medicare LCA A52514.

Back to Top

03/08/2021	Added clarifying language around Wagner grading system; also clarified requests will be limited to no more than 40 treatments, as well as sudden hearing sensorineural hearing loss

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Implanted Infusion Pumps

For Insulin Pumps See Separate Criteria

- Intra-Arterial Infusion Pump
- Intraspinal Pump
- Intrathecal Pump

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Implanted Infusion Pump for Chronic Pain (A55323)

For Non-Medicare Members

The following criteria must be met for each specific type of treatment:

1. Chemotherapy for Liver Cancer must meet **ALL of the following**:
   a. Is receiving intra-arterial infusion of 5-FUdR for the treatment of liver cancer.
   b. Must meet **ONE of the following**:
      - Liver cancer for patients with primary hepatocellular carcinoma.
      - Duke's Class D colorectal cancer, in whom the metastases are limited to the liver, and where (1) the disease is unresectable or (2) the patient refuses surgical excision of the tumor.

2. Anti-Spasmodic Drugs for Severe Spasticity must meet **ALL of the following**:
   a. Use to administer anti-spasmodic drugs intrathecally (e.g., baclofen).
   b. The patient has chronic intractable spasticity with a baseline average Ashworth Scale* score of at least 3 (or a Modified Ashworth Scale* score of 2), and a Spasm Frequency score** of at least 2.
   c. The spasticity is unresponsive to less invasive medical therapy as determined by the following criteria:
      - A 6-week trial, the patient cannot be maintained on noninvasive methods of spasm control, such as oral anti-spasmodic drugs, either because these methods fail to control adequately the spasticity or produce intolerable side effects.
      - The patient has responded favorably to a trial intrathecal dose of the anti-spasmodic drug, e.g., demonstrates at least a 2-point reduction in the Ashworth Scale or Spasm Frequency score for 4 hours following an intrathecal bolus of baclofen.

   *Ashworth and Modified Ashworth Scale (scale appears in middle of document)
   **Spasm Frequency Score

3. Opioid Drugs for Treatment of Chronic Intractable Pain must meet **ALL of the following**:
   a. Used to administer opioid drugs intrathecally or epidurally.
   b. Patient has severe chronic intractable pain of malignant or nonmalignant origin with a life expectancy of at least 3 months.
   c. Patient agrees to a 50% reduction in systemic opiates prior to undergoing an intrathecal opiate trial.
   d. Are proven unresponsive to one or more of the following less invasive medical therapies:

Back to Top

Date Sent: 4/29/24

- Trial of neuropathic pain medication
- Trial of nonsteroidal anti-inflammatory drugs (NSAIDs)
- Trial of physical therapy
- Trial of behavioral health treatments (e.g., CBT, ACT)
- The patient's history indicates that he/she would not respond adequately to non-invasive methods of pain control, such as systemic opioids (documentation should include attempts to eliminate physical and behavioral abnormalities which may cause an exaggerated reaction to pain)

e. No acute psychiatric instability or uncontrolled suicide risk
f. No diagnosed substance-related disorder (other than nicotine) or patient currently receiving active treatment for disorder
g. A preliminary trial of intraspinal opioid drug administration has been undertaken with a temporary intrathecal/epidural catheter to substantiate adequately acceptable pain relief and degree of side effects (i.e. patient has experienced > 50% reduction in pain and concomitant increase in function) and patient acceptance.

In addition to meeting the appropriate above criteria the patient does not have one of the following contraindications:
1. A known allergy or hypersensitivity to the drug being used (e.g., oral baclofen, morphine, etc.);
2. An infection;
3. Body size at the implant site is insufficient to support the weight and bulk of the device;
4. Other implanted programmable devices since crosstalk between devices may inadvertently change the prescription.

If requesting this service, please send the following documentation to support medical necessity:

- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Implantable pumps are designed to provide a continuous infusion of medication to a specific body site. The pumps are used with morphine for malignant pain management, and the drug 5-FUdR for liver cancer chemotherapy and Baclofen for intractable spasticity.

About two-thirds of metastatic cancer patients experience moderate-to-severe pain (Smith et al., 2002). Chronic non-malignant pain is also common. One type of non-malignant pain, chronic low back pain, is the second most frequent cause of hospital admissions in the United States (Deer et al., 2004).

Options for initial treatment of chronic pain include exercise, physical therapy, individual counseling, pain education classes, medications such as NSAIDS and complementary/alternative treatments such as massage or acupuncture. Opioids are an option as part of a comprehensive treatment plan if patients fail other therapies (GHC chronic non-malignant pain guideline). A meta-analysis of studies on oral morphine by the Cochrane Collaboration found it to be an effective analgesic for cancer pain (Wiffen et al., 2003). Another Cochrane review on chronic low-back pain found a lack of high-quality evidence and concluded that the benefits of opioids for this type of pain remain uncertain (Deshpande et al., 2007). Disadvantages of opioid analgesics include potential side effects such as nausea and vomiting, constipation, itching and respiratory depression. Moreover, during long-term opioid therapy patients may develop a tolerance leading to a need for higher doses, and patients may become physically dependent on opioids, and experience withdrawal symptoms if the medication is suddenly stopped (Wiffen et al., 2003).

The delivery of pain medication in directly into the fluid that surrounds the spinal cord (intrathecal analgesia) began in the 1970s following the discovery of opioid receptors in the central nervous system. Potential advantages of intrathecal analgesia include the ability to relieve pain in patients with previously intractable pain; the need for a lower milligram dose of opioids compared to systemic administration which may result in fewer side effects; and the ability to easily adjust the dose of opioids. Spinal analgesia was first used to treat chronic cancer-related pain. The use of intrathecal pain pumps for non-malignant pain is more controversial due to the limited

Back to Top

evidence on the ability of opioids to relieve non-malignant pain over the long-term. As with oral opioids, there are concerns about tolerance, dependence and addiction (Williams et al., 2000; Cohen & Dragovich, 2007). Side effects that have been associated with long-term intrathecal morphine therapy include nausea, vomiting, itching urinary retention, constipation, sexual dysfunction and edema (Ruan, 2007).

Chronic pain is a major public health problem in the United States and across the world. It has significant negative effects on patients' functional capacity and quality of life, as well as high direct and indirect costs for the health care system. In a Gallup Survey of "Pain in America" more than 4 out of 10 adults indicated that they experience pain on a daily basis. Chronic pain is a complex phenomenon that is difficult to define. The American Society of Interventional Pain Physicians (ASIPP) defined it as:

1. Pain that persists beyond the usual course of an acute disease or a reasonable time for any injury to heal that is associated with chronic pathologic processes that cause continuous pain or pain at intervals for months or years.
2. Persistent pain that is not amenable to routine pain control methods, and
3. Pain where healing may never occur (Boswell 2007).

Chronic non-cancer pain (CNCP) has also been defined as ongoing pain that lasts over six months, that is due to non-life-threatening causes, and does not respond to available treatment methods (Ghafoor 2007).

A key to successful management of chronic pain is a multidisciplinary approach that optimizes medication use in conjunction with other nonpharmacological therapies including exercise, physical therapy, individual counseling, pain education classes, and complementary/alternative treatments such as massage or acupuncture. When conservative treatments fail, surgery to correct underlying causes is considered. These conservative and surgical therapies provide adequate pain relief for most but not all CNCP patients (Ghafoor 2007).

Intrathecal (IT) analgesia was introduced in the 1970s following the discovery of opioid receptors in the central nervous system and was initially used for malignant pain in patients who have failed to obtain adequate pain relief, or those with adequate analgesia but with intolerable side effects to drug therapy. Currently, it is being used for other indications such as chronic back pain, neuropathy, mixed neuropathic-nociceptive pain, and radicular pain from failed back syndrome. IT analgesia involves the delivery of pain medication directly into the fluid that surrounds the spinal cord to target the pre- and post-synaptic receptors in the dorsal horn of the cord (Koulousakis 2007, Smith 2008, Patel 2009).

There are two types of implantable intrathecal drug delivery systems (IDDS) available in the US. The fixed rate pump allows continuous infusion and bolus dose administration but does not have the option of changing the flow rate. The other, and most common implantable pump is a programmable infusion system which is available in different reservoir sizes. The infusion pumps are typically implanted in the lower abdomen, just beneath the skin. A catheter is inserted into the intrathecal space of the spine, tunneled under the skin and connected to the implanted pump for medication delivery, and to an external programmer that controls infusion rate and records medication concentration, volume, and dosage. A drug is infused over an extended period and may be delivered at a constant or variable rate by calibrating the infusion pump according to the physicians' specification. The pump requires refilling regularly via subcutaneous port injections. A variety of analgesic/co-analgesic agents have been utilized to provide spinal analgesia however, morphine remains the gold standard and is the only opioid approved by the FDA for intrathecal delivery to treat chronic pain. The FDA approved the use of ziconotide, for patients unresponsive to intrathecally delivered morphine. It also approved the use baclofen with the use of implantable infusion pumps for patients with severe spasticity of spinal origin. However, off-label use of other drugs in IT pumps is common (Ghafoor 2007, Koulousakis 2007, Turner 2007).

The implantable infusion pump is an invasive alternative for medication delivery and requires ongoing maintenance and surgeries to periodically replace the pump. It has the potential benefit of providing more effective pain control by administering the analgesic drug directly to the target area, using lower doses of opioids compared to systemic administration, and the ability to adjust the dose of opioids. However, there are many risks and potential harms associated with IT drug therapy. These involve the problems related to the intrathecal drug delivery systems (IDDS), and the adverse events of the medications used. Serious complications that may occur after the intrathecal catheter placement include postoperative subarachnoid hemorrhage, meningitis, catheter tip inflammatory masses, infection, root irritation, reactive arachnoiditis, catheter dislocation, and pump failure. Drug-related side effects consist of dose-independent effects as urinary retention, pruritis, pain due to bolus injection, perspiration, and sedation; and dose-dependent side effects as nausea, constipation, dysphoria, euphoria, sedation, respiratory depression, hypotension, central depression, and tachyphylaxis. As with oral opioids, there are concerns about tolerance, dependence, and addiction. Drug overdose could take place if the pump is

Back to Top

inappropriately used or monitored; and drug withdrawal symptoms may occur with mechanical problems as pump failure or catheter blockage and kinking. There are also reports that patients with CNCP treated with intrathecal opioid therapy experience increased mortality compared to others with similar conditions treated with other therapies. It is thus recommended that pumps for chronic IT opioid application should only be implanted in specialized center. Before implantation the therapeutic effect of IT application should be assessed by a bolus trial or continuous injection via an external pump, connected to the intrathecal catheter through an implanted port (Cohen 2007, Koulousakis 2007, Smith 2008, Pasutharnchat 2009, Rathmell 2009, Coffey 2009).

In 1991, the Medtronic SynchroMed infusion system was approved by the FDA for the intrathecal delivery of morphine to treat malignant and non-malignant pain. The system consists of a pump that is generally implanted subcutaneously in the lower abdominal wall, a spinal catheter implanted into the lumbar intrathecal space between L1 and L4 and a programmer. The pump can be programmed via telemetry to control infusion modes and flow rates. SynchroMed is the only commercially available pump system that can be programmed outside the body. There are various models that differ in the size of the reservoir and the presence of a side catheter access port. Other implantable infusion pumps that have received FDA premarket approval include the Codman 3000 (Codman), Model 300 Constant Flow Implantable Infusion Pump (Arrow international) and the infused implantable Infusion Pump (Strato/infusaid).

Assessment objectives:

- To determine whether implanted infusion pumps for delivering intrathecal opioids are effective for the control of chronic noncancer pain (CNCP).
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids improves the quality of life and functioning in patients with CNCP.
- To determine whether the use of implanted infusion pumps for delivering intrathecal opioids are more effective than other non-invasive alternative therapies for pain control in patients with CNCP.
- To determine whether the technology is safe for use in patients with CNCP.

Medical Technology Assessment Committee (MTAC)

Implanted Pain Pumps for the Intrathecal Delivery of Opioids

08/06/2007: MTAC REVIEW

Evidence Conclusion: Cancer pain: The best evidence on the safety and effectiveness of implanted intrathecal pain pumps is an RCT with 200 patients. Of the 74% of patients with follow-up data at 4 weeks, there was a significantly greater reduction in toxicity, marginally significant reduction in pain and marginally significant increase in clinical success in the group assigned to receive a SynchroMed implantable pain pump in addition to comprehensive medical management (CMM) compared to CMM alone. Estimated survival at 6 months was higher in the group assigned to pain pumps, but the difference did not reach statistical significance. Limitations of the study include lack of blinding which could lead to biased estimates of self-report pain outcomes, funding by the device manufacturer and substantial cross-over (only 70% of the patients evaluated at 4 weeks in the pain pump group actually received implants and 5% of patients in the non-implant group received implants). Non-malignant pain: The evidence on safety and effectiveness is insufficient. There were case series and a cohort study that only compared pre- to post-implant changes, not between-group differences. The studies tended to find a reduction in self-reported pain after pump implantation and a reduction in oral morphine use (1 or 2 year follow-up). There were no comparison interventions and sample sizes were small. Device-related complications were relatively common.

Articles: The Medline search yielded one systematic review. This was published by the British Health Technology Assessment (HTA) group in 2000 and they did not identify any high-grade evidence. One randomized controlled trial was identified on malignant pain. Several articles were published based on this trial, the first on study outcomes in 2002. The article presenting the primary study outcomes (Smith et al., 2002) was critically appraised. No randomized controlled trials on non-malignant were identified. There was one non-randomized comparative trial which was critically appraised. (Thimineur et al., 2004). Two uncontrolled studies were also reviewed. Deer et al. (2004) reported data from the National Outcomes Registry for Low Back Pain. This registry was set up to prospectively collect data on patients with chronic low-back pain who underwent screening or a trial or an implanted pain pump. The other study was a prospective series using the Medtronic SynchroMed device (Anderson and Burchiel, 1999). There were other case series that had small sample sizes and/or did not mention whether a commercially available device was used. *Studies selected for critical appraisal were:*

Smith TJ, Staats PS, Deer T et al. for the Implantable Drug Delivery Systems (IDDS) study. Randomized clinical trial of an implantable drug delivery system compared with comprehensive medical management for refractory cancer pain. J Clin Oncol 2002; 20: 4040-4049. See Evidence Table. Thimineur MA, Kravitz E, Vodapally MS. Intrathecal opioid treatment for chronic non-malignant pain: a 3-year prospective study. Pain 2004; 109: 242-249. See Evidence Table. Deer T, Chapple I, Classen A et al. Intrathecal drug delivery for treatment of chronic low

Back to Top

back pain. Am Acad Pain Med 2004; 5: 6-13. See Evidence Table. Anderson VC, Burchiel KJ. A prospective study of long-term intrathecal morphine in the management of chronic nonmalignant pain. Neurosurg 1999; 44: 289-300 See Evidence Table.

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of malignant pain meets the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

10/18/2010: MTAC REVIEW
Implanted Pain Pumps for the Intrathecal Delivery of Opioids
Evidence Conclusion: This re-review of the implantable infusion pumps for delivering intrathecal opioids did not identify any studies that would change the conclusion from the 2007 MTAC review of the technology for the control of chronic noncancer pain (CNCP). There is still insufficient published evidence on the safety and effectiveness of the infusion pump for the control of CNCP and/or improving the QoL of the patients. The published studies for this indication were small case series and observational studies with no control groups. Comparisons were made between pre- and post-implant changes, not between differences among groups receiving different therapies or interventions. The studies had multiple threats to validity and may only provide low quality evidence; they are subject to selection and observation bias and did not take into account the placebo effect of the treatment or assess outcome for patients who had not received the therapy. Moreover, the studies did not compare characteristics of patients who completed the study to those who dropped out, did not adjust for the use of additional therapies or other confounding factors, and were funded by the manufacturer. Overall, the results of the published studies indicate a reduction in self-reported pain, reduction in oral morphine use, and /or improvement in quality of life and psychological function. However, there was a significant proportion of side effects associated with the implanted pump, the catheter, and the IT opioid use.

The Washington State Health Technology Assessment (HTA) program reviewed the implantable infusion pump for drug administration to treat chronic non-cancer pain, in August 2008. After reviewing the evidence, the Health Technology Clinical Committee (HTCC) concluded, “The evidence on infusion pumps did not demonstrate net health benefit because weak or unproven evidence of some effectiveness for certain patients was undermined by significant evidence of serious harms and adverse events associated with the implantation of infusion pumps. The committee found that infusion pumps were not proven to be equally or more safe or effective, and the cost, while not a significant factor for this decision was likely equivalent. Based on these evidentiary findings, the committee voted 8 to 2 for non-coverage.” Conclusion: There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is effective for the control of chronic non-cancer pain (CNCP).There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids improves quality of life and functioning in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is more effective than other non-invasive alternative therapies for pain control in patients with CNCP. There is insufficient published evidence to determine that the use of implanted infusion pumps for delivering intrathecal opioids is safe for use in patients with CNCP.
Articles: The available published literature on intrathecal (IT) opioid therapy delivered through implanted pumps for chronic noncancer pain is limited and consists of systematic reviews that did not pool the results in meta-analyses, small case series, and observational cohort studies with no control or comparison groups. The literature search did not identify any meta-analyses or randomized controlled trials that compared IT opioid therapy with other non-invasive therapies published since the 2007 MTAC review. There was one retrospective cohort study (Atli 2010) reporting on 3-years outcome of chronic pain patients receiving IT treatment through implanted pumps, one case series (Shaladi 2007) of 24 patients with osteoporotic vertebral fractures treated with intrathecal morphine infusion, and another series (Duse 2009) reporting on psychological functionality of 30 patients with CNCP. The larger cohort study with a long-term follow-up was selected for critical appraisal: Atli A, Theodore BR, Turk DC, et al. Intrathecal opioid therapy for chronic nonmalignant pain: a retrospective cohort study with 3-year follow-up. *Pain Medicine* 2010; 11:1010-1016. See Evidence Table.

The use of implanted pain pumps for the intrathecal delivery of opioids in the treatment of non-malignant pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
36260	Insertion of implantable intra-arterial infusion pump (eg, for chemotherapy of liver)
62360	Implantation or replacement of device for intrathecal or epidural drug infusion; subcutaneous reservoir
62361	Implantation or replacement of device for intrathecal or epidural drug infusion; nonprogrammable pump
62362	Implantation or replacement of device for intrathecal or epidural drug infusion; programmable pump, including preparation of pump, with or without programming
HCPC Codes	**Description**
C1772	Infusion pump, programmable (implantable)
C1891	Infusion pump, nonprogrammable, permanent (implantable)
C2626	Infusion pump, nonprogrammable, temporary (implantable)
E0782	Infusion pump, implantable, nonprogrammable (includes all components, e.g., pump, catheter, connectors, etc.)
E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
E0785	Implantable intraspinal (epidural/intrathecal) catheter used with implantable infusion pump, replacement
E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
11/23/1999	02/02/2010[MDCRPC], 12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013 [MDCRPC], 04/01/2014 [MPC], 02/03/2015 [MPC], 12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC] , 07/07/2020[MPC] , 07/06/2021[MPC], 07/05/2022[MPC] , 07/11/2023[MPC]	07/24/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
04/10/2017	Added Coverage Article A55323
07/07/2020	Removed CPT code 36563 and added 36260
09/01/2020	MPC approved to adopt updates to clinical criteria for non-Medicare. Indications added under spasticity and chronic pain sections. Requires 60-day notice, effective 02/01/2021.
04/03/2023	Updating Medicare links.
07/24/2023	Updated Medicare links.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intensity Modulated Radiation Therapy (IMRT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Intensity Modulated Radiation Therapy (IMRT) (L34080) – **RETIRED** 08/01/2020 Noridian retired Intensity Modulated Radiation Therapy (IMRT) (L34080). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34080 for determining medical necessity.
Local Coverage Article	Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245) **RETIRED** 11/01/2023 Noridian retired Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34080 and A58245 for determining medical necessity.

For Non-Medicare Members

Kaiser Permanente has elected to use the Intensity Modulated Radiation Therapy (IMRT) (KP-0455 06012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

If requesting this service, please send the following documentation to support medical necessity:

Back to Top

- Last 6 months of clinical notes from oncologist and radiation oncologist

***MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

Background

The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves its goal but leads to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70Gy to the prostate. This dose may be sufficient for many, but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells.

Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-dimension conformal radiotherapy (3D-CRT) is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue.

Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue.

The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates.

Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of inhomogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment.

Medical Technology Assessment Committee (MTAC)

Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer

BACKGROUND

Intensity-modulated radiation therapy (IMRT) is a type of external beam radiation therapy that permits complex three-dimensional shaping of the radiation beams to precisely target the tumor. This allows for a larger dose of

Back to Top

radiation to be applied to the tumor site, while minimizing exposure of the surrounding healthy tissue. Instead of a single, uniform beam as in traditional external beam radiation, IMRT involves the delivery of many small beams of varying intensity. Computer algorithms are used to coordinate the beams and plan the delivery of the radiation dose. Compared to other types of external beam radiation, IMRT is best able to generate concave dose distributions. Head and neck cancers may be particularly suited to treatment with IMRT because these tumors often have concave volumes and because head and neck tumors generally require relatively high doses (i.e. 60-70 Gy) of radiation and are in close proximity to critical tissues and organs that are radiation-sensitive (such as the salivary glands, inner and middle ears, temporomandibular joints, temporal brain and optic nerve). Head and neck cancers may also be good candidates for IMRT because of the relative lack of organ motion compared to other areas of the body. Due to the highly focused radiation dose, lack of motion is important. The most prevalent long-term adverse effect with radiation therapy for head and neck cancers is xerostomia (dry mouth) caused by damage to the salivary glands. This adverse effect may be reduced with IMRT. To date, several thousand patients worldwide have received IMRT treatment; so far, most of this has been for the treatment of prostate cancer. Several centers in the U.S. have been providing IMRT for head and neck cancer, most notably Washington University in St. Louis, the University of California, San Francisco (UCSF) and the University of Michigan (Cozzi & Fogliata, 2002). IMRT is a rapidly evolving technology that experienced clinicians believe will continue to evolve in the near future (Eisbruch, 2002).

04/09/2003: MTAC REVIEW
Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Evidence Conclusion: There is insufficient evidence to determine the effect of IMRT on health outcomes in patients with head and neck cancer compared to other types of radiation therapy. There is only one published comparative study with clinical outcomes, a retrospective cohort study. This study is limited because only 26 patients received IMRT (14 had post-operative IMRT and 12 had definitive IMRT). Although the findings suggest that there is a higher survival rate and lower rate toxicity rate with IMRT compared to other forms of radiation therapy, the statistics are unreliable due to the small number in the IMRT group. (Percentages are generally considered unstable when the sample size is less than 100). In the Lee case series, actuarial 4-year survival estimates were 98% for local-regional progression-free survival and 66% for distant metastasis-free survival. Two years after IMRT, 32% of patients had Grade I xerostomia and only 1 patient had Grade 2 xerostomia. In the Chao case series, the 2-year actuarial survival estimates was 85% for loco-regional control, (89% after salvage surgery). The case series were limited by lack of comparison groups, variable length of follow-up and inconsistent interventions (e.g. three different IMRT techniques were used over time in the Lee study, and in both case series, some patients had chemotherapy). In addition, each included a heterogeneous patient population in terms of cancer location and stage.
Articles: The search yielded 120 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedure or addressed treatment planning only. There were no randomized controlled trials comparing clinical outcomes after IMRT versus other forms of radiation therapy. There was one non-randomized comparative clinical study, a retrospective cohort study. The other empirical studies were all case series. The most recent case series from the three major institutions performing IMRT for head and neck cancer (Washington University, UCSF and the University of Michigan) were identified. Two of these institutions had published series of over 50 patients with head and neck cancer who had received IMRT. The comparative study and the two largest case series were critically appraised: Chao KSC, Majhail N, Huang C et al. Intensity-modulated radiation therapy reduces late salivary toxicity without compromising tumor control in patients with oropharyngeal carcinoma: A comparison with conventional techniques. *Radiother Oncol* 2001; 61: 275-280. See Evidence Table

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/01/2004: MTAC REVIEW
Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer
Evidence Conclusion: No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. The new literature does not substantially change the conclusions of the April 2003 MTAC review.
Articles: Medline was searched from 2003 to May 2004 using the terms, “intensity-modulated radiation therapy”, “IMRT”, and “head and neck cancer”, with variations. The search was limited to English language publication and human populations. No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. Lee N, Xia P, Quivey JM. Intensity-modulated radiotherapy in the treatment of nasopharyngeal carcinoma: An update of the UCSF experience. *Int J. Radiation Oncology Biol Phys* 2002; 53: 12-22. See Evidence Table Chao KSC, Ozyigit G, Tran BN et al. Patterns

Back to Top

of failure in patients receiving definitive and postoperative IMRT for head-and-neck cancer. *Int J Radiation Oncology Biol Phys* 2003; 55: 312-321. See Evidence Table

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

BACKGROUND

The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves this goal but may lead to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70 Gy to the prostate. This dose may be sufficient for many but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells. Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-dimension conformal radiotherapy (3D-CRT), is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue. Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue. The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates. Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of homogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment. IMRT for prostate cancer was previously reviewed by MTAC in April, 2002. At that time, the evidence consisted of case series on the toxicity of IMRT and the item failed MTAC evaluation criteria.

4/10/02: MTAC REVIEW

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

Evidence Conclusion: The studies reviewed aimed at determining the toxicity of the high-dose radiation delivered by IMRT. In both studies IMRT was not compared to a low dose conventional treatment, instead it was compared to 3D-CRT, which also uses a high dose irradiation, yet not modulated. Compared to 3D-CRT, IMRT was found to cause significantly lower acute, and late rectal toxicity in Zelefsky's study, and significantly higher acute rectal toxicity in the Shu study. In the two studies reviewed, there was no significant difference between the two treatments in the acute or late bladder toxicity. Both studies were not randomized and non-blinded, there were some variations in the base-line characteristics in the treatment groups, and no adjustments were made for confounding factors. Randomized controlled studies with long-term follow-up are needed to study the effect of IMRT on the outcome of the cancer, as well as the morbidity from the radiation.

Articles: The search yielded 55 articles most of which were reviews, case reports, editorials, and letters. The literature did not reveal any randomized controlled studies or meta-analyses.

It also did not reveal any study on the effect of IMRT on the outcome of the prostate cancer. There were 2 articles on studies made to determine the toxicity of IMRT, and compare it to 3D-CRT. *The following articles were critically appraised:* Zelefsky MJ, et al. Clinical experience with intensity modulated radiation therapy (IMRT) in prostate cancer. *Radiotherapy and Oncology* 2000;55:241-9. See Evidence Table Shu H G, et al. Toxicity following high-dose three-dimensional conformal and intensity modulated radiation therapy for clinically localized prostate cancer. *Urology* 2001;57:102-7. See Evidence Table

Back to Top

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

2/11/04: MTAC REVIEW
Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer
Evidence Conclusion: The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates. Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group. The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates. Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group.
Articles: The search yielded 102 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedures or were on related procedures. There were no randomized controlled trials. There were three new case series publications by the Memorial Sloan-Kettering Cancer Center research group (led by Zelefsky). The patients included in the three publications overlapped. Two of the articles also included patients who were treated with 3D-CRT, but IMRT and 3D-CRT were not compared in analysis. The Zelefsky case series with the largest number of IMRT cases was critically appraised. In addition, there was a study conducted at the Cleveland Clinic which compared series of patients treated with short-course IMRT and 3D-CRT. There were no studies comparing IMRT to lower dose conventional radiotherapy. *The studies reviewed were:* Zelefsky MJ, Fuks Z, Hunt M et al. High-dose intensity modulated radiation therapy for prostate cancer: Early toxicity and biochemical outcome in 772 patients. *Int J Radiation Oncology Biol Phys* 2002; 53: 1111-1116. See Evidence Table Kuplian PA, Reddy CA, Carlson TP. et al. Preliminary observations on biochemical relapse-free survival rates after short-course intensity-modulated radiotherapy (70Gy at 2.5Gy/Fraction) for localized prostate cancer. *Int J Radiation Oncology Biol Phys* 2002; 53: 904-912. See Evidence Table.

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
HCPC Codes	**Description**

Back to Top

G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/22/2003	07/02/2013[MPC] 05/06/2014[MPC], 03/03/2015[MPC], 07/07/2015[MPC], 01/05/2016[MPC],11/01/2016[MPC], 09/05/2017[MPC], 07/10/2018[MPC], 07/09/2019[MPC], 07/07/2020[MPC], 07/06/2021[MPC], 07/05/2022[MPC], 07/11/2023[MPC], 04/02/2024[MPC]	01/10/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/07/2015	MPC approved to reinstate IMRT criteria for medical necessity review. New criteria effective date 11/2015.
09/08/2015	Revised LCD Intensity Modulated Radiation Therapy (IMRT) L34251 and L34080
03/01/2016	Added indication to policy
11/01/2016	MPC approved revised indication for lung cancer
12/05/2017	MPC approved new indication for esophageal cancer
07/07/2020	Added Medicare LCA (A57231); removed deleted CPT code 77418
03/02/2021	MPC approved to expand coverage to the IMRT criteria by including additional indications for coverage which include Cholangiocarcinoma, Gallbladder carcinoma, Gastric cancer, Hepatocellular carcinoma, Liver metastases, Lymphoma with mediastinal involvement, in proximity to lung and heart, Pancreatic cancer; Breast Cancer will still require MD review. Requires 60-day notice, effective date 08/01/2021.
01/10/2023	MPC approved to adopt the revised changes the IMRT criteria to include indications for Breast Cancer (APBI). Requires 60-day notice effective 06/01/2023.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Infertility Services

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

Non-Medicare Members

For baseline policy for all plans, click here to view the criteria. *(Internal use only)*
*Individual groups may provide additional benefits or exclusions – see current coverage agreement or contact member services for specific exceptions and limitations.

Based on Kaiser Permanente policy, a member is considered infertile if they are unable to conceive or produce conception:

- After 1 year of frequent, unprotected heterosexual sexual intercourse for members 35 and under
- After 6 months of frequent, unprotected heterosexual sexual intercourse if the female partner is over age 35 years.
- Alternately, a woman without a male partner may be considered infertile if she is unable to conceive or produce conception after at least 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older).
  - The initial 12 trials of medically supervised donor insemination (6 cycles for women aged 35 or older) to establish an infertility diagnosis, are not covered under the infertility benefit.
- A member is not considered “infertile” if they have had a voluntary sterilization (e.g. tubal ligation, vasectomy). Infertility treatment post-voluntary sterilization is not covered, even if the plan has an SI rider.

As of 1/1/2022, the following plans waived the requirement for a diagnosis of infertility but may still require prior authorization or clinical review based on individual benefits and plan riders.
Association of Washington Cities (AWC)
Boeing
City of Seattle
Meta (Facebook) – for cryopreservation only
SEIU

For *only* Kaiser Permanente Individual & Family (I&F) and Small Business Group (SBG) contracts

In addition to base infertility/sterility services listed in the Infertility and Sterility policy, member is eligible for:

Back to Top

Date Sent: 4/29/24

- Tubal patency/uterine irregularities- HSG (radiology)
- TSH, prolactin (lab)
- Testing for Ovarian reserve –Day 3 FSH. (lab)
- Semen analysis (if member has Kaiser coverage) (lab)
- Member must use in-network lab

If requesting these services, please send the following documentation to support medical necessity:

• Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Infertility is a common problem. According to the Centers for Disease Control and Prevention (CDC), about 10 percent of U.S. women ages 15 through 44 years have difficulty getting pregnant or staying pregnant.[1]

Both women and men can have problems that cause infertility. About one-third of infertility cases can be connected to the woman. Another third of the cases of infertility can be connected to the man. In the remainder of instances, a cause can't be found.

Applicable Codes

Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.

To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.

Creation Date	Review Date	Date Last Revised
1/25/2019	02/05/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	12/16/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt coverage for KP I&F and SBG plans
06/04/2019	Added SEIU has no requirements regarding: age, duration of time, or gender per SEIU contract
05/05/2020	Information regarding the SI-AO rider for SIEU cryopreservation (Effective 8/1/2020) was added
01/04/2022	Added definition of infertility from KP policy document. Listed groups that are no longer requiring a diagnosis of infertility for members to access benefit as of 01/01/2022.
12/16/2022	Updated criteria to include indication for, *"A member is not considered "infertile" if they have had a voluntary sterilization."*

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Infrared Thermography

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Thermography (220.11). *This service is not covered per Medicare criteria*.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Effective until August 1st, 2024

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective August 1st, 2024

Infrared Thermography will be reviewed using the Medically Necessary Services medical policy

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Infrared thermography is a non-invasive imaging procedure. It produces representations of variation in temperature on the surface of the human skin. Distribution of skin temperature depends on complex relationships between the skin tissue, inner tissue, local vasculature and metabolic and hormonal activity. Use of thermography as a diagnostic tool is based on the premise that the abnormal issue, such as a tumor, would raise the temperature on the skin surface due to increased metabolic activity. In the 1950s and 60s, researchers found that local skin temperatures over a breast tumor were about 2-3 degrees higher than normal skin temperature.

Although, over the past several decades, there has been experimentation with protocols for obtaining and interpreting thermograms, to date there no established procedures for using thermography to enhance diagnosis of breast cancer or other abnormalities (Mital & Scott, 2007; Ohashi & Uchida, 2000). Among the conditions for which thermography has been proposed are Raynaud's phenomenon, gastric cancer, headaches, deep vein thrombosis, and impaired spermatogenesis in infertile men.

Several thermography devices have been approved by the FDA, including the Mark I Thermal Imager (IX-DR; Howell, MI) in 2002 and EMD Thermography System in 2006. The EMD Thermography system includes an infrared sensor that is placed in contact with the skin to measure temperature. In addition, special software is used to analyze and display the temperature measurements.

Back to Top

Both recently approved devices were considered to be substantially equivalent to predicate devices. Approval was based on the technology's ability to measure skin temperature, rather than their proven ability to improve diagnosis of any disease. According to FDA documents, thermography is indicated for use as an adjunctive medical imaging modality in situations where a physician chooses to use it.

Medical Technology Assessment Committee (MTAC)

Infrared Thermography

06/04/2008: MTAC REVIEW

Evidence Conclusion: There is no empirical evidence that adjunctive infrared thermography improves the diagnosis of any disease or abnormality.

Articles: No technology assessments conducted by other organizations were identified. The Medline search did not yield any empirical studies that evaluated the diagnostic accuracy of thermography as an adjunctive diagnostic modality for any indication. Several articles were identified that proposed methods for analyzing thermograms or discussed technical aspects of using thermography.

The use of infrared thermography does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
93740	Temperature gradient studies

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
07/17/2008	05/03/2011 MDCRPC, 03/06/2012 MDCRPC ,01/08/2013 MDCRPC ,11/05/2013 MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC,12/07/2021MPC,12/06/2022MPC, 12/09/2023MPC, 03/12/2024MPC	03/12/2024

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
03/12/2024	MPC approved to archive criteria & move to Medically Necessary Services effective August 1st, 2024. Requires 60-day notice.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
InFUSE™ Bone Graft
Bone Graft Substitutes & Adjuncts

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "**InFUSE™ Bone Graft**," for medical necessity determinations. Use the Non-Medicare criteria below.

See reference: Technology Assessment for Spinal Fusion for Treatment of Degenerative Disease Affecting the Lumbar Spine

For Non-Medicare Members

Service	Criteria
InFUSE™ Bone Graft/LT-CAGE™ Lumbar Tapered Fusion Device (Bone Morphogenetic Protein-2)	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.
Bone Graft Substitutes & Adjuncts	The following Bone Graft Substitutes & Adjuncts but not limited to are considered experimental and investigational, therefore are not covered: • Celling Biosciences Solum IV allograft • Cerament® • ChronOS bone graft substitute • Equivabone® Graft • Healos Sponge • Healos® bone graft replacement • i-FACTOR™ Peptide-enhanced bone graft • InterGro® DBM Fibers • Optium® DBM putty • OsteoAmp® • Osteofuse®

Back to Top

	• OSTEOMATRIX+ Arthrex Quickset™ • OsteoVive® • TrueFuse • Vivex (Amendia) • Vivigen Formable® • Vivigen® ***Note:*** Products listed above are considered experimental and investigational, this is not an exhausted or comprehensive list

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Degenerative disc disease (DDD) resulting from wear and tear of the discs between vertebrae can lead to a painful condition that may require spinal fusion (arthrodesis) of the vertebrae on both sides of the degenerative disc. Spinal arthrodesis was introduced over a century ago for treating vertebral fractures, spinal tuberculosis, tumors and severe scoliosis. These indications were later expanded to include spondylolisthesis, spondylosis, intervertebral disc disorders, and discogenic low back pain. Spinal interbody fusion restricts the unstable spinal motion segment and may provide relief from the pain associated with DDD, when all other methods have failed. It involves the removal of the degenerated intervertebral disc and fusion of the adjacent vertebral bodies. This can be achieved through an anterior approach (anterior lumbar interbody fusion or ALIF), posterior fusion (PLIF), or transforaminal approach (TLIF) (Blumenthal 1988, Baskin 2003, Glassman 2005, Papakostidis 2008, Fu 2013, Skovrlj 2014, Noshchenko 2014, Bodalia 2016, Hofstetter 2016).

Vertebral fusions usually use graft material to stimulate the fusion. For decades autogenous iliac crest bone (ICB) has been, and is still considered, the gold standard bone grafting material for its superior osteoinductive and osteogenic properties. However, its harvest may be associated with postoperative complications including persistent pain from the donor site, deep infection, scarring, and other donor site morbidity. Another limitation of using iliac crest bone graft (ICBG) is the relative inadequate supply of graft tissue for multilevel fusions. Spine surgeons have thus been looking for alternative methods to promote spinal fusion. A variety of bone graft materials and substitutes such as local bone, bones from bone banks, demineralized bone matrix, synthetic grafts, platelet gels, and other materials have been introduced into clinical practice, but did not prove to be as effective as ICBG (Blumenthal 1988, Baskin 2003, Glassman 2005,papakostidis 2008, Fu 2013, Skovrlj 2014, Noshchenko 2014, Bodalia 2016, Hofstetter 2016).

Bone morphogenetic protein (BMP), a prototypical osteoinductive protein, was first described by Marshall Urist in 1965. BMPs are members of the superfamily of transforming growth factor-beta and play an important role in embryonic development including bone formation. In the late 1990s recombinant human bone morphogenetic protein type 2, a genetically engineered osteoinductive protein, was tested for use in lumbar fusion among humans in preclinical and clinical studies (Zhang 2014, Hofstetter 2016).
InFUSE® Bone Graft (Medtronic Sofamor Danek, Memphis, TN) is a recombinant human bone morphogenetic protein type-2 (rhBMP-2) applied to an absorbable collagen sponge (ACS) carrier that localizes the protein at the site of implantation and provides a scaffold for the formation of the new bone. The sponge is manufactured from bovine Type I collagen and is designed to resorb over time. InFUSE® Bone Graft is used in conjunction with a proprietary small thimble like titanium lordotic tapered cage (LT-Cage) implant, which is intended to restore the degenerated disc space to its original height. The LT-Cage Devices come in multiple sizes (from XX Small to Large II) to match various patient anatomies. The InFUSE® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device is implanted through an open or laparoscopic anterior surgical approach. The bone graft is prepared immediately prior to its use during surgery*; the protein solution is soaked into the sponge, which is then inserted into the LT-Cage. After removing the contents of the disc space, two devices are implanted side by side in the prepared intervertebral disc space. The fusion cage maintains the spacing and temporarily

 Back to Top

stabilizes the diseases region of the spine while the InFUSE® Bone Graft induces new bone tissue at the site of implantation to fuse this portion of the spine. The fusion process requires several months to complete (Baskin 2003, Glassman 2005, Medtronic website accessed 2017)

*Once prepared, the INFUSE® Bone Graft contains rhBMP-2 at a concentration of 1.5 mg/mL

In 2002, the US Food and Drug Administration (FDA) approved the use of InFUSE® Bone Graft for anterior interbody fusion as an alternative to the iliac crest bone graft for use in conjunction with lordotic tapered cages (LT-CAGE) lumbar fusion device. According to the FDA, the device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at a single level from L4-S1. Patients should have had at least six months of nonoperative treatment prior to treatment with the Infuse Bone Graft. Later the FDA approved rhBMP-2 with other interbody fusion devices (INTER FIX™ Threaded Spinal Fusion Device and INTER FIX™ RP Threaded Fusion Device) also manufactured by Medtronic.

InFUSE® Bone Graft is contraindicated in patients who are pregnant, who may be allergic to any of the materials contained in the device, have in infection in the area of the incision, are skeletally immature, or with an existing or removed tumor in the area.

Medical Technology Assessment Committee (MTAC)

InFuse Bone Graft

10/08/2003: MTAC REVIEW

Evidence Conclusion: The trial reviewed does not provide sufficient evidence to conclude that InFUSE Bone Graft is equivalent or superior to the standard treatment. It was randomized and controlled; yet the authors compared improvements associated with the InFUSE Bone Graft with the preoperative condition, and not with the standard treatment. The trial shows that both treatments led to significant improvement in the back pain, leg pain, as well as pain associated with activity when compared to the preoperative scores. The two procedures were also associated with post-operative vs. baseline, high neurological success, patient satisfaction and bone fusion. The authors noted that the success rates and pain scores were similar between the two groups, based on the values observed and not on statistical tests of significance. It seems unlikely that there are any significant differences between the two groups, as the numbers, and scores are close. This may suggest that the effect of the two treatments may be similar, but the study isn't conclusive as it may have been underpowered to detect a difference and was not designed as an equivalence trial that requires a larger sample size, and a different method of analysis than superiority trials.

Articles: The search revealed 4 randomized controlled studies and one case series. Three of the RCTs were conducted by the same principle investigator and included patients from the same center: one large trial with 279 patients, and two smaller RCTs with 46, and 42 patients. The other trial revealed included only 14 patients. The search also revealed an article where the same principle investigator of the three RCTs pooled data form his trial as well as other 3 unpublished studies, two of which were non-randomized. It had a poor methodology and cannot be categorized as a meta-analysis. The largest of the three RCTs conducted by the same investigator group was selected for critical appraisal. *The following study was critically appraised:* Burkus JK, Gornet MF, Dickman CA, et al. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. J Spinal Disord Tech. 2002; 15:337-49. See Evidence Table.

The use of recombinant human bone morphogenetic protein (rhBMP-2) placed on an absorbable collagen sponge (ACS) in the treatment of degenerative disc disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/07/2009: MTAC REVIEW

InFuse Bone Graft

Evidence Conclusion: There is a lack published material on the use of InFUSE Bone Graft for anterior lumbar interbody fusion, the indication for which the technology received the FDA approval. Glassman and colleagues' trial (2008) had the advantage of comparing rhBMP-2 to iliac crest bone graft in a randomized controlled trial with 2-year follow-up duration. However, the technology was used off-label for a posterolateral lumbar fusion among patients older than 60 years of age. Moreover, the trial was not blinded, and the authors did not discuss the method of randomization, or clearly describe the inclusion/ exclusion criteria. Non-blinding may be a source

Back to Top

of observation bias, especially with the subjective primary outcomes of the trial. The investigators tried to partially overcome this limitation by blinding the orthopedic surgeons who evaluated the radiological outcomes. The authors also did not discuss any power analysis for determining the sample size, and analysis was not based on intention to treat. Overall, the results of the trial show significant improvements in health-related quality of life, as well as the leg, and back pains at one and two years of follow-up among the patients in the two treatment groups, when compared to the preoperative status. There were no significant differences in the primary outcomes between the two interventions. The outcomes may appear similar, but the lack of significant statistical significance does not necessarily imply equivalence. The study was relatively small and might have been unpowered to detect significant differences between the study groups. It was not designed as an equivalence trial that requires a larger sample size and different method of analysis than a superiority trial. Radiographic evaluations at two years showed higher fusion rate with rhBMP-2 vs. ICBG (86.3% and 70.8%, respectively). In conclusion there is insufficient published evidence to conclude that InFUSE Bone Graft is equivalent, noninferior, or superior to the standard iliac crest bone graft in improving functional ability and quality of life of patients with symptomatic degenerative disc disease.
Articles: The search revealed over 30 articles on rhBMP-2 /InFUSE Bone Graft. Many were unrelated to the current reviews; others used rhBMP-2 in different formulations or in combination with other elements e.g. ceramic granules. Two articles (Glassman, et al 2005 and 2008) reporting on one- and two-years results of a randomized controlled study comparing the use of rhBMP-2 versus iliac crest bone graft (ICGB) for lumbar spine fusion, were identified as well as a small nonrandomized trial and two case series studies on the use of InFUSE Bone Graft. The RCT with the 2-year follow-up was selected for critical appraisal. Glassman SD, Carreon LY, Djurasovic M, et al. RhBMP-2 versus iliac crest bone graft for lumbar spine fusion: A randomized, controlled trial in patients over sixty years of age. Spine. 2008; 33:2843-9. See Evidence Table.

The use of recombinant human bone morphogenetic protein (rhBMP-2) placed on an absorbable collagen sponge (ACS) in the treatment of degenerative disc disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/21/2017: MTAC REVIEW
InFuse Bone Graft
Evidence Conclusion: As indicated in the previous section, the literature search did not identify any more recent RCTs evaluating InFUSE® Bone Graft for ALIF, but a number of qualitative reviews and quantitative meta-analyses of the published trials. All trials were open-label, the great majority was industry sponsored, and the principal authors had financial ties with the industry.
Efficacy and safety of InFUSE® Bone Graft compared to the gold standard autogenous iliac crest bone graft (ICBG) Carragee and colleagues (2011) conducted a systematic review and critical analysis of the original peer reviewed industry-sponsored publications and compared their results and conclusions versus the available FDA summaries, follow-up publications, and administrative and organizational database analyses. According to the authors, the systematic review was prompted by complaints to the editorial board of the *Spine Journal* including allegations of research bias, failure to report adverse event recorded by the study surgeons, and discrepancies between FDA summaries and published data. The authors reviewed the results of 13 original industry-sponsored rhBMP-2 publications regarding safety and efficacy, including reports and analyses of 780 patients receiving rhBMP-2 within prospective controlled study protocols. These included studies using anterior, posterior and posterolateral interbody fusion. The estimated rate of adverse events associated with rhBMP-2 use in spinal interbody fusion ranged from 10% to 50% depending on the approach and spinal level of fusion.

- Anterior interbody lumbar with rhBMP-2 was associated with higher rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation versus the controls.
- Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.
- In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events. Higher doses of rhBMP-2 were associated with a greater apparent risk of new malignancy.
- Anterior cervical fusion with rhBMP-2 had an estimated 40% greater risk of adverse events in the early postoperative period including life-threatening events.

The authors provided evidence showing discrepancy between the FDA documents and the published results of industry-sponsored trials on rhBMP-2. He noted that while the authors of the industry sponsored trials on ALIF,

 Back to Top

reported no adverse events, the FDA concluded that the original data form the trials indicate that “The incidence of adverse events that were considered device related, including implant displacement/loosening, implant malposition and subsidence were all greater in the investigational [rhBMP-2] groups compared to the control group” (Carragee 2011). Carragee and colleagues summarized the areas of concern regarding the safety and efficacy reported by the industry sponsored trials as follows:

1. Underestimation of adverse events and serious harms associated with rhBMP-2.
2. Presence and magnitude of conflict of interest and potential for reporting bias.
3. Invalid assumption and methodology used for estimating adverse events associated with iliac crest bone grafts, which led to exaggeration of the benefits underestimating the morbidity of rhBMP-2.
4. Significant bias against the selection of the control and techniques used in the PLIF and PLF.

The reviewers concluded that Level I and Level II evidence from original FDA summaries, original published data, and subsequent studies suggest possible study design bias in the original trials, as well as a clear increased risk of complications and adverse events to patients receiving rhBMP-2 in spinal fusion. This risk of adverse events associated with rhBMP-2 is 10 to 50 times the original estimates reported in the industry-sponsored peer-reviewed publications. Fu and colleagues, 2013 (Evidence Table 1) performed a meta-analysis to evaluate the effectiveness and harms of rhBMP-2 in spinal fusion and to assess the reporting bias in industry sponsored journal publications. The authors used data from the literature and individual patient level data of the rhBMP-2 trials (including unpublished data from the trials) provided by the manufacturer through the Yale Open Data Aces (YODA) Project. The latter project was sponsored by the manufacturer for an independent review of all published and unpublished data. The analysis included=13 RCTs (12 sponsored by Medtronic) and 31 cohort studies, 47 intervention series, and 35 case series or reports. The primary outcome was the overall success and fusion. The meta-analysis had generally valid methodology, and the studies included were rated by the authors to be of moderate quality. However, all were unblinded; industry sponsored, and according to the authors, had poor ascertainment of harm. The authors analyzed anterior and posterior fusion separately as well as cervical and lumbar fusion. The pooled results of studies comparing rhBMP-2 versus ICBG for ALIF, showed no significant differences in overall success except for very slight improvement in leg pain at 6 weeks with rhBMP-2. There were higher rates to urogenital complications and retrograde ejaculation with rhBMP-2, the difference was not significant but could be due to insufficient power. The cancer risk was significantly higher with rh-BMP-2. The authors of the meta-analysis noted that early journal publications misrepresented the effectiveness and harms through selective reporting, under-reporting, and duplicate publications. They concluded that their technology had no proven advantage over bone graft and may be associated with important harms. Simmonds et al, 2013 meta-analysis (Evidence Table 2) also used data from the YODA project to evaluate the safety and effectiveness of rhBMP-2 compared to ICBG. The analysis included 12 RCTs (11 Medtronic sponsored) for effectiveness plus 35 additional controlled adverse events studies for safety analysis. The primary outcomes were patient centered pain and function, fusion and adverse events. The results of the analysis showed that from 6 months after surgery up to 2-years, rhBMP-2 led to greater pain reduction compared to ICBG. The authors noted however; the difference may not be clinically significant as patients in both treatment groups experienced considerable reduction in pain. Successful fusion rates were found to be higher with rhBMP-2 but there was significant heterogeneity between studies in the relative risk of fusion, and the authors noted that Medtronic definitions of fusion may have been stringent as only 69% of ICBG recipients achieved fusion in 24 months. The authors found no correlation between successful fusion with rhBMP-2 and pain reduction. As regards safety, the analysis showed that pain (which was reported as an outcome and as an adverse effect) was significantly higher with rhBMP-2 shortly after surgery and lower at 24 months, compared to ICBG. Other adverse events including Implant-related events, neurologic events, retrograde ejaculation, vascular events, wound complications, and cancer, all occurred at a higher rate with rh-BMP-2, but the difference did not reach a significant level, which could be attributed to the small number of events. Zhang and colleagues, 2014 (Evidence table 3) conducted a meta-analysis of randomized controlled trials to compare the effectiveness and safety of fusion with BMPs (-2 or -7) versus ICBG for the treatment of degenerative lumbar conditions. The analysis included 19 RCTs involving 1,852 patients. The studies recruited patients with a variety of spinal disorders and different approaches were used for the fusion. In 14 of the 19 trials rhBMP was used off-label. The co-primary outcomes of the analysis were solid fusion rate, clinical outcomes, complications, and reoperation rate. The pooled results showed that the rate of fusion was significantly higher among patients in BMPs group; however, this difference was no longer significant with the sensitivity analysis that excluded 7 studies with high risk of bias. There were statistically significant differences in the overall success of clinical outcomes, complication rate, blood loss, hospital stay, patient satisfaction, or

 Back to Top

work status. Significant reductions in the operating time and reoperation rate were found in BMPs. This was a high-quality meta-analysis as regards its methodology, analysis and grading the evidence for each outcome. However, the quality of the results of a meta-analysis relies heavily on the quality of the studies it includes. Due to the nature of the intervention, all published trials evaluating rh-BMP-2 were unblinded, which is a source of bias, especially with subjective outcomes. In addition, there were other limitations to the published studies regarding methods of randomization and allocation procedures. There were variations between the trials in BMP used and the approach for fusion as well the methods and standards used for assessing the bone fusion which. The studies included in the meta-analysis used plain radiography, CT scan, or surgical exploration for evaluating the fusion rate. The authors explained that imaging was used to assess the status of spinal fusion, and that it provides less accurate data compared to direct operative exploration. In addition, the majority of the studies were industry sponsored and some of the authors reported conflict of interest. Overall, the authors concluded that the limited evidence does not show that BMP is superior to ICBG for the treatment of lumbar DDD and that more high-quality trials with long-term outcomes are needed. Other published meta-analyses (Chen, 2012 and Noshchenko, 2014) included the same industry sponsored RCTs, and had similar results showing that rhBMP-2 may lead to slightly higher fusion rates compared to ICBG, but with possible harm and no significant clinical improvement. **Impact of patient characteristics on the effectiveness and harms of rhBMP-2 compared with ICBG.** Laurie and colleagues' (2016) meta-analysis used the data from the YODA project to examine the impact of patient characteristics on the effectiveness and harms of rhBMP-2 as compared with ICBG. The analysis included 10 industry sponsored RCTs involving 1,255 participants. 5 trials used the anterior lumbar approach, 4 used the posterior lumbar, and one used the posterolateral lumbar approach for the interbody fusion with rhBMP-2. The population sizes of the individual trials varied from 10 to 463 participants. The results of the analysis suggest that there may be a differential treatment effect between rhBMP-2 and ICBG according to some patient characteristics. Fusion success was found to be higher with rhBMP-2 vs. ICBG in patients under the age of 60 at 6 months after the surgery and among smokers and normal weight individuals at 24 months postoperatively. No significant differences were observed between the two procedures for overweight or obese patients. The analysis also showed that the rate of device-related adverse events with rhBMP-2 was lower in individuals with no previous back surgery. **Impact of rh-BMP-2 dosing on outcomes** The BMP dose varied widely among the published studies which may indicate that is uncertainty regarding the optimal dose for the spinal fusion procedures. Hofstetter and colleagues' meta-analysis (2016) examined the effect of BMP dosing on successful fusion and morbidity with the common fusion procedures. The analysis included 48 articles involving 5,890 patients. 9 trials were on ALIF, 17 on transforaminal or posterior lumbar interbody fusion (TLIF/PLIF), 7 on anterior cervical discectomy and fusion (ACDF), and 9 trials on posterior lumbar fusion (PLF) supplemented with BMP. The authors performed separate meta-analyses for each procedure. The results of the analyses suggest that there is a wide range in the BMP dosing used for specific spinal fusion procedures (from 2.5mg/level for posterior cervical fusion [PCF] to 10.5mg/level in ACDF). The meta-analysis of studies on ALIF showed a trend toward an association between the likelihood of complications and the dose of BMP. In reports of ALIF supplemented with high doses of BMP (4.3-12.0 mg/level) the rates of endplate resorption and graft subsidence were high. More studies are needed to determine the safe and effective BMP dosing for the different applications.

Conclusion:

- The published literature does not provide sufficient evidence to determine that rh-BMP-2 has superior or equivalent effectiveness and safety compared standard iliac crest bone graft for adult patients with symptomatic lumbar degenerative disc disease referred to anterior interbody lumbar fusion.
- A number of meta-analyses and systematic reviews, including those using data from the Yale University Open Database Project, suggest that spinal interbody fusion using InFUSE® Bone Graft had a small or no advantage when compared to the standard use of iliac crest bone graft (ICBG), and may be associated with more serious adverse events.

Articles: The updated literature search did not reveal any recent trials that examined the efficacy and safety of using InFUSE® Bone Graft for anterior lumbar interbody fusion (ALIF) in patients with symptomatic single level degenerative disc disease from L1-L4. There was a number of systematic reviews with or without meta-analyses as well as several retrospective analyses on the effectiveness and safety of rhBMP-2 for spinal fusion. There were more publications and studies on the use of InFUSE® Bone Graft for cervical interbody fusion, or using the posterior, lateral, or posterolateral approaches for lumbar interbody fusion, all of which are off-label use of InFUSE® and out of scope for the current review. Two meta-analyses that included individual patient data of the rhBMP-2 trials provided by the manufacturer through the Yale Open Data Access (YODA) project, as well as

 Back to Top

another meta-analysis of published trials were selected for critical appraisal. Fu R, Selph S, McDonagh M, et al. Effectiveness and harms of recombinant human bone morphogenetic protein-2 in spine fusion: a systematic review and meta-analysis. *Ann Intern Med*. 2013 Jun 18; 158(12):890-902. Simmonds MC, Brown JV, Heirs MK, et al. Safety and effectiveness of recombinant human bone morphogenetic protein-2 for spinal fusion: a meta-analysis of individual-participant data. *Ann Intern Med.* 2013 Jun 18; 158(12):877-889. Zhang H, Wang F, Ding L, Zhang Z, et al. A meta-analysis of lumbar spinal fusion surgery using bone morphogenetic proteins and autologous iliac crest bone graft. *PLoS One.* 2014 Jun 2; 9(6): e97049.

The use of the InFUSE® Bone Graft/LT-Cage® Lumbar Tapered Fusion Device for Anterior Lumbar Interbody Fusion (Recombinant Bone Morphogenetic Protein Type 2 [rhBMP-2]) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary for InFUSE™:

CPT® Codes	Description
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
10/08/2003	10/08/2003 MPC, 12/07/2009 MPC, 07/07/2015MPC, 05/03/2016MPC, 06/07/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC , 10/05/2021MPC, 10/02/2022MPC , 10/03/2023MPC	12/06/2022

MPC Medical Policy Committee

Revision History	Description
08/01/2017	Added MTAC second review
07/24/2020	Added code 20930 to criteria
12/06/2022	MPC approved to adopt a non-covered list of bone grafts substitutes and adjuncts. No 60-day notice required.

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Inhaled Nitric Oxide (iNO) Therapy

Criteria

For Non-Medicare Members

A. Treatment of pulmonary hypertension (PHN) to reduce risk of chronic lung disease, and respiratory failure in infants born or at near term (>34 weeks)
   1. Neonate does not have congenital diaphragmatic hernia, and
   2. Conventional therapies such as administration of high concentrations of oxygen, hyperventilation, high-frequency ventilation, the induction of alkalosis, neuromuscular blockade, and sedation have failed or are expected to fail.
   3. Treatment of Congenital Diaphragmatic Hernia (CDH)
      a. iNO is required to stabilize a patient during transition to ECMO (Usually required for a few hours before)
      b. iNO is required during transition off of ECMO when pulmonary arterial pressures are high (this can be a period of time ranging from hours to several days)

B. Treatment of pulmonary hypertension in pre-term newborns (≤34 weeks)
   There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

C. Treatment of acute respiratory distress syndrome (ARDS) in adults and children
   There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

D. Treatment of Cyanotic Congenital Heart Disease with pulmonary hypertensive crisis (all pediatric patients)
   1. The patient is being managed for acute pulmonary hypertension crisis and acute right heart failure with a predisposition to unrestricted over-circulation. OR
   2. The patient requires a surgical intervention with increased risk of pulmonary hypertension crisis and is receiving pulmonary vascular therapy AND
      a. Typical course of treatment 3 days (this may be longer on a case by case basis) to transition to oral medications and wean-off iNO OR
      b. The patient needs transplant for right heart failure and requires iNO for 1 week to several months.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term.

Persistent pulmonary hypertension of the newborn (PPHN) is an important cause of cardiorespiratory failure in the near-term neonate (>34 weeks). It occurs when normal cardiopulmonary transition fails to take place after birth; the newborn's arteries to the lungs remain constricted limiting the amount of blood flow to the lungs and therefore

Back to Top

Date Sent: 4/29/24

the amount of oxygen into the blood stream. PPHN can occur either as a primary condition of neonatal maladaptation or secondary to other conditions such as pneumonia, sepsis, hyaline membrane disease, meconium aspiration, congenital diaphragmatic hernia, or pulmonary hyperplasia. Causes of PPHN may be variable, but all lead to same physiologic changes; a persistently raised pulmonary vascular resistance that leads to severe hypoxemia due to extra pulmonary shunting. Even with appropriate therapy, the mortality for PPHN remains between 5 and 10% (Gonzales 2009, Finer 2009, Steinhorn 2010).

The goal of therapy of PPHN is to maximize the amount of oxygen transported to the lungs and in turn to the systemic circulation. Conventional therapies include supplemental oxygen with often requires intubation and mechanical ventilation, induction of alkalosis, paralysis, sedation, as well as maintenance of temperature, electrolytes, glucose, and intravascular volume. Infants who fail conventional therapies may require treatment with extracorporeal membrane oxygenation (ECMO). During ECMO, the jugular vein and/or carotid artery is surgically bisected and connected to a heart-lung machine with a cannula to oxygenate the infant's blood. ECMO therapy can be lifesaving, but is highly invasive, labor intensive, and has potential side-effects such as intracranial hemorrhage and ligation of the right common carotid artery (Steinhorn 2010).

Inhaled nitric oxide (iNO) has been investigated for the treatment of PPHN to improve oxidation, reduce the need for ECMO, and decrease mortality. Nitric oxide is a colorless, almost odorless gas that is naturally produced by various human tissues and is involved in several physiologic functions. It is a rapid and potent vasodilator, and because of its small gas molecule, it can be delivered as inhalation therapy to airspaces in close proximity to the pulmonary vascular bed. Once in the blood stream NO binds to hemoglobin and is rapidly inactivated with an estimated half-life of 3-5 seconds. The effect of iNO is limited to the lungs making it a selective pulmonary vasodilator without adverse systemic hemodynamic effect (DiBlasi 2010, Steinhorn 2010).

iNO therapy is not without harmful side effects. When oxygen and nitric oxide mix together, they chemically react to form nitrogen dioxide (NO2), which is toxic to the lungs. Nitrogen dioxide concentrations greater than 10 parts per million (ppm) have been known to induce pulmonary edema, alveolar hemorrhage, changes in the surface tension properties of surfactant, and death. NO2 is dose- dependent and its concentrations should be maintained below 3 ppm by decreasing the iNO concentration if its level increases. Methemoglobinemia (MetHb), which impairs the ability of the hemoglobin molecule to bind with oxygen, is another harmful side effect of iNO therapy. MetHb is dose-dependent and its levels must be carefully monitored. Significant methemoglobinemia has been reported after accidental overdose of iNO, and a level >10% may cause cyanosis, headaches, muscle weakness, and tissue hypoxia. Laboratory and clinical studies have suggested that high doses of inhaled nitric oxide may increase the risk of bleeding, which is a serious concern because of the predisposition of premature newborns to intracranial hemorrhage (Kinsella 2006, Finer 2009, Henry 2012).

The recommended initial dose of iNO is 20 ppm, and the duration of its use is normally less than 5 days but may be maintained for up to 14 days, or until the underlying oxygen desaturation has been resolved. Abrupt discontinuation of the therapy can lead to worsening of PaO2 and increasing pulmonary artery pressure. The use of iNO was approved by the Food and Drug Administration (FDA) in 1999 for the treatment of term and near-term neonates (>34 weeks) with hypoxic respiratory failure with clinical or echocardiographic evidence of pulmonary hypertension. Using iNO for other medical conditions is considered "off label" usage.

iNO therapy is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. Nitric oxide delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999 to be used as a vasodilator in conjunction with ventilatory support and other appropriate agents. In 2009, the FDA updated the INOmax safety labeling indicating that in patients with pre-existing left ventricular dysfunction, iNO may increase pulmonary capillary wedge pressure leading to pulmonary edema, even when used for a short time (FDA webpage accessed July 20, 2012).

Treatment of pulmonary hypertension in pre-term newborns
Approximately 8-13% of all babies are born preterm (<37 weeks of gestation) across developed countries. Although survival rates have improved markedly in recent decades, preterm delivery still accounts for more than 75% of all perinatal complications and death. It is estimated that three fourths of preterm infants with birth weight <1000g develop respiratory distress syndrome (RDS), and 30- 40% are still oxygen dependent at a postmenstrual age (gestational age plus chronological age) of 36 weeks. Breathing failure in premature newborns may be complicated by raised pressure within the vessels that carry blood to the lungs (pulmonary hypertension). Those who require assisted ventilation are at high risk of developing long-term medical and neurocognitive impairment including bronchopulmonary dysplasia (BPD), which is characterized by arrested lung growth, reduced

Back to Top

alveolarisation, and dysmorphic vasculature (i.e. the infants' lungs are not fully formed or are not able to make enough surfactant, which is a liquid that coats the inside of the lungs and helps keep them open so an infant can breathe in air once he or she is born). Without surfactant, the lungs collapse, and the infant may not be able to breathe in enough oxygen to support the body's organs. This may lead to neurodevelopmental impairment and damage to other organs (Barrington 2006, Askie 2010, 2011).

Conventional therapy of respiratory failure complicated by pulmonary hypertension in preterm newborn involves respiratory support, which includes assisted ventilation and continued distending pressure, the administration of surfactant, and sedation or muscle relaxation if needed.

iNO has been investigated as a treatment to prevent lung injury in preterm infants based on the findings from experimental studies performed on a variety of fetal animals and/ or premature animal models with hyaline membrane disease and elevated pulmonary artery pressure. These experiments showed that iNO therapy may enhance pulmonary angiogenesis and lung alveolarisation, reduce the pulmonary vascular resistance and improve oxygenation. Studies in full-term infants also showed that iNO may cause selective pulmonary vasodilatation to reduce pulmonary artery pressure and improve ventilation /perfusion mismatch. However, the results of studies conducted among term or near-term infants cannot be extrapolated to the preterm babies because of the difference in pathophysiology of respiratory failure, and the difference in the potential risks of iNO in preterm infants. If iNO therapy leads to a decrease in required ventilation support, it may also lead to a reduction in lung injury and bronchopulmonary dysplasia. However, it is still uncertain which subpopulation of premature infants may profit most from iNO. There is also opposing data on whether exogenous NO is protective or destructive in the presence of hyperoxia. Inhaled nitric oxide has pro-oxidation and antioxidants activities and can potentially worsen lung injury. Preterm infants are also at higher risk of developing intracranial hemorrhage, and there is a concern about the effect of iNO in increasing the bleeding time (Barrington 2006, Love 2012).

Inhaled nitric oxide is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. iNO delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999 to be used as a vasodilator in conjunction with ventilatory support and other appropriate agents for the treatment of term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The use of iNO for other neonatal medical conditions is considered "off label" use.

Treatment of acute respiratory distress syndrome (ARDS) in adults and children
Acute respiratory distress syndrome (ARDS) is a major source of morbidity and mortality, with a case fatality rate exceeding 30%. ARDS is defined by acute non-cardiogenic pulmonary edema, acute severe hypoxemia irrespective of positive end expiratory pressure, bilateral infiltrates on chest radiography, and a pulmonary artery occlusion pressure $\leq$18 in any adult or child more than one month old. Acute lung injury (ALI) is a milder form of the syndrome and both conditions are often referred to as acute hypoxemic respiratory failure (AHRF). They are characterized by an inflammatory process of the alveolar-capillary membrane that may result from a primary lung disease or is secondary to a number of systemic diseases. AHRF results in intrapulmonary shunting with hypoxemia and pulmonary hypertension. Hypoxemia in ARDS is mainly caused by ventilation perfusion mismatch leading to increased pulmonary shunting due to pulmonary vasodilatation in non-ventilated lung regions and vasoconstriction in ventilated areas (Milberg 1995, Afshari 2011, 2012).

Treatment of ARDS/ALI is mainly supportive and aims at improving gas exchange, control of infection, and preventing complications. The optimal therapy involves judicious fluid management, protective mechanical lung ventilation with low tidal volumes and moderate positive end expiratory pressure, multi-organ support, and treatment of the underlying cause, when possible. Pharmacotherapies have a very limited role in the management of ARDS, and to-date there is no effective medical treatment that improves survival for adult patients with the syndrome, although exogenous surfactant is beneficial in the pediatric population (Dushianthan 2011).

In 1991, inhaled nitric oxide (iNO) was shown to be a selective pulmonary vasodilator in patients with pulmonary hypertension, as well as in animals with pulmonary hypertension induced by drugs or hypoxia. Two years later, inhaled nitric oxide was introduced as a potential therapy for ARDS. Nitric oxide is a colorless, odorless gas that rapidly diffuses from alveoli through epithelial cells to gain direct access to the vasculature. Once in the blood stream it binds to hemoglobin and is rapidly inactivated with an estimated half-life of 3-5 seconds. The effect of iNO is limited to the lungs making it a selective pulmonary vasodilator without adverse systemic hemodynamic effects. iNO causes vasodilatation of ventilated lung units and redistribution of pulmonary blood flow away from non-ventilated lung areas. It decreases pulmonary vascular resistance, improves the ventilation perfusion

Back to Top

mismatch, and subsequently reduces the elevated vascular resistance and pulmonary hypertension. It is also believed that iNO may also regulate both the immune and inflammatory responses (oxygenation by redistributing pulmonary blood flow toward ventilated lung units in patients with this condition (Griffiths 2005. DiBlasi 2010, Dushianthan 2011, Pierrakos 2011).

iNO therapy is also associated with harmful side effects. Nitric oxide is unstable in air and when inhaled with high concentrations of oxygen, the gaseous NO slowly forms nitrogen dioxide which is potentially cytotoxic. A NO_2 concentrations higher than 10 parts per million (ppm) has been known to induce pulmonary edema, alveolar hemorrhage, changes in the surface tension properties of surfactant, and death. NO_2 is dose-dependent and its concentration should be maintained at a level below 3 ppm by decreasing the iNO concentration if it goes any higher. Methemoglobinemia (MetHb), which impairs the ability of the hemoglobin molecule to bind with oxygen, is another harmful side effect of iNO therapy. MetHb is dose-dependent and must be carefully monitored as significant methemoglobinemia has been reported after accidental overdose of iNO. A MetHb level >10% may cause cyanosis, headaches, muscle weakness, and tissue. Renal failure has also been reported with iNO use (Kinsella 2006, Finer 2009, Dushianthan 2011, Henry 2012).

Inhaled nitric oxide is provided through a delivery system used in conjunction with a ventilator or other breathing gas administration system. The delivery system consists of a nitric oxide administration apparatus, a nitric oxide gas analyzer, and a nitrogen dioxide gas analyzer. INOmax® (INO Therapeutics Inc., Clinton NJ) is a commercially available brand of iNO that received initial Food and Drug Administration approval in 1999. It was approved for use as a vasodilator, in conjunction with ventilatory support and other appropriate agents for the treatment of term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension. The use of iNO for other neonatal medical conditions and for treatment in the adult patient population is considered "off label" usage.

Medical Technology Assessment Committee (MTAC)

iNO for Treatment of Persistent Pulmonary Hypertension

08/20/2012: MTAC REVIEW

Evidence Conclusion:

There is fair evidence that inhaled nitric oxide therapy for adult patients with acute respiratory distress syndrome or acute lung injury does not improve survival or other clinical outcomes and may increase the risk of renal impairment. There are insufficient published pediatric trials to determine any benefit or harm of iNO therapy in children with ARDS or ALI.

Articles: Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term: The literature search revealed a number of randomized controlled studies and a Cochrane review with a meta-analysis that pooled the results of 12 RCTs. The Cochrane review and the RCT published after the meta-analyses were selected for critical appraisal. Finer N and Barrington KJ. Nitric Oxide for respiratory failure in infants born at or near term. *Cochrane Database Syst Rev.* 2006 (updated 2009) Issue 4. Art No. CD000399. See Evidence Table . Gonzalez A, Fabres J, D'Apremont I, et al. Randomized controlled trails of early compared with delayed use of inhaled nitric oxide in newborns with a moderate respiratory failure and pulmonary hypertension. *J Perinatol* 2010; 30:420-424. See Evidence Table . Treatment of pulmonary hypertension in pre-term newborns. The literature search revealed a number of randomized controlled studies published between the late 1990s and 2010 and four meta-analyses that pooled the results of all, or some of these trials including a Cochrane review (Burrington and Finer) first published in 2006 and last updated in 2010, an earlier meta-analysis (Hoehn 2000 updated in 2006) and two more recent meta-analysis (Askie 2011, and Donahue 2011). The Cochrane review and Askie and colleagues' meta-analysis of individual patient data from the same trials included in the Cochrane review were selected for critical appraisal. Askie LM, Ballard RA, Cutter GR, Dani C, et al for the Meta-analysis of Preterm Patients on Inhaled Nitric Oxide (MAPPiNO) Collaboration. Inhaled nitric oxide in preterm infants: An individual -patient data meta-analysis of randomized trials. *Pediatrics*. 2011; 128:729-739. See Evidence Table . Barrington KJ, Finer N. Inhaled nitric oxide for respiratory failure in preterm infants. *Cochrane Database Syst Rev.* 2010 Dec 8;(12):CD000509. See Evidence Table . Treatment of acute respiratory distress syndrome (ARDS) in adults and children. The literature search revealed a number of randomized controlled studies and two meta-analyses of RCTs (Adhikari 2007, and Afshari (described in 2 publications 2010 and 2011). No trials published after the last meta-analysis were identified by the search. The more recent meta-analysis was selected for critical appraisal. Afshari A, Brok J, Moller AM et al. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) and acute lung injury in children and adults. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD002787.pub2. See Evidence Table **.** Afshari A, Brok J, Moller AM et al. Inhaled nitric oxide for acute respiratory distress syndrome (ARDS) and acute lung injury in children and adults. A systematic review with meta-analysis and trial sequential analysis. Anesth Analg 2011; 112:1411-1421. See Evidence Table.

Back to Top

The use of iNO for Treatment of persistent pulmonary hypertension (PPHN) and respiratory failure in infants born or at near term does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

The use of iNO for treatment of pulmonary hypertension pre- term newborns does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

The use of iNO for treatment of ARDS in adults and children does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No Specific Codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Review Dates	Date Last Revised
09/04/2012	09/04/2012[MDCRPC], 10/02/2012 [MDCRPC,] 08/06/2013 [MPC], 11/05/2013 [MPC], 09/02/2014[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 12/04/2018[MPC], 12/03/2019[MPC], 12/01/2020[MPC],12/07/2021[MPC],12/06/2022[MPC], 12/09/2023[MPC], 03/12/2024[MPC]	08/06/2013

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dermal Fillers for Facial Lipoatrophy

- Sculptra
- Radiesse

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS) (250.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Dermal filler injections are covered when **ALL** of the following criteria are met:

1) The member has **ALL** of the following:

   a) a diagnosis of human immunodeficiency virus (HIV), and

   b) a diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4*, related to HIV or highly active antiretroviral therapy (HAART), and

AND

2) The dermal filler is approved by the Food and Drug Administration for Facial Lipodystrophy Syndrome (LDS), e.g. Sculptra® and Radiesse®.

Multiple sessions may be necessary to complete the therapy, depending upon the severity of the lipodystrophy. The following link provides examples of the Carruthers grading system*: www.facialwasting.org.

If the patient has:

1) Grade 3 lipodystrophy, up to 4 sessions may be required
2) Grade 4 lipodystrophy, up to 8 sessions may be required

*If additional treatments are desired, the treating provider will need to reevaluate the patient or repeat photos of the patient's face will be required to determine if further treatments are warranted.

Repeat treatment is typically necessary one to two years after the initial therapy, when the patient has regressed to Grade 2 or greater lipoatrophy.

CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function as determined by HIV provider.

Back to Top

Date Sent: 4/29/24

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

HIV-associated lipodystrophy has been reported in the literature starting in the late 1990s. This condition involves loss of subcutaneous fat or fat accumulations in particular regions of the body. It can include fat accumulation around the abdomen, dorsocervical area (buffalo hump) and breast hypertrophy. Regions affected by fat loss (lipoatrophy) include the limbs, buttocks and face, especially the nasolabial regions, the temples and the eye sockets. The condition is different from HIV wasting syndrome that is mainly due to loss of muscle mass. HIV-associated lipodystrophy is also associated with insulin resistance, hyperglycemia and low levels of high-density lipoprotein (HDL) (James et al., 2002).

Although the cause of HIV-associated lipodystrophy is not well understood, some investigators believe there is a link with HIV protease inhibitors (PI). The condition started being reported in the literature around the time that protease inhibitors were introduced and prescribed to HIV-infected patients. In addition, the prevalence of lipodystrophy is higher in HIV-infected patients who received PIs compared to PI-naïve patients (James et al., 2002). Lipoatrophy may be associated with the use of specific nucleosides such as stavudine and didanosine in treatment while lipoaccumulation may be associated with protease inhibitors, especially ritonavir (Dr. Wayne Dodge, personal communication).

The treatment of facial lipoatrophy is the subject of the current MTAC review. There is little published literature on this topic, but anecdotal information suggests that facial lipoatrophy negatively affects HIV-infected individuals' body image and self-esteem and can lead to social and sexual problems. The long-term natural history of lipoatrophy is also not well known. Lipoatrophy does not appear to resolve on its own, or after discontinuation of PIs and other medication (James et al., 2002; Huff, 2004).

Sculptra, an injectable form of poly-L-lactic acid (PLA) is the first FDA-approved treatment for HIV-associated facial lipoatrophy. PLA is a biocompatible, biodegradable substance that is synthetically derived from natural components. It was been used in surgical products such as dissolvable stitches and bone screws. PLA was approved in Europe in 1999 for cosmetic treatment of scars and wrinkles, under the brand name New-Fill. The FDA did not approve Sculptra for the treatment of wrinkles. FDA approval of Sculptra for facial lipoatrophy was based on unpublished data submitted by the manufacturer Dermik Laboratories. A condition of FDA approval was that Dermik agreed to conduct a registry study for five years to evaluate Sculptra's long-term safety (FDA press release; James et al., 2002). Potential limitations of injectable PLA for severe cases of facial lipoatrophy are that large quantities of material are needed to fill the defects and there may be high maintenance costs (Binder & Bloom, 2004).

Medical Technology Assessment Committee (MTAC)

Injectable Poly-L-Lactic Acid (PLA)

12/08/2004: MTAC REVIEW

Evidence Conclusion: There was one randomized controlled trial with 30 patients (Moyle, 2004) and this compared immediate treatment with PLA to delayed treatment after 12 weeks. The 12-week follow-up is the appropriate point in the study to compare treatment with no treatment. At 12 weeks, there were no significant differences between groups in depression or anxiety scores. A significantly greater proportion of patients in the immediate treatment group perceived "less thinness" in the face. The study was limited by the short follow-up period, small sample size with no statistical power analysis and lack of clear primary outcomes. The other empirical study reviewed was a case series with 50 patients (Valentin, 2003). Although there was no comparison group, advantages of the Valentin study were that there was objective measurement of changes in facial thickness and follow-up was longer, 96 weeks. There was a significant increase in total cutaneous thickness (TCT) of the face after a series of treatments with PLA and the increase in TCT persisted until the 96-week follow-up. There was a significant increase in the quality of life score compared to baseline at the 24- and 48 weeks follow-ups, but not at the 72- or 96-week follow-ups. No serious adverse effects were reported in either study. Safety and efficacy beyond 96 weeks is not known. The generalizability of Valentin study has been criticized because one dermatologist performed all of the injections; it is not known whether there would be similar results

Back to Top

with other dermatologists. In summary, there is some evidence from an uncontrolled case series that treatment with Sculptra can reduce facial lipoatrophy for up to 96 weeks and has no serious adverse effects, when used by a trained dermatologist. There are no good data from controlled studies. The impact on quality of life is less clear. There are no published data on safety and efficacy of Sculptra beyond 96 weeks.

Articles: The search yielded 10 articles. Several were reviews or opinion pieces. Three empirical studies were identified. The ideal study would have the following characteristics: Randomized controlled trial, Comparison of Sculptra to alternative treatment, or placebo, Long-term follow-up, sufficiently large sample size, Important outcomes include whether treatment with Sculptra is effective at increasing facial fat and reduces any adverse psychosocial effects. In this case, there is no standard alternate treatment and no other FDA-approved new treatments for HIV-associated facial lipoatrophy. No placebo-controlled studies were identified. There was one randomized controlled trial that compared immediate treatment with PLA to delayed treatment. There was also a case series with 96 weeks' follow-up. Case series can provide important long-term safety data. The RCT and case series were critically appraised. Both used New-Fill, the European version of PLA. The third empirical study was a case report presenting data on 4 patients and was excluded from review. The following studies were critically appraised: Valantin M-A Aubron-Olivier C, Ghosn J et al. Polylactic acid implants (New-Fill) to correct facial lipoatrophy in HIV-infected patients: results of the open-label study VEGA. AIDS 2003; 17: 2471-2477. **See** Evidence Table. Moyle GJ, Lysakova L, Brown S et al. A randomized open-label study of immediate versus delayed polylactic acid injections for the cosmetic management of facial lipoatrophy in persons with HIV infection. *HIV Medicine* 2004; 5: 82-87. See Evidence Table.

The use of injectable poly-L-lactic acid (PLA) in the treatment of facial lipoatrophy does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
G0429	Dermal filler injection(s) for the treatment of facial lipodystrophy syndrome (LDS) (e.g., as a result of highly active antiretroviral therapy)
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, Sculptra, 0.5 mg

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check.**

Date Created	Date Reviewed	Date Last Revised
12/08/2004	12/08/2004, 07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 01/08/2013MDCRPC, 11/05/2013MPC, 09/02/2014MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC, 01/09/2018MPC, 12/04/2018MPC, 12/03/2019MPC, 12/01/2020MPC, 12/07/2021MPC,12/06/2022MPC, 12/09/2023MPC, 03/12/2024MPC	05/04/2021

MDCRPC Medical Director Clinical Review and Policy Committee

MPC Medical Policy Committee

Revision History	Description
05/04/2021	MPC approved coverage criteria for non-Medicare members. Requires 60-day notice, effective date 10/01/2021.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Injectable Bulking Agents for Fecal Incontinence

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Injectable Bulking Agents for the Treatment of Fecal Incontinence (A52923) Noridian ***retired*** Local Coverage Article (LCA A52923). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on Kaiser Permanente commercial criteria or literature search.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Fecal incontinence occurs when a person loses the ability to control his/her bowel movements and is unable to retain feces in the rectum. It can be caused by a wide variety of conditions that affect either the anatomy or function of the anal sphincter. Perineal injury during childbirth is a common cause of fecal incontinence in women. It can also be caused by neurological disorders such as spinal injury and multiple sclerosis, or it can result from anorectal surgery. In any case, fecal incontinence is common and, due to its association with considerable physical and social disability, is often under-reported (Tjandra, Chan et al. 2009).

First line treatment for fecal incontinence is usually conservative and includes antidiarrheal medication and pelvic floor muscle training. In patients for whom conservative treatment fails, alternative treatments include surgery to tighten the anal sphincter, sacral nerve stimulation, creation of a new sphincter from other suitable muscles,

Back to Top

Date Sent: 4/29/24

implantation of an artificial sphincter or a permanent colostomy. Injectable bulking agents offer an additional, less invasive, second line treatment for fecal incontinence. The concept is to inject a biocompatible material to close the anal canal to avoid fecal incontinence (Siproudhis, Morcet et al. 2007; Maeda, Vaizey et al. 2008; Graf, Mellgren et al. 2011).

At least ten different materials have been used as bulking agents for fecal incontinence including autologous fat, Teflon, bovine glutaraldehyde, cross-linked collagen, carbon coated zirconium beads, polydimethylsiloxane elastomer, dextranomer in nonanimal stabilized hyaluronic acid, hydrogel cross-linked with polyacrylamide, porcine dermal collagen, synthetic calcium hydroxylapatite ceramic microspheres and polyacrylonitrile in cylinder form (Maeda, Laurberg et al. 2013). The material can be injected either via the perianal skin or via the anal mucosa. The procedure may be performed under local, regional or general anesthesia and the injection may be guided by the surgeon's finger in the anal canal or by ultrasound. This treatment is potentially attractive in its simplicity and minimal invasiveness and can be performed in an outpatient setting.

Several injectable bulking agents have been approved by the U.S. Food and Drug Administration (FDA) in recent years for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.

The Medical Technology Assessment Committee (MTAC) previously reviewed and failed bulking agents for the treatment of GERD in 2003. Currently, the committee has been asked to review the literature on the safety and efficacy of injectable bulking agents for the treatment of fecal incontinence compared to standard treatment for fecal incontinence. This is the first time that bulking agents have been reviewed for this indication. The topic is being reviewed for decision making guidance.

Medical Technology Assessment Committee (MTAC)

Injectable Bulking Agents for Fecal Incontinence

10/21/2013: MTAC REVIEW

Evidence Conclusion: ***EFFICACY*** ***THE*** Cochrane Collaboration identified five randomized trials for inclusion in their review to determine if the injection of bulking agents is better than currently available treatments or no treatments for fecal incontinence in adults. Only two of the trials compared a bulking agent to sham treatment and none of the studies made a comparison of bulking agents versus other therapies. On the whole, the studies were of poor quality with only two providing adequate information to reliably assess bias. In addition, most of the studies were small and limited to short-term follow up. Two of the trials reported on the short-term benefit from injections as outcome measures improved with time but neither trial had follow up beyond 12 months (Siproudhis, Morcet et al. 2007; Graf, Mellgren et al. 2011). In addition, there appeared to be some short-term benefits from injections given with ultrasound guidance compared with digital guidance (Tjandra, Han et al. 2004). Two of the studies compared different types of bulking agents with the larger trial reporting that silicone material was better than the carbon coated beads in terms of fecal incontinence at six and 12 months (Tjandra, Chan et al. 2009). The smaller trial, which was not included in this critical appraisal, compared the injection of Bulkamid™ with Permacol™ and showed some improvement in outcomes in both groups but ultimately was too small to detect differences between groups (Maeda, Vaizey et al. 2008). Currently the literature addressing the efficacy of injectable bulking agents is limited for a variety of reasons. First and foremost, outcome measures and the definition of response to treatment are varied, and as a result, problematic for this indication. Furthermore, it is unclear how severity of incontinence at baseline affects outcomes data. Finally, there is a lack of information regarding the volume, the precise location where the agent should be placed, and the choice of guidance of the needle track. Several different techniques were employed with various bulking agents used across all studies making comparisons complicated. **SAFETY** Four of the five studies reported on adverse effects (Tjandra, Han et al. 2004; Siproudhis, Morcet et al. 2007; Tjandra, Chan et al. 2009; Graf, Mellgren et al. 2011). Overall, the observed adverse events were similar across all the studies with few complications reported and the most commonly reported complication being pain at injection site. Safety data collected from these trials is limited as it is not clear if complications were recorded systematically. The severity and duration were not always mentioned, and in many cases, adverse events were recorded with no information on the number of patients reporting these events. (For example, Graf and colleagues reported 128 adverse events in patients treated with NASHA Dx and 29 events in the sham treatment group but do not detail the number of patients reporting these adverse events.) Furthermore, the safety of injectable bulking agents has not been studied past 12 months. Other studies not included in this review also reported experiencing pain or minor ulceration at the injection site or in the anal canal for up to 10 weeks after the procedure (Malouf, Vaizey et al. 2001). Further complications included leakage of the bulking agent in 1 of 10 patients and, in a different study, passing of the bulking agent in 2 of 18 patients (Davis, Kumar et al. 2003). Conclusion: There is evidence from one large randomized trial to suggest that injectable bulking agents are effective up to 12 months. There is evidence to suggest that injectable bulking agents are reasonably safe in the short term. There is no evidence to permit conclusions about long term safety or efficacy of injectable bulking agents for fecal incontinence.

Back to Top

Articles: A literature search was conducted revealing a variety of publications including multiple case-series reports as well as case-control and cohort studies. One recent Cochrane review was also revealed which included five randomized trials measuring the effects of bulking agents versus placebo, bulking agents versus other types of bulking agents and bulking agents versus other minimally invasive interventions. No studies that compared the injection of bulking agent versus conservative treatment were revealed. Four of the studies included reporting of adverse events up to 12 months post treatment. The Cochrane review did not pool the results of the trials due to their heterogeneity. Four of the five trials included in the Cochrane Review were selected for appraisal:
Graf W, Mellgren A, Matzel KE, Hull T et al. Efficacy of dextranomer in stabilized hyaluronic acid for treatment of faecal incontinence: a randomized, sham-controlled trial. *Lancet* 2011; **377**(9770):997-1003.
See Evidence Table 1. Siproudhis, L., J. Morcet, et al. Elastomer implants in faecal incontinence: a blind, randomized placebo-controlled study. *Alimentary Pharmacology & Therapeutics* 2007;**25**(9):1125-1132.
See Evidence Table 2. Tjandra, J., W. Han, et al. (2004). "Injectable silicone biomaterial for faecal incontinence due to internal sphincter dysfunction is effective." *Diseases of the Colon & Rectum* **47**(12): 2138-2146. See Evidence Table 3. Tjandra, J, Chan M, et al. Injectable silicone biomaterial (PTQTM) is more effective than carbon-coated beads (Durasphere®) in treating passive faecal incontinence – a randomized trial." *Colorectal Disease* 2009;**11**(4):382-389. See Evidence Table 4.

The use of Injectable Bulking Agents for Fecal Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
12/03/2013	01/07/2014[MPC], 11/04/2014[MPC], 09/01/2015[MPC], 07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 02/05/2019[MPC], 02/04/2020[MPC], 02/02/2021[MPC], 02/01/2022[MPC], 02/07/2023[MPC], 03/12/2024[MPC]	12/09/2015

[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/9/2015	Added LCA A52922

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Inpatient Rehabilitation

- Admission guidelines

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	See the Medicare Benefit Policy Manual Chapter 1 - Inpatient Hospital Services Covered Under Part A 110 - Inpatient Rehabilitation Facility (IRF) Services
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Inpatient Rehabilitation Facility (IRF - acute rehabilitation) admission is indicated by **ALL of the following**:

1) No acute hospital care needs.
   The inpatient rehabilitation benefit is not to be used as an alternative to completion of the full course of treatment in the referring hospital. (e.g. for completion of antibiotics or to observe renal failure)
2) A preadmission screening assessment must be completed. A preadmission screening assessment is an evaluation of the patient's condition and need for rehabilitation therapy and medical treatment that must be conducted by licensed or certified clinician(s) (Registered Nurse, Physical or Occupational Therapist, Nurse Practitioner, or Medical Doctor) within the 48 hours immediately preceding the IRF admission. A preadmission screening that includes all of the required elements, but that is conducted more than 48 hours immediately preceding the IRF admission, will be accepted as long as an update is conducted in person or by telephone to document the patient's medical and functional status within the 48 hours immediately preceding the IRF admission in the patient's medical record at the IRF.
3) There must be documentation in the preadmission screening assessment (a copy of the assessment must available for review) that includes **ALL of the following**:
   a) Must indicate the patient's prior level of function (prior to the event or condition that led to the patient's need for intensive rehabilitation therapy),
   b) Expected level of improvement and
   c) Expected length of time necessary to achieve that level of improvement.
   d) Nature and degree of improvement identified with practical goals established for patient's condition
   e) Conditions that caused the need for rehabilitation,
   f) Treatments needed (i.e., physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics),
   g) Expected frequency and duration of treatment in the IRF,
   h) Discharge plan that includes **ALL of the following**:
      - Anticipated discharge destination including documentation that patient will be appropriate for discharge to home or to a community-based environment. (not to a SNF or LTC facility)
   i) Any anticipated post-discharge treatments and any other information relevant to the care needs of the patient.

Back to Top

4) In order for IRF care to be considered reasonable and necessary, the documentation must demonstrate a reasonable expectation that **ALL of the following** criteria will be met at the time of admission to the IRF:
   a) The patient must require the active and ongoing therapeutic intervention of more than two therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy.
   b) Need for an intensive rehabilitation therapy program that includes **ONE or more** of the following:
      - Therapy at least 3 hours per day for 5 days per week OR
      - Therapy at least 15 hours per week consecutive days
   c) Therapy must not exceed the patient's need or tolerance or compromise the patient safety.
   d) The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program. Also, there should be a reasonable expectation that a measurable, practical improvement in the patient's functional condition can be accomplished within a predetermined and reasonable period of time.
   e) Close physician involvement with need for treating rehabilitation physician face-to-face assessment at least 3 days per week (e.g. monitoring of uncontrolled pain, bowel and bladder issues, and complex rehabilitation needs such as adapting mobility devices.)
   f) The patient must require an intensive and coordinated interdisciplinary approach to providing rehabilitation

5) Document must state why an equivalent outcome will not be achieved in a Skilled Nursing Facility.

The following indications are not covered:
- Coma stimulation
- Custodial care
- Routine services for maintenance of medication administration, routine enteral feedings, routine colostomy care, ongoing straight catheterization for chronic conditions.
- Single joint replacement unless the individual has significant comorbidity(ies) resulting in functional deficits which would necessitate an acute inpatient level of rehabilitation in order to achieve a satisfactory outcome within a reasonable time period.

If requesting these services, please send the following documentation to support medical necessity:
- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Inpatient rehabilitation hospital admissions provide intensive rehabilitation to patients with various neurological, musculo-skeletal, orthopedic and other medical conditions following stabilization of their acute medical issues. The inpatient rehabilitation bed is specifically licensed for the rehabilitation services and is sometimes part of an acute hospital or a separate facility.

Rehabilitation hospitals were created to meet a perceived need for facilities which were less costly on a per diem basis than general hospitals, but which provided a higher level of professional therapies such as speech therapy, occupational therapy, and physical therapy than can be obtained in a "skilled nursing care" facility. Prior to admission to an inpatient rehabilitation facility an evaluation is conducted by a physiatrist to determine appropriateness for this level of admission.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

Back to Top

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
03/04/2014	02/02/2010 MDCRPC, 01/04/2011 MDCRPC, 01/03/2012 MDCRPC, 02/05/2013 MPC, 2/04/2014 MPC, 03/04/2014 MPC, 02/03/2015MPC, 11/03/2015 MPC, 09/06/2016MPC, 07/11/2017MPC, 05/01/2018MPC, 05/07/2019MPC, 05/05/2020MPC, 05/04/2021MPC, 05/03/2022MPC, 05/02/2023MPC	06/21/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
06/21/2017	Added a clarifying sentence to 4 d

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Insulin Pump
- InPen System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Infusion Pumps (280.14)
Local Coverage Determinations (LCD)	External Infusion Pumps (L33794)
Local Coverage Article	External Infusion Pumps – Policy Article (A52507)
Kaiser Permanente Medical Policy	For **InPen System Requests** Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"***InPen System***"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Initial Insulin Pump:

I. To qualify for an insulin pump the member must meet **ALL of the following:**
   - A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
   - B. Referral initiated by a Diabetes specialist* that will manage therapy with an insulin pump.
   - C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
     1. Assessment for clinical therapeutic value of an insulin pump.
     2. Assessment of patient pump education and skill training preparation prior to pump start (either one-on-one or within a group).
     3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an insulin-pump self-management plan.
   - D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the insulin pump.
   - E. Require less than 200 units of total insulin per day prior to pump therapy.
   - F. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an insulin pump.
   - G. Meets **ONE or more of the following** while on an MDI regimen:
     1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
     2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
   - H. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing

Date Sent: 4/29/24

I. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
J. Has no other illness that could impede use of the pump (i.e., alcohol/chemical abuse, psychological instability, difficulty with digital dexterity, visual impairment).
K. Pediatric Patients
    1. On a case-by-case basis, upon review by a clinical review medical director, pediatric patients under the age of 13 may waive the 6-month time period, if patient monitoring is occurring per the diabetes management plan outlined by an Endocrinologist.

*Note – Requests for an insulin infusion pump used with continuous glucose sensing (HCPCS code E0787 or E0784 for Medicare) will only be authorized if the patient meets both criteria for initial or replacement insulin pump as outlined in this criteria and all criteria outlined in the Continuous Glucose Monitoring clinical review criteria including that current device is no longer under warranty.

Ongoing Coverage of Pump and Supplies:
To qualify for ongoing coverage of an insulin pump the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting pump malfunction
D. Patient does not have other conditions or psychosocial stressors which might impede safe use of an insulin pump
E. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

InPen System
To qualify for an InPen System the member must meet **ALL of the following:**
A. Patient has Type 1 diabetes of at least six months' duration or Type 2 diabetes requiring a basal/bolus insulin regimen of multiple daily injections using long-acting basal insulin and a rapid-acting analogue
B. Referral initiated by a Diabetes specialist* that will manage therapy with an InPen System.
C. Documentation from the Diabetes specialist* that includes **ALL of the following:**
    1. Assessment for clinical therapeutic value of an InPen System.
    2. Assessment of patient InPen education and skill training preparation prior to InPen start (either one-on-one or within a group).
    3. Assessment of the patient's (or caregiver's) ability to safely and appropriately participate in an InPen System self-management plan.
D. Has been on a treatment regimen of multiple daily injections (MDI) of insulin that includes a trial of both a long-acting insulin analog and a short-acting insulin analog with a plan for pre-meal short acting insulin dose adjustment for at least 3 – 6 months prior to initiation of the InPen System.
E. Has documented logs of glucose self-testing or CGM results - at least 4 times per day during the 1 month prior to consideration of an InPen System.
F. Meets **ONE or more of the following** while on an MDI regimen:
    1. Recent history (within last six months) of significant, recurring hypoglycemia (blood glucose < 70 mg/dl).
    2. Wide fluctuations (well below and above the set glycemic targets) in blood glucose before and after mealtimes, despite appropriate MDI using up to date insulins (analogs) and dose adjustments to affect control.
G. Patient has advanced carbohydrate counting skills and actively uses this information for insulin dosing
H. Patient demonstrates ability to recognize their glucose patterns and safely problem-solve these
I. Prescriber has documented a need for detailed electronic monitoring the patient's blood glucose levels and insulin dose administered

Ongoing Coverage of InPen System:
To qualify for ongoing coverage of an InPen System the member must meet **ALL of the following**:
A. There is documentation that patient monitors glucose at least four times daily, or appropriately uses a continuous glucose monitor.
B. Patient maintains advanced carbohydrate counting skills and actively uses this information for insulin dosing
C. Patient maintains ability to recognize their glucose patterns and safely and appropriately problem-solve these, including troubleshooting InPen malfunction
D. Patient has at least one visit per year with diabetes specialist* (face-to-face, secure message, or telephone encounter)

Date Sent: 4/29/24

Replacement When Insulin Pump is No Longer under Warranty

The following considerations apply for replacement of an insulin pump that is no longer under warranty:

A. The warranty for the current device has expired (requests for replacement are not covered when the device is still under warranty). Currently, Medtronic and Tandem have 4-year warranty periods, OmniPod Dash does not have a warranty period. It is recommended to check the manufacturer's website for current information.
   A prior-authorization request from the treating diabetes specialist* managing the insulin pump to the Kaiser Permanente Pre-Service department is always required when an insulin pump is being replaced.
B. A face-to-face visit with the treating diabetes specialist* managing the insulin pump is documented within the past year.
C. The reason for the replacement request is fully documented in the member's medical treatment plan.
D. The current pump was previously approved by Kaiser Permanente or the current pump was approved by another non-Medicare plan, and the member meets the medical necessity and coverage criteria for Kaiser Permanente.
E. Suitability for continuance of pump therapy has been reviewed and confirmed by the Diabetes specialist*.
F. The item is not lost or damaged as a result of abuse.

A treating provider may order ongoing pump supplies in the interval between annual visits with the Diabetes specialist*

*Diabetes Specialist= Adult or Pediatric Endocrinologist or a provider under his or her direct supervision (eg. PA or ARNP with CDE or BC-ADM certification or Diabetes Team RN-CDE) or a Perinatologist managing a patient with diabetes during pregnancy.

Documentation requirements to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (endocrinology, primary care)
- Last 6 months of lab work
- Last 1-2 months of legible home monitoring logs or a printout of CGM results

Links to Request Forms:
Insulin Pump Request for New Pump Start Form
Insulin Pump Replacement Request Form

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

In January 1998, the state of Washington passed the Diabetes Cost Reduction Act that requires that major health carriers provide coverage (all, or in part) for diabetes supplies (insulin, syringes, and delivery devices) and education. This new law includes insulin pumps.

Insulin pumps are high technology infusion devices, about the size of a small tape cassette. Flexible tubing connects to the pump that contains the insulin, and then to the patient via a needle that is put in place and changed every 2 to 3 days. The pump itself can then be programmed to deliver 'background' insulin on a continuous basis, and also allow pre-meal "boluses" to accommodate meals. The pump is NOT a system that a patient can just plug into and forget diabetes.

In fact, patients who use the pump have to learn how to program and trouble-shoot the technology, and also learn how to do complex decision-making. This intensive management approach requires multiple daily blood testing, learning how to recognize and use types of food in a very sophisticated way, keeping records, and learning to use the information for complex problem solving. This education is an absolute prerequisite to being on the insulin pump, so special education classes and supervised care are required.

Medical Technology Assessment Committee (MTAC)

Insulin Pump Type II Diabetes
04/20/2015: MTAC REVIEW

Date Sent: 4/29/24

Evidence Conclusion: *Effectiveness* At baseline, the mean HbA1c was 9.0% (75 mmol/mol) in both groups. At six months, both groups saw a decrease in HbA1c (7.9% in the pump group vs. 8.6% in the MDI group) with a -0.7% (95% CI -0.9 to -0.4; -8 mmol/mol, 95% CI -10 to -4 mmol/mol, adjusted p<0.0001) difference between groups favoring pump treatment. Reduction in HbA1c in the pump group was also associated with a 20% lower daily dose of insulin compared with the MDI group, and was not accompanied by an increase in hypoglycemia or weight gain. Ultimately, the investigators concluded that patients with poorly controlled T2DM who received CSII over six months achieved significantly greater reductions in HbA1c.In a separate analysis, the investigators retrospectively stratified the study population according to concentrations of two different biomarkers determined from plasma collected at baseline. The first biomarker, anti-glutamic acid decarboxylase (anti-GAD) antibody (Ab), was present in 18% of the population at baseline indicating that the study population may include patients with T1DM. The investigators attribute this high rate to false-positives, relatively low cutoff values or a combination of both. The second biomarker, C-peptide, a measure of insulin production, did not appear to be associated with A1C level. Ultimately, the analysis demonstrated that HbA1c values were independent of both biomarkers (Reznik and Huang 2014). *Safety* The investigators reported five episodes of hyperglycemia related to the device or study procedure in the pump group and two diabetes related serious adverse events (SAE) resulting in hospital admission. Comparison with the MDI group is not possible as the collection of safety data appears to be incomplete. The investigators noted that data on self-reported mild hypoglycemia and hyperglycemia were not collected, nor were data for hyperglycemia in the MDI group. The studies strengths include randomization, sufficient sample size and the utilization of an intent-to-treat (ITT) analysis. To add to this, the study was conducted across 36 hospitals in five different countries. Methodological limitations of the study can be attributed to the nature of the treatments preventing blinding of patients and assessors. In addition, the investigators acknowledge that the average number of daily glucose self-monitoring tests in both groups was below the generally recommended standard of care, however, this may be consistent with real-life experiences. Finally, the investigators note that due to the inclusion/exclusion criteria and run-in phase, the results of the study may not be generalizable. As a final note, the study was designed and sponsored by Medtronic, the manufacturer of the device. Although they had no role in data collection, the analysis was carried out by statisticians employed by Medtronic. Conclusions: There is evidence to support the efficacy of CSII in achieving glycated hemoglobin targets in highly motivated patients with T2DM with have poor glycemic control, who are taking a total daily dose of insulin less than 220 units. There is limited evidence to support the safety of CSII patients with T2DM.
Articles: The literature was searched for studies assessing the effectiveness of CSII for glycemic control in patients with T2DM. A variety of publications were revealed including several observational studies and four small randomized controlled trials (RCT) with conflicting results. The best available evidence was a recent RCT comparing CSII with multiple daily injections (MDI). The following articles were selected for critical appraisal:
Reznik Y, Cohen O, Aranson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (opT2mise): a randomized open-label controlled trial. The Lancet. 2014;384(9950):1265-1272.
See Evidence Table 1

The use of Insulin Pump for Type II diabetes does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Pancreas

BACKGROUND

Diabetes mellitus is a metabolic disorder resulting from a defect in insulin secretion, insulin action or both. More specifically, in type 1 diabetes, the pancreas is unable to produce insulin which results in increased blood glucose levels, and ultimately, leads to complications which may affect the eyes, kidneys, nerves, heart and blood vessels. As a result, an essential part of diabetes management is to maintain blood glucose levels to as near normal as possible over all hours of the day. Implementation of this approach requires the individual to be capable of and committed to a day-to-day medical program. It requires ongoing compliance with multiple daily glucose measurements accompanied by appropriate adjustments in insulin dose and insulin injection. Additionally, successful intensive diabetic management requires response to a variety of external factors including changes in diet, exercise, and presence of infection.

Typically, patients self-monitor their blood glucose via fingerprick in an effort to optimize glycemic control, however, this technique is tedious and uncomfortable for the patient. In addition, this technique only provides information about a single point in time making it difficult to recognize trends. In any case, intensive glucose monitoring and insulin therapy can be challenging as they require obtaining, retaining, processing and applying vast amounts of information in the course of everyday life (Watkins, Connell et al. 2000; Boland, Monsod et al. 2001; Brauker 2009).

Back to Top

Evolving technologies such as continuous subcutaneous insulin infusion (CSII), and continuous glucose monitoring (CGM) have allowed patients to safely maintain glycemic goals and prevent other related complications. While there is evidence to support the efficacy of CSII (Misso, Egberts et al. 2010), the reliability and robustness of CGMs leaves much to be desired. Even with the aid of these devices, maintaining blood glucose concentrations within a suggested optimal range is a constant struggle.

Most recent technologic advancements have integrated these components into an Artificial Pancreas Device System (APDS). In addition to CSII and CGM, the APDS incorporates a control algorithm designed to facilitate communication between the different components thus automating the process of maintaining blood glucose concentrations at or near a specified target or range and, ultimately, improving glucose control, preventing complications, and decreasing disease burden. With a wide range of current products available on the market, there is potential for a large variety of different types and designs of ADPSs.

In an effort to help advance the development of the diabetes technologies, the U.S. Food and Drug Administration (FDA), in 2011, established three new product classifications for APDSs including threshold suspend, single hormonal control, and bihormonal control, all of which are regulated as class III device systems (general controls and premarket approval). In September of 2013, Medtronic's MiniMed® 530G was the first system approved under this new product classification. ADPSs have not previously been reviewed by the Medical Technology Assessment Committee (MTAC) and are currently being reviewed due to provider request.

The development of an "artificial pancreas" has been the "holy grail" for management of Type 1 diabetes for several decades. To understand why this is such a difficult task it helps to understand what the normal non-diabetic person's body actually does in response to changes in blood glucose. Within the pancreas we all have 1-2 million groups of cells called the Islets of Langerhans which function together to help maintain the blood glucose levels within a quite narrow range (of around 70-160mg/dl). The islets make two main hormones (insulin from the beta-cells and glucagon from the alpha cells) which work together in concert. These islet cells monitor the blood glucose flowing through them constantly. Whenever the blood goes up (after a meal, for example) the islets increase the amount of insulin that they are secreting from the beta-cells and decrease the amount of glucagon that they are secreting from the alpha cells. Whenever the blood glucose drops below normal the beta-cells turn off completely (so that no insulin is secreted) and the alpha cells crank out lots of glucagon. Glucagon (as well as other hormones like epinephrine, growth hormone and cortisol) stimulate the liver to release glucose into the blood stream (the liver stores about 300 grams of glucose in the form of a kind of starch called glycogen). The insulin and glucagon are released directly into the portal circulation of blood flowing from the pancreas to the liver. In other words, a non-diabetic person is functioning with millions of blood glucose measurements being done every day with the results connected to a continuously variable secretion of both insulin and glucagon released directly into the blood flowing to the liver. Even though the commercially made components of an "artificial pancreas" may seem very sophisticated they are a very crude and imprecise way of trying to do what the real non-diabetic person's pancreas can do.

First consider the delivery of insulin. Rather than having both insulin and glucagon being released directly into the blood flowing to the liver we have a continuous subcutaneous infusion of insulin alone. The insulin is absorbed out of the subcutaneous fat into the peripheral systemic circulation and only then gets to the liver. This can give a fairly accurate and stable basal delivery of insulin but when larger amounts of insulin are delivered immediately before meals (bolus insulin delivery) the rate of rise and fall of insulin in the bloodstream is a lot slower than in a healthy non-diabetic person's body.

Second, consider the measurement of blood glucose. Typically, diabetic patients test the capillary glucose level in their fingertips 2-8 times per day. This can give useful information but does not show the constant rising and falling of blood glucose excursions throughout the day. If needle sensors are placed in the subcutaneous tissue this can give a reading of interstitial fluid glucose (similar to plasma glucose) every 10-20 minutes throughout the day and so can show the trends as the blood glucose rises and falls. Several companies now make these continuous glucose monitoring systems (CGMS). There are two practical issues with CGMS, however: a) the interstitial fluid glucose lags behind the actual plasma glucose by 15-20 minutes and so can give a falsely low or high value if it is measured at times when the blood glucose is rising rapidly (after a meal) or is falling rapidly (after exercise or after injecting a bolus of insulin), and b) the glucose oxidase enzyme system for measuring blood glucose can drift over time and so the readings from a CGMS will be inaccurate unless they are calibrated several times a day by doing a capillary blood glucose test at a time when the blood glucose is expected to be stable (not rising or falling rapidly).

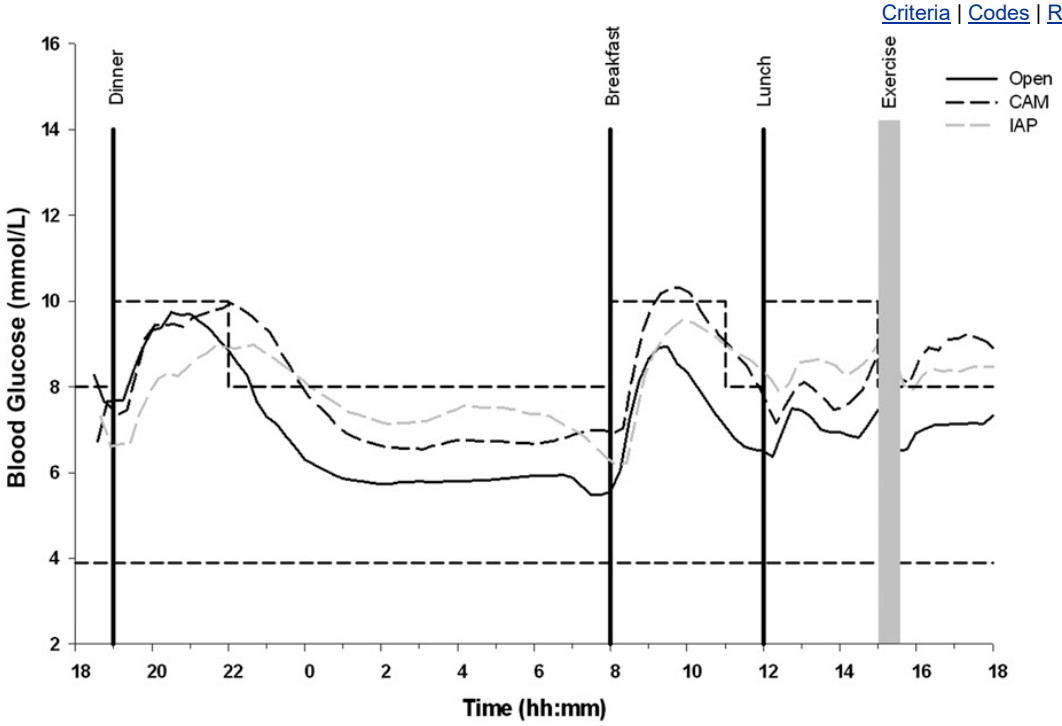
The concept of an "artificial pancreas" is that a person could wear both and insulin pump and a CGMS device and that the insulin pump uses the information from the CGMS to automatically make adjustments to the rate of insulin

Date Sent: 4/29/24

infusion. The person would not need to worry about testing their blood glucose or of thinking about what they eat and when they exercise but could go about their day-to-day life safe in the knowledge that their blood glucose would stay within normal limits. It is because of the practical limitations of the technology (outlined above) that we are still a long way away from that idealized situation.

02/14/2014: MTAC REVIEW
Artificial Pancreas

Evidence Conclusion: In this review, the results of four RCTs were included. One of these studies compared sensor-augmented insulin pumps to multiple daily insulin injections while two of them compared threshold suspense systems with standard insulin pumps. The last study compared two closed-loop algorithms to patient self-control with CSII. *Effectiveness*: Comparison of the effectiveness of sensor augmented pump therapy versus multiple daily injections (MDI) was examined in a one year multicenter, randomized and controlled phase of the sensor-augmented pump therapy for hemoglobin A_{1C} reduction (STAR-3) study. Compared with 241 subjects on MDI, those on pump therapy (n=244) experienced greater reductions in A_{1C} levels by three months, with the trend continuing throughout the remainder of the study. By the end of the study, the baseline A_{1C} level (8.3% in the two study groups) had decreased to 8.1% in the MDI group compared with 7.5% in the pump therapy group (P<0.001). Participants were offered an optional six-month continuation phase which allowed subjects in the pump therapy group to continue therapy and allowed subjects in the MDI group to cross over to pump therapy. The continuation phase resulted in a sustained lower mean A_{1C} value for patients in the pump therapy group and decreased the mean A_{1C} values to 7.6% (P<0.001) among MDI subjects who crossed over to pump therapy for the continuation phase. (Bergenstal, Tamborlane et al. 2010; Bergenstal, Tamborlane et al. 2011).See Evidence Table. In the three-month automation to simulate pancreatic insulin response trial (ASPIRE), 247 patients with type 1 diabetes and nocturnal hypoglycemia were randomized to sensor augmented insulin pump therapy with the threshold suspend feature (Paradigm group) or to the standard sensor-augmented insulin pump therapy (control group). The primary efficacy outcome was the area under the curve (AUC) for nocturnal hypoglycemic events. At the end of three months, the mean AUC for nocturnal hypoglycemic events was found to be significant through supportive analysis at 37.5% lower in the Paradigm group than in the control group (P<0.001) (Bergenstal, Klonoff et al. 2013). See Evidence Table. In another trial, 95 adults and children with type 1 diabetes were randomized to use of a sensor-augmented insulin pump with threshold suspension or a standard insulin pump. After six months, the combined incidence of moderate and severe hypoglycemic events was significantly lower in patients using the pump with the threshold suspension compared with the standard insulin pump (9.5 vs. 34.2 per 100 patient-months) (Ly, Nicholas et al. 2013). See Evidence Table. Most recently, Luijf and colleagues compared two validated closed-loop algorithms versus patient self-control with CSII in terms of glycemic control. The investigators concluded that both the algorithm developed by the University of Cambridge (CAM) and the algorithm developed by the University of Pavia, Padova, University of Virginia and University of California Santa Barbara (international artificial pancreas [iAP]) provide safe glycemic control. This study, however, occurred in a highly controlled environment for short periods of time. While the algorithms may have the benefit of less time in hypoglycemia, this came at the expense of higher mean glucose values when compared to self-management (open loop) and thus, more time spent in hyperglycemia (Luijf, DeVries et al. 2013). See Evidence Table.



Safety and Adverse Events: Safety and adverse events were included as endpoints in two of the four selected studies. In the STAR 3 study, data on adverse events were collected at each follow up clinic visit. Severe hypoglycemia was defined as an episode requiring assistance and was confirmed by documentation of a blood glucose value of less than 50 mg per deciliter (Bergenstal, Tamborlane et al. 2010). In the ASPIRE study, the primary safety endpoint was the change in glycated hemoglobin level. The change in the glycated hemoglobin level from randomization to study end was not significant in both groups, and the difference in hemoglobin level between groups was only 0.05 percentage points. Beyond that, no episodes of diabetic ketoacidosis occurred in either group or no severe hypoglycemic events occurred in the Paradigm group. During the study phase there were seven adverse events thought to be related to the study device which included skin irritation and device malfunction resulting in severe hyperglycemia (Bergenstal, Klonoff et al. 2013). Generally speaking, the studies had the advantage of randomization and control, however, the lack of blinding makes the evidence vulnerable to bias. In addition, the Ly et al. study relied on patient recall for their results and some of the experimental subjects may have had more contact with physicians opening up the results to recall and observation bias. Sample size ranged anywhere from 48 to 495 participants and most of the studies, with the exception of the STAR 3 Trail, did not report on the racial and ethnic composition of the study samples, and for those that did, participants were predominantly white. Furthermore, inclusion criteria were extremely selective with few studies including children younger than 12 years. In the same way, the data lack generalizability because management was limited to expert settings and among highly motivated patients. Further limitations include heterogeneity in definitions of hypoglycemia and short duration of follow-up ranging anywhere from 24 hours to 18 months. With many complications of diabetes developing over many years it would be ideal to see results allowing for multiple periods of sensor wear and to evaluate changes in subject needs over time. With that said, at the current point in time, APDSs are a rapidly evolving technology that should only be considered in select patients.

Conclusion:

- The results of the published studies suggest that APDS may be effective in reducing hypoglycemia in highly selected, motivated and compliant groups of individuals.
- There is some evidence to support the safety of APDS in highly compliant adult patients.

Articles: The search revealed over 500 articles many of which were commentary, discussion, or systematic review articles. Articles were screened for randomized, comparison studies of outcomes between patients using APDS and a control group of patients using currently available technology. The following articles were selected for critical appraisal: Bergenstal RM, Tamborlane WV, Ahmann A, et al. Effectiveness of sensor-augmented insulin-pump therapy for type 1 diabetes. *New England Journal of Medicine*. 2010;**363**(4):311-320. See Evidence Table. Bergenstal RM, Klonoff DC, Garg SK, et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. *New England Journal of Medicine*. 2013;**369**(3):224-232. See Evidence Table. Ly TT, Nicholas JA, Retterath A, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspensions vs standard insulin pump therapy on hypoglycemia in patients with type 1 diabetes a randomized clinical trial. *JAMA*. 2013; 310:1240-1247. See Evidence Table**.** Luijf YM, DeVries JH, Zwinderman K, et al. Day and night closed-loop control in adults with type 1 diabetes. *Diabetes Care.* 2013;**36**: 3882-3887. See Evidence Table.

Back to Top

Date Sent: 4/29/24

The use of Artificial Pancreas does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Insulin Pump and supplies – Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0784	External ambulatory infusion pump, insulin
A4230	Infusion set for external insulin pump, nonneedle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
K0552	Supplies for external noninsulin drug infusion pump, syringe type cartridge, sterile, each

Insulin Pump *used with continuous glucose monitor*
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week

Artificial Pancreas -
Medicare - Considered not medically necessary
Non-Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® or HCPC Codes	Description
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

InPen Smart Insulin Pen –
Considered medically necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
No specific codes – often submitted as *E1399 Durable medical equipment, miscellaneous* or *A4211 Supplies for self-administered injections*	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised

Date Sent: 4/29/24

09/1988	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012 [MDCRPC], 06/04/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPCC], 07/07/2015[MPC], 08/04/2015[MPC], 09/01/2015[MPC], 06/07/2016[MPC], 01/03/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 01/09/2024[MPC]	12/02/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description of Change
04/07/2015	Revised C-peptide testing requirement.
04/27/2015	Added MTAC review on Insulin Pump for Type II Diabetes
07/07/2015	Revised criteria to include indications for Type II Diabetes
09/03/2015	Added criteria for Pediatrics – 18 years and under
11/09/2015	Merged Artificial Pancreas criteria with Insulin Pump
02/17/2016	Added HCPCS codes
01/03/2017	Revisions made to insulin pump criteria; combined adult and pediatric into one policy
02/07/2017	MPC approved criteria to manage insulin pumps for pregnant patients
10/08/2018	Updated request form links
11/03/2020	Added note about combined insulin pump/CGM device and documentation requirements to support medical necessity; removed insulin brand names
07/20/2021	Added note about InPen Smart Insulin Pen not currently considered medically necessary pending MTAC review.
11/02/2021	MPC approved to waive the 6-month period typically used to learn how to monitor diet and other factors that impact blood sugar results prior to being eligible for an insulin pump for patients under the age of 13. This will be on a case-by-case basis as approved by a medical director. Requires 60-day notice, effective 04/01/2022.
01/04/2022	Updated required length of time to provide self-testing/CGM logs from 2 months to 1 month for initial insulin pump. MPC approved clinical criteria for the InPen System. 60-day notice is required; effective June 1, 2022.
02/24/2022	Updated applicable codes
07/05/2022	MPC approved to cover the Omnipod 5 system and will apply to the Insulin Pump criteria.
12/02/2022	Updated Medicare Policy to defer to KP Non-Medicare criteria for InPen system requests. Updated Medicare LCD L33794 and LCA A52507 links.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intrastromal Corneal Ring Segments (INTACS Inserts)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Intrastromal Corneal Ring Segments (INTACS Inserts)***," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

1) Implantation of intrastromal corneal ring segments may be considered medically necessary for the treatment of keratoconus when **ALL of the following** criteria are met:
   - Functional vision cannot be achieved with contact lenses or spectacles
   - Age 21 years or older
   - Clear central cornea
   - Corneal transplantation is the only other remaining option to improve functional vision
2) Implantation of intrastromal corneal ring segments is considered not medically necessary for the treatment of myopia.
3) Implantation of intrastromal corneal ring segments is considered investigational for all other conditions including, but not limited to, pellucid marginal degeneration.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Keratoconus is a progressive noninflammatory corneal disorder characterized by corneal thinning and protrusion of the central cornea. Signs and symptoms of keratoconus vary and depend on disease severity. In the early stages of keratoconus, individuals may be asymptomatic; however, as the disease progresses, there is considerable distortion of vision in the form of myopia and irregular astigmatism. For patients with mild to moderate keratoconus, vision may be corrected with spectacles or contact lenses. However, as the disorder progresses, or when the patients can no longer tolerate contact lenses, they are referred for corneal transplant (penetrating keratoplasty). The outcomes of this surgery are generally favorable; however, the surgery is not

Back to Top

without complications. Complications of penetrating keratoplasty include graft rejection, intraocular damage, postoperative astigmatism, recurrence of keratoconus, and side effects from the long-term use of topical corticosteroids (Ambekar 2011, Ertan 2007, Romero-Jiménez 2010).

Intrastromal corneal ring segments (Intacs®) inserts are an alternative treatment strategy for patients with mild to moderate keratoconus who are no longer able to achieve adequate vision using contact lenses or glasses and for whom corneal transplant is the only remaining option. Intacs® inserts are small rings of synthetic material that are implanted in the deep corneal stroma with the aim of generating modifications of corneal curvature in an attempt to improve visual acuity, contact lens tolerance, and prevent or delay corneal transplant. The procedure is performed outside the corneal visual axis and the inserts may be removed or replaced if the desired outcome is not achieved. Intacs® inserts should not be used in patients who can achieve functional vision on a daily basis using contact lenses, are younger than 21 years of age, do not have clear corneas, or have corneal thickness less than 450 microns at the proposed incision site. Complications associated with Intacs® inserts include patient dissatisfaction with visual quality, discomfort, and ring segment extrusion or migration (Ambekar 2011, Bromley 2010, Ertan 2007, Romero-Jiménez 2010).

Intacs® inserts received FDA approval in 2004.

Medical Technology Assessment Committee (MTAC)

INTACS Inserts in the Treatment of Keratoconus

10/03/2005: MTAC REVIEW

Evidence Conclusion: The studies reviewed, as well as others revealed by the literature search, were all case series comparing the postoperative results to the preoperative values among the same groups of patients. Case series have potential selection and observation biases as well as other threats to internal validity. The results of these series may indicate some improvement in visual acuity after the implantation of Intacs in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to penetrating keratoplasty or other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (PK). In conclusion, larger studies with longer follow up and that compare the outcomes of the technology with those achieved with PK are needed to determine the efficacy and long-term stability, benefits, and harms of the technology.
Articles: The search revealed 18 articles. There were no meta-analyses or randomized controlled trials. All published studies identified were prospective or retrospective case series and had no control groups. Two prospective series on the use of Intacs for the management of keratoconus were selected for critical appraisal. Selection was based on the sample size, duration of follow-up, and quality of study. *Evidence tables were created for the following studies:* Hellstedt T, Makela J, Uusitalo R, et al. Treating keratoconus with Intacs corneal ring segments. *J Refract Surg.* 2005; 21:236-246. See Evidence Table. Siganos CS, Kymionis GD, Kartakis N, et al. Management of keratoconus with Intacs. *AM J Opthalmol* 2003; 135:64-70. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/19/2011: MTAC REVIEW

INTACS Inserts in the Treatment of Keratoconus

Evidence Conclusion: The study reviewed for the 2011 update, as well as those reviewed in the original 2005 MTAC review, were all case series comparing postoperative results to the preoperative values among the same groups of patients. Results from case series should be interpreted with caution as this type of study design is prone to bias. The results of these studies may indicate some improvement in visual acuity after the implantation of Intacs® inserts in patients with keratoconus with a clear central cornea and intolerability to contact lenses. However, the technology was not compared to other alternative therapies, and the follow-up duration was insufficient to determine the stability of the observed outcomes and the long-term harms that could be associated with Intacs inserts. Moreover, these studies do not provide evidence to determine if this technology would prevent the progression of keratoconus and eliminate the need for penetrating keratoplasty (Colin 2007, Hellstedt 2005, Siganos 2003). Conclusion: There is insufficient evidence to determine the safety and efficacy of Intacs® inserts for the treatment of keratoconus.
Articles: The literature search did not reveal any meta-analyses or randomized controlled trials. The published studies identified were prospective or retrospective case series. The largest prospective case series with the longest duration of follow-up was selected for review.

Back to Top

The following study was critically appraised: Colin J and Malet F. Intacs for the correction of keratoconus: two-year follow-up. *J Cataract Refract Surg. 2007;* 33:69-74. See Evidence Table.

The use of INTACS Inserts in the treatment of keratoconus does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
65785	Implantation of intrastromal corneal ring segments

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Dates Reviewed	Date Last Revised
10/03/2005	Reinstated criteria on 01/03/2012 MDCRPC, 12/04/2012 MDCRPC ,10/01/2013 MPC, 08/05/2014 MPC, 06/02/2015 MPC, 04/05/2016MPC, 02/07/2017MPC, 12/05/2017MPC, 10/02/2018MPC, 10/01/2019MPC, 10/06/2020MPC, 10/05/2021MPC , 10/04/2022MPC , 10/03/2023MPC	12/05/2017

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/18/2015	Revised LCD L35008
12/05/2017	Adopted Kaiser Permanente Policy for Medicare

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Intermittent Pneumatic Compression for the Treatment of Peripheral Arterial Occlusive Disease

- ArtAssist Device
- ArterialFlowTM System
- Flow MedicTM System

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Pneumatic Compression Devices (280.6)
Local Coverage Determinations (LCD)	Pneumatic Compression Devices (L33829)
Local Coverage Article	Pneumatic Compression Devices (A52488)

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Peripheral arterial disease (PAD) is a common condition that affects approximately 8-12 million people in the US. The prevalence of the disease increases rapidly with age and is associated with significant morbidity and mortality. PAD commonly affects the arteries supplying the leg and is mostly caused by atherosclerosis. Restriction of blood flow due to arterial stenosis or occlusion is commonly clinically presented as intermittent claudication which is pain in the calf muscles that occurs on walking or exercising and is rapidly relieved by resting.

The clinical course of patients with intermittent claudication is variable. Most patients either improve or have a stable condition, but over one fourth will experience deterioration in symptoms. These patients may eventually develop critical leg ischemia or gangrene which can lead to amputation. Fontaine classified chronic leg ischemia into four stages: Stage I: asymptomatic, stage II: intermittent claudication, stage III: ischemic rest pain, and stage IV: ulceration, gangrene, or both (Hirsch 2001, Leng 1993, Delis 2000, 2005, Beard 2000).

The treatment of PAD aims at increasing blood flow to alleviate symptoms and prevent arterial leg ulcers, critical leg ischemia, and major complications. Management options for claudication include a structured program of regular exercise, smoking cessation, control of risk factors or associated medical diseases, percutaneous

Back to Top

Date Sent: 4/29/24

transluminal angioplasty, and surgical revascularization. Drug therapy, even with the most effective agents, was found to result in only a modest improvement. Surgical bypass reconstruction is indicated for severe cases and after failure of other forms of conservative therapy. Patients with non-healing ulcers may not be suitable for revascularization for technical reasons, frail condition, or rejection of surgical intervention. Due to the limited non-operative treatment options, long-term graft failure, perioperative deaths, and imitations or contraindications to intervention, researchers have focused their attention on mechanical methods as potential means for augmenting arterial volume flow in lower limbs (Delis 2000, Montori 2002, 2005).

The concept of using mechanical means to increase blood flow to an ischemic limb dates back to 1930s when a group of investigators applied alternating external pressure to ischemic legs with advanced atherosclerotic peripheral vascular disease. They were however unable to measure blood flow or optimize pneumatic compression. The interest in using intermittent pneumatic compression was renewed in the late 1970s when researchers observed that intermittent pneumatic compression can temporarily increase the arterial blood flow to the limbs. The devices developed apply high pressures by compression cuffs placed on the thigh, calf, and/or foot, intermittently inflate and deflate with cycle times and pressures that vary between devices.

The ArtAssist© Device (ACI Medical Inc., San Marcos, California), is a mechanical pneumatic pump consisting of an impulse generator and two plastic inflatable cuffs. It applies high pressure in a synchronized manner to the foot and calf. This outpatient treatment usually performed for three 1-hour sessions per day while the patient is sitting upright. According to the manufacturer, when the device compresses tissue below the knee, venous blood is emptied, and the venous pressure drops to near zero. The resultant increase in the arteriovenous pressure gradient increases arterial blood inflow. Another potential mechanism also described by the manufacturer involves the release of vasodilating substances as endothelial nitric oxide due to the decreased local vascular resistance. Stimulation of collateral blood vessel formation may also occur (ACI medical Inc. web site).

The ArtAssist device as well as the Flow MedicTM system, and ArterialFlowTM system are all FDA approved for use to improve blood circulation in the lower extremities to help prevent and reduce complications of poor circulation.

Medical Technology Assessment Committee (MTAC)

Intermittent Pneumatic Compression

02/04/2008: MTAC Review

Evidence Conclusion: The trials on intermittent pneumatic compression (IPC) studied the efficacy of the therapy, mainly using the ArtAssist device, for patients with stable intermittent claudication. There were no RCTs with clinical outcomes that evaluated the IPC for use among patients with more severe condition or those who failed revascularization. All published trials were small, single centered, conducted among highly selected groups of patients, were not blinded, short-term, and none compared IPC to a sham therapy. Kakkos and colleagues (2005), randomized 34 highly selected patients with stable intermittent claudication to receive IPC (n=13), supervised exercise (n=12), or unsupervised exercise (n=9). The study was too small, was unblinded, and had a high dropout rate. Its results show that compared to the unsupervised exercise, both IPC and supervised exercise increased the initial claudication distance (ICD) and the absolute claudication distance (ACD). The difference in improvement observed was statistically significant at the end of the six-month treatment and after six additional months of follow-up. There was no significant difference however between the IPC and supervised exercise groups.

In their pilot study, Ramaswami and colleagues (2005) evaluated the efficacy of IPC among 34 patients with stable intermittent claudication who were randomized to receive IPC with daily unsupervised exercise or to just perform daily unsupervised exercise. IPC was not compared to sham treatment or to a supervised exercise program. The results showed an increase in the initial and absolute claudication distances with IPC at 4 and 6 months of treatment and the improvement was sustained at 1 year. Delis and Nicolaides (2005) also evaluated the effectiveness of IPC in 41 highly selected patients with stable intermittent claudications. These were randomly assigned to receive IPC and salicylic acid (75 mg/dL), or salicylic acid (75 mg/dL) alone. All participants in the two groups were encouraged to exercise daily and were followed up for 12 months after the treatment period. The results of the trial show that the ICD, ACD, increased significantly in the IPC group starting at the first month of treatment and was sustained for one year after completing the therapy. Only a small insignificant change was observed in the control group, and the difference between the two study groups was significant. The quality of life also improved significantly in the IPC group, but not in the control group. *Conclusion*: The available evidence from these trials as well as other earlier studies and case series suggest that intermittent pneumatic compression therapy of the foot and calf with ArtAssist device might be associated with improvement in the arterial blood flow and in the walking distance over a short term among patients with stable intermittent claudication. However, the studies included highly selected groups patients with stable claudications who had superficial femoral artery

Back to Top

occlusion, and patent iliac arteries (also patent popliteal artery as indicated by some studies). Those with a history of a lower extremity revascularization history were excluded, as well as those with several other comorbidities. Moreover, the studies had control groups not placebo groups undergoing a sham IPC treatment. There were no long-term outcomes beyond one year of follow-up, and the studies did not determine the effectiveness of treatment in improving rest pain, ulcer healing, or reducing amputation rate, all of which may limit generalization of the results. In conclusion there is insufficient evidence to determine the efficacy of pneumatic compression devices for the treatment intermittent claudication, or more severe symptoms among patients with peripheral artery occlusive disease.

Articles: There were five small RCTs, one nonrandomized controlled study, and several prospective and retrospective small case series with no control or comparison groups. The majority of trials were conducted among patients with stable claudication. There was a small trial, with intermediate outcomes that compared three modes of IPC in healthy limbs as well as those with successful grafts. The literature search did not reveal RCT that evaluated the IPC use for patients with more severe condition or those who failed revascularization. *Studies with an appropriate comparison group and/or longer follow-up duration were selected for critical appraisal:* Kakkos SK, Geroulakos G, Nicolaides AN. Improvement of the walking ability in intermittent claudication due to superficial femoral artery occlusion with supervised exercise and pneumatic foot and calf compression: A randomized controlled trial. Eur J Vasc Endovasc Surg. 2005; 30:164-175. See Evidence Table
Ramaswami G, D'ayala M, Hollier LH, et al., rapid foot and calf compression increases walking distance in patients with intermittent claudication: Results of a randomized study. J Vasc Surg. 2005; 41:794-801. See Evidence Table Delis KT, Nicolaides AN. Effect of intermittent pneumatic compression on foot and calf on walking distance, hemodynamics, and quality of life in patients with arterial claudication. A prospective randomized controlled study with 1-year follow-up. Ann Surg 2005;241:431-441 See Evidence Table

The use of Intermittent pneumatic compression in the treatment of peripheral arterial occlusive disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary:

HCPC Codes	Description
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Date	Date Last Revised
02/26/2008	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC], 01/09/2024[MPC]	08/04/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/04/2020	Added Medicare LCD L33829 and LCA A52488

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Patient Referral Guidelines
Intestinal and Multi-Visceral Transplantation

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Intestinal and Multi-Visceral Transplantation (260.5)
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

For Non-Medicare Members

Transplantation may be considered for patients with end-stage or life-threatening disease who have no prospect for prolonged survival, or whose quality of life is severely impaired. These guidelines for referral for transplant evaluation are not intended as an automatic inclusion or exclusion of a candidate for referral.

Intestinal Transplantation alone may be considered for selected pediatric and adult patients with Short Bowel Syndrome and/or intestinal failure who require chronic Total Parenteral Nutrition (TPN) and have severe complications that lead to serious morbidity and could lead to mortality.

Combined Intestinal/Liver Transplantation may be considered in selected pediatric and adult patients with Short Bowel syndrome and irreversible progressive chronic liver disease when there is no prospect for prolonged survival with conventional therapy.

The following are current, generally accepted, guidelines for Intestinal Transplantation.

1. GENERAL PRINCIPLES

1.1. If clinical parameters of end-stage or life-threatening disease indicate the need for transplantation, then early referral should be made.

1.2. Patients with a history of malignancy with a moderate to high risk of recurrence (as determined after consultation with oncologist considering tumor type, response to therapy, and presence or absence of metastatic disease) may be unsuitable candidates for transplantation. Patients with low risk of recurrence may be considered.

1.3. Uncontrollable active infection is a contraindication to transplant.

1.4. Candidates with a history of substance abuse must be free from alcohol and other substance abuse for six (6) months and have been evaluated by a substance abuse program. The risk of recidivism, which has been documented to negatively impact transplant outcomes, must be addressed and considered to be low[1,2,3] Exceptions may be made on a case-by-case basis.

1.5. Candidates for thoracic organ (heart, lung and heart/lung) transplants must be free from tobacco use for the previous six (6) months. Routine monitoring may be required. Specific programs for abdominal organs (liver, intestines, and kidney) may require abstinence from tobacco products in order to be actively listed.

1.6. Candidates must have adequate social support systems and display a proven record of adherence to medical treatment.

Back to Top

Date Sent: 4/29/24

1.7. Patients must be willing and able to travel within short notice to a KP approved transplant Center of Excellence and, if necessary, return for treatment of complications.

1.8. Patient must have a caregiver or caregivers who are physically and cognitively able to assist the patient with self-care activities and are available to travel within short notice to the KP approved transplant Center of Excellence.

1.9. The presence of significant irreversible neurologic dysfunction, active psychological and/or psychiatric conditions, and/or other social behaviors that prevent adherence with a complex medical regimen, are considered contraindications for referral for transplant.

1.10. Evidence of such nonadherence may be: failure to keep appointments, failure to make steady progress in completing pre-transplant evaluation requirements, failure to accurately follow medication regimens or failure to accomplish the activities required.

1.11. Whenever transplant is considered as an option and discussed with the patient and/or family, consultation with Advanced Life Care Planning/Palliative Care resources is strongly recommended.

2. INDICATIONS FOR INTESTINAL TRANSPLANT

2.1. Intestinal Transplant

2.1.1. Pediatric or adult patients with irreversible Short Bowel Syndrome or intestinal failure[4], who have severe complications of TPN, including, but not limited to the following:

2.1.1.1. Lack of vascular access

2.1.1.2. Recurrent central venous catheter-related infections

2.1.1.3. Metallic bone disease

2.1.1.4. Evidence of severe or progressive hepatic dysfunction

2.2. Combined intestinal-liver transplant.

2.2.1. Adult and pediatric patients with Short Bowel Syndrome and/or intestinal failure and irreversible progressive chronic liver disease.

3. CONTRAINDICATIONS FOR INTESTINAL TRANSPLANT

3.1. Advanced cardiopulmonary disease or any other life limiting disorders, excluding hepatopulmonary syndrome.

3.2. Inability to accept the procedure, understand its nature, or cooperate with the treatment protocol.

3.3. Patients with HCC, who exceed Region 5[5]/UCSF[4] criteria, should not be sent for intestinal transplant evaluation at this time because they are not medically appropriate. Exceptions may be made on a case by case basis for hepatoblastoma.[5]

3.4. Irreversible brain damage or significant neurologic dysfunction.

4. RELATIVE CONTRAINDICATIONS FOR INTESTINAL TRANSPLANT

4.1. Relative contraindications include, but not necessarily limited to:

4.1.1. Renal Failure (excluding hepatorenal syndrome)

4.1.2. Portal Vein thrombosis

4.1.3. Active infection outside the hepatobiliary system

4.1.4. Advanced malnutrition

4.1.5. Severe diabetic complications

4.1.6. Multiple abdominal surgeries

Footnotes:

1. Liver Transplantation 2006, .12:813-820. Alcohol consumption patterns and predictors of use following liver transplantation for alcoholic liver disease.

2. Liver Transplant Surg, 1997, Vol 3, 304 – 310. The natural history of alcoholism and its relationship to liver transplantation.

3. Alcohol abstinence prior to liver transplantation for Alcoholic Liver Disease (G110807), TPMG New Medical Technology

Back to Top

4. May be due, but not necessarily limited, to the following examples:
   a. Volvulus
   b. Atresia
   c. Necrotizing Enterocolitis
   d. Crohn's Disease
   e. Gastroschisis
   f. Superior Mesenteric Artery Thrombosis
   g. Trauma

5. The Region 5 criteria for intestinal patients with HCC is 1 tumor: S5 cm or 2 – 3 lesions, none >3 cm and no vascular invasion. NEJM 1996, 334: 633-699. Pediatr Surg Int. 2016 Oct 11., J Pediatr Surg. 2007 Jan;42(1):184-7., Pediatr Transplant. 2016 Jun;20(4):515-22. doi: 10.1111/petr.12699. Epub 2016 Mar 27.

REVISED BY CLINICAL MANAGEMENT SUBCOMMITTEE: SEPTEMBER 23, 2020
ADVISORY COUNCIL APPROVED AND EFFECTIVE DATE: OCTOBER 22, 2020

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Intestinal transplantation is an evolving procedure that was experimentally developed more than 30 years ago. It involves transplantation of a cadaveric intestinal allograft for the purpose of restoring bowel function for patients with irreversible failure. The intestine's massive lymphocyte content and heavy bacterial load provided barriers for nearly three decades. Intestines are more susceptible to rejection and carry higher risk of graft versus host disease (GVHD). The procedure proved to be clinically feasible for humans in the late 1980s but had considerable morbidity and mortality. The initial recipients of the intestinal grafts did poorly because of technical complications, graft rejection and sepsis. Recently better results were reported due to improved surgical techniques, more potent immunosuppressive drugs, and standard prophylaxis for infections and lymphoproliferative disease. Although the purpose of intestinal transplantation is to restore bowel function, patient survival should be considered the primary outcome of interest.

The first long-term success was reported in 1988 when cyclosporin-based immunosuppression was used, yet there were many failures due to rejection. The introduction of FK 506 or Tacrolimus have led to an explosion of the intestinal transplantation activity in the 1990s. It is 100 times more potent than cyclosporin and is somewhat less toxic. Steroids are administered during the early postoperative period and discontinued completely within a month. Since 1990 surgeons at the University of Pittsburgh Medical Center (UPMC) and Children's Hospital of Pittsburgh have performed more than 115 transplants involving the small intestine. This is close to half the total number performed worldwide.

There are three types for intestinal transplantation: small bowel transplantation (SBT), Small bowel/liver transplantation (SB/LT), and multivisceral transplantation (MVT) which is defined as en-bloc transplantation of 3 or more abdominal organs that include liver, stomach, pancreatic-duodenal complexes as well as the intestine with or without the right hemi-colon. Intestinal transplantation is not an alternative to total parenteral nutrition (TPN) but is only intended for selected patients who are predicted to have poor survival on TPN. It should be considered as a life-saving procedure. Patients who can be maintained on long term TPN are not considered for transplantation at the present time.

An isolated intestinal graft is recommended for patients who have fluid and electrolyte loss that cannot be managed by TPN, those with severely limited venous access and/or moderate liver dysfunction secondary to TPN. Combined SB/LT is offered to patients with irreversible liver failure due to TPN, or intestinal/liver failure associated with a hyper-coagulable state that is corrected by a simultaneous liver graft. Multivisceral

Back to Top

transplantation is offered to patients with locally aggressive tumors that can only be removed by a massive evisceration of the abdominal organs. Intestinal transplantation is contraindicated in old age, cardiopulmonary deficiency, AIDS, systemic malignancy and life-threatening infections.

The FDA does not regulate surgical procedures such as intestinal and multivisceral transplantation. However, immunosuppressive drugs are FDA regulated. Tacrolimus, the primary immuno-suppressant used with these transplants was approved by the FDA in April 1994 for rejection prophylaxis in allogenic liver transplantation.

Medical Technology Assessment Committee (MTAC)

Intestinal Transplantation

04/10/2002: MTAC REVIEW

Evidence Conclusion: The literature reviewed did not reveal any study that compared intestinal transplantation to the long term TPN therapy, and the evidence available does not allow for definitive conclusions. The studies reviewed show that the one- year survival rate of intestinal transplantation varied among studies from 54% to 75%. This dropped to around 42-50% at 5 years. Infection was responsible for more than 40% of the deaths. All studies were case series with limitations including potential selection bias, and lack of control or comparison group. However, it is unlikely that controlled trials, in which outcomes from intestinal/multivisceral transplantation are compared to TPN and medical management, would be conducted. The current use of intestinal transplantation as a rescue therapy for TPN-dependent patients invalidates any comparison with TPN.
Articles: Articles were selected based on study type. The search yielded 175 articles most of which were reviews, opinion pieces, editorials, and letters. The literature did not reveal any randomized controlled trials, or meta-analyses, only clinical reports and case series. The articles with the largest size, longest follow-up duration, and with patient survival as the primary outcome of interest were selected for critical appraisal. *Evidence tables were created for the following case series:* Abu-Elmagd K, et al. Clinical intestinal transplantation. Annals of Surgery 2001;234(3):404-17. See Evidence Table Jamieson NV. Adult small intestine transplantation in Europe. Acta Gastro- Enterologica Belgian 1999;62(2):239-43. See Evidence Table Madariaga JR, et al. The long-term efficacy of multivisceral transplantation. Transplantation proceedings 2000; 32:1219-20. See Evidence Table.

The use of Intestinal Transplantation in the treatment of irreversible intestinal failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
05/30/2001	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 10/02/2012[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] ,08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	06/12/2020

[MDCRPC] Medical Director Clinical Review and Policy Committee

[MPC] Medical Policy Committee

Revision	Description

Back to Top

History	
04/07/2020	MPC approved to adopt Kaiser Permanente National coverage policy
06/12/2020	Added “Patient Referral Guidelines” to title

Date Sent: 4/29/24
These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intraocular Lens Following Cataract Extraction

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Intraocular Lens (80.12)
Local Coverage Determinations (LCD)	Refractive Lenses (L33793) *When hydrophilic soft contact lenses (V2520, V2521, V2522, V2523) are used as a corneal dressing, they are denied as noncovered because in this situation they do not meet the definition of a prosthetic device.*
Local Coverage Determinations (LCA)	Refractive Lenses (A52499)

For Non-Medicare Members

Accommodative Intraocular Lens

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Multifocal Intraocular Lens

Multifocal intraocular lenses will not be covered. Standard monofocal intraocular lenses are covered following cataract surgery. The patient may elect to pay for the multifocal lens.

Toric Intraocular Lens

Toric intraocular lenses to correct astigmatism are not covered. The purposes of these lenses are to reduce dependence on glasses. Improved vision with glasses is the purpose of standard cataract surgery, the additional benefit of improved vision without glasses is not a covered service.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

It is estimated that over 20 million Americans older than 40 years have cataract in at least one eye. It is predicted that this number will increase to 30 million by 2020. The current approach of treating cataracts is to replace the natural crystalline lens of the eye with an artificial intraocular lens (IOL). Traditionally intraocular lenses are monofocal lenses, which can provide excellent distance vision and optical quality, but they do not deliver functional vision at other ranges of distance. After their implantation most patients need spectacles at least for near vision. Bifocal and multifocal IOLs were developed to overcome the lack of accommodation in these pseudophakic patients (i.e. patients with an artificial IOL). They provide good functional distance, near, and

Back to Top

Date Sent: 4/29/24

intermediate vision without the use of corrective lenses. However, multifocal and bifocal IOLs may have optical side effects such as decreased contrast sensitivity, glare disability, and halos, which can reduce the retinal image quality and affect the patient's visual performance (Harman 2008, Alio 2010, Alio 2011, Cochener 2011).

Accommodative Intraocular Lens

Positional accommodating IOLs were developed to avoid the optical side effects of the multifocal IOLs and provide some accommodative capability and functional near vision. The basic mechanism of these lenses is the transmission, by haptics (plastic plates or struts), of the contracting forces of the ciliary body to the flexible lens. The design of these IOLs is based on the optic-shift concept i.e. on the axial (backward and forward) movement of the optic resulting from the contraction and relaxation of the ciliary muscle. A hinge between the optic and haptics allows the lens to move forward as the eye focuses on near objects and backward as the eye focuses on distant objects, thereby increasing the dioptric power of the pseudophakic eye. The first developed accommodative IOLs were positional single optic lenses used for both cataract and surgical correction of presbyopia. Among these are the Crystalens™ (Eyeonis, Inc., 1CU [Human Optics Erlangen, Germany], and Tetraflex [KH3500, Lenstec, St Petersburg Florida]) (Marchini 2007).

The Crystalens™ AT-45 IOL is the seventh design of the Crystalens™. It consists of a single biconvex lens with a 4.5 mm optic with two plate haptics each terminating in two polyamide loops that anchor it to the capsular bag. Adjacent to the optic are grooved flexible hinges in the plates that allow forward movement of the optic during accommodative effort to provide near and intermediate vision in pseudophakic patients. The optic is square-edged and is made of silicone to maximize biocompatibility and flexibility and allow easy insertion of the lens through a 3 mm corneal incision. A newer Crystalens™ model (Crystalens HD) has a mechanism of action based on the transitional movement of the lens in anterior and posterior direction due to ciliary muscle contraction and vitreous mass displacement (Macsai 2006, Cumming 2006).

The Tetraflex (Lenstec) lens is an anteriorly vaulted, single-piece, foldable, accommodating IOL that is implanted using a custom-designed injector system through an incision as small as 3 mm. The lens' optic is 5.75 mm and is made of a highly biocompatible and extremely flexible hydrophilic acrylic material (HEMA). The IOL's two haptics, each with two footplates, sit posteriorly in the peripheral capsular bag (Sheppard 2010).

The 1CU is a foldable single-piece lens with an optic diameter of 5.5 mm and an overall length of 9.8 mm. It is made of a hydrophilic acrylic material and has a biconvex square-edged optic and 4 modified flexible haptics that are designed to bend when constricted by the capsular bag after ciliary muscle contraction. This allows anterior displacement of the optic resulting in an increase in the refractory power (Pallikaris 2011).

The single-optic passive shift IOLs are considered pseudoaccommodative and have limited accommodative ability as their anterior movement is insufficient to provide functionally significant amplitudes of accommodation. The limited optic power of the single optic lenses led to the development of dual-optic devices as the Synchrony (Visiogen, Irvine, California, USA), and the Sarfarazi IOL (developed by FM Sarfarazi of Shenasa Medical LLC, Carlsbad, CA, USA). The configuration of these devices with a high positively-powered mobile anterior optic, connected to a stationary negatively-powered posterior optic, is designed to increase the potential accommodative amplitude (Alio 2009, Sheppard 2010).

Investigators indicate that the way of measuring the range of accommodation in pseudophakic eyes is still unclear. In a recent review article, Pallikaris and colleagues state "Objective measurement of the accommodative capability offered by the accommodative IOLs is extremely difficult to obtain, and different methods such as autorefractometers, retinoscopy, and ultrasound imaging during accommodative effort, ray tracing, or pharmacological stimulation have been developed but the results are sometimes inconsistent… Pseudophakic accommodation, that is, the dynamic component of ocular refractive variation during near vision, and pseudophakic pseudoaccommodation, that is, the depth of focus and the subjective adaption to defocus during near vision, are the two core parts of pseudoaccommodation. Currently there is no consensus in the literature on the percentage of the participation of each part in the phenomenon of pseudoaccommodation. Several different methods are utilized by investigators for the study of the phenomenon thus resulting in different results." (Pallikaris 2011).

Multifocal Intraocular Lens

Bifocal and multifocal intraocular lenses have optical side effects such as glare, halos, and decreased contrast sensitivity, which can reduce the retinal image quality and affect the patient's visual performance. The Array IOL (Advanced Medical Optics [AMO], Santa Ana, CA), one of the first IOLs approved by the FDA (1997) is a typical refractive multifocal IOL. Earlier trials demonstrated that Array IOL improved distance and near visual acuity and reduced spectacle dependency after cataract extraction, but it was also associated with problems as decreased

Back to Top

contrast sensitivity, glare, and halos. Newer generations of multifocal IOLs have been developed with the aim of providing better visual acuities at various distances with less glare and halos and without need for any spectacles. Currently in the United States, multifocal lens options include the ReZoomTM lens (Abbott Medical Optics [AMO] Inc, Santa Ana, CA), ReSTOR® lens (Alcon Laboratories Inc, Fort Worth, TX), and the Tecnis® lens (Abbott Medical Optics Inc, Santa Ana, CA) (Kawamorita 2009).

The ReZoom™ (AMO) is a second-generation multifocal refractive lens that improved on the design of the Array with the aim of decreasing the symptoms of glare and halos. It is a three-piece multifocal lens made of hydrophobic acrylic material and has five refractive optical zones; each zone designed for different light and focal distances: zones 1, 3, and 5 are adjusted for far vision, while zones 2 and 4 are adjusted for near vision. The design of ReZoom is different from the Array in that the second and third zones have been enlarged, and the fourth and fifth zones have been reduced in size. An aspheric transition between zones provides balanced intermediate vision. These changes potentially reduce in night-time glare and improves uncorrected near visual acuity (Forte 2009, Kawamorita 2009, Alio 2011, Kubal 2011, Lichtinger 2012).

The ReSTOR® (Alcon Laboratories Inc) is a diffractive one-piece posterior chamber IOL. It is the first diffractive IOL to be approved by the FDA. ReSTOR® is a biconvex lens made of a soft plastic that can be folded prior to insertion, allowing placement through an incision smaller than the optic diameter of the lens. After surgical insertion into the eye, the lens gently unfolds to restore vision. The supporting arms (haptics) provide for proper positioning of the IOL within the eye. ReSTOR® lens has 12 concentric diffractive rings that cover the central 3.6 mm of the lens. The diffractive portion of the lens is apodized i.e. the height of each diffractive step decreases with increasing distance from the lens center in order to create a smoother transition between focal points. The ReSTOR® is considered a hybrid of diffractive and refractive IOLs with the lens periphery functioning as a refractive zone focusing for distance vision. In 2007, the FDA approved the aspheric version of the ReSTOR® (AcrySof IO, ReSTOR), which has a 10 µm of negative asphericity, while maintaining its apodization and diffractive and refractive components. Recently, a new +3.0 diopter (D) was introduced to improve intermediate vision, which was suboptimal with the +4 D models (Alio 2011, Sood 2011, Zhang 2011, Kubal 2011, Lichtinger 2012).

The Tecnis® Multifocal Intraocular Lens (AMO) is an ultraviolet light-absorbing posterior chamber lens. It was first available as a 3-piece silicone lens (ZM900), then later it became available as a 3-piece acrylic (ZMA00), or a single piece acrylic (ZMB00) lens. The lens is foldable so that it can be inserted into the eye through a very small incision that is actually smaller than the diameter of the lens itself. It has an optical design based on a principle of diffraction similar to the AcrySof ReSTOR® IOL, but with the diffractive rings covering the entire posterior surface of the lens. The rings start very close to the center of the lens and then continue out toward the periphery, usually with an increasing distance between the rings. As a result, the lens achieves its multifocal effects with minimal dependence on the size of the pupil (Sood 2011, Lichtinger 2012).

The ReZoom™, AcrySof ReSTOR 3.0 and 4.0 D, and Tecnis® multifocal intraocular lenses have all received FDA clearance for the visual correction after cataract extraction in adult patients with and without presbyopia.

Medical Technology Assessment Committee (MTAC)

Multifocal Intraocular Lens

04/11/2001: MTAC REVIEW

Evidence Conclusion: A single well-done RCT provides evidence that multifocal IOL are as effective as monofocal IOL for distance acuity. Patients with multifocal IOL had better uncorrected near VA and distance-corrected near VA than monofocal IOL patients, but similar best-corrected near VA add power. A case series with long-term follow-up showed a high rate of efficacy on visual acuity with multifocal IOL. All studies reviewed indicated that a limitation of multifocal IOL is decreased contrast sensitivity. The cohort study, which had compromised validity, found less contract sensitivity with multifocal compared to monofocal IOL in daylight and twilight with no glare and twilight with central glare. The benefits of multifocal IOL should be weighed against possible decreases in contrast sensitivity and the efficacy of monofocal IOLs with glasses for near focus.
Articles: The search yielded 30 articles. There were 2 RCT articles; these were based on data from the same study. The majority of the articles were case series with small numbers of patients. Evidence tables were created for three studies: The most recent report of RCT data: Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation: A multinational clinical trial evaluating clinical, functional and quality-of-life outcomes. Am Acad Ophthalmol 2000; 107: 2040-2048. See Evidence Table. A cohort study examining possible adverse effects of multifocal IOL: Winther-Nielsen A, Corydon L, Olsen T. Contrast sensitivity and glare in patients with a diffractive multifocal intraocular lens. J Cataract Refract Surg 1993; 19: 254-257. See Evidence Table. A

case series with long-term follow-up data: Slagsvold JE. 3M diffractive multifocal intraocular lens: Eight year follow-up. J Cataract Refract Surg 2000; 26: 402-407. See Evidence Table.

The use of multifocal Intraocular Lens in the treatment of visual correction following cataract surgery does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/2005: MTAC REVIEW
Intraocular Lens
Evidence Conclusion*: Accommodative Intraocular Lens* The evidence on Crystalens™ is insufficient to draw conclusions about its efficacy and safety compared to standard intraocular lenses. The single published comparative study (Alio et al., 2004) had threats to validity. It was a non-randomized comparison of three case series, one on Crystalens, one on the Array multifocal lens and one on the Twinset bifocal IOL. The study is subject to selection bias because patients were not randomized, and the authors did not control statistically for confounding factors. The study was also non-blinded and thus subject to observation bias. The study had four primary outcomes. Between-group differences were statistically significant for one out of the four outcomes, mean best corrected near acuity, but not for mean uncorrected distance acuity, mean best corrected distance acuity or mean uncorrected near acuity. There were two studies on the 1CU IOL by HumanOptics, a non-FDA approved accommodative IOL. This evidence is also weak. One of the studies (Kuchle et al., 2004) was non-randomized and did not control for confounding factors and is therefore subject to selection bias. The other study (Dogru et al., 2005) was randomized, but the study methodology was not well described, making it impossible to assess validity. There were also validity issues with the statistical analysis in the Dogru study.
Articles: *Accommodative Intraocular Lens* There was one study comparing the FDA approved accommodative IOL, Crystalens, to other types of IOLs. There were two studies comparing the non-FDA approved 1CU accommodative IOL (HumanOptics: Erlangen, Germany) to other IOLs. Like Crystalens, the 1CU IOL has a hinge-like design which allows for forward and backward movement. These three empirical studies were critically appraised. In addition, there was a small case series (n=14) reporting on the initial phase of the Crystalens FDA clinical trial. This study was excluded from further review. Evidence tables were created for the following studies: Crystalens™ Alio JL, Tavalato M, De la Hoz F et al. Near vision restoration with refractive lens exchange and pseudoaccommodating and multifocal refractive and diffractive intraocular lens. J cataract Refract Surg 2004; 30: 2494-2503. See Evidence Table. Human Optics 1CU. Dogru M, Honda R, Omoto M. Early visual results with the 1CU accommodating intraocular lens. J Cataract Refract Surg 2005; 31: 895-902. See Evidence Table. Kuchle M, Seitz B, Langenbucher A et al. Comparison of 6-month results of implantation of the 1CU accommodative intraocular lens with conventional intraocular lens. Ophthalmology 2004; 111: 318-324. See Evidence Table.

The use of Accommodative Intraocular Lens in the treatment of visual correction following cataract surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/16/2012: MTAC REVIEW
Intraocular Lens
Evidence Conclusion: *Accommodative Intraocular Lens* Crystalens™: AT-45 The literature search did not reveal any published large good quality RCTs that compared the implantation of the accommodative Crystalens™ with multifocal or monofocal intraocular lenses after cataract extraction. The best published evidence on Crystalens™ comes from the FDA multicenter clinical trial with 12 months follow-up (Evidence table 1). The initial study was a phase II trial that evaluated the efficacy and safety of the CrystalensTM AT-45. It was a prospective cohort study with no control or comparison group. The results of 12 months follow-up of 263 patients receiving the implant in the primary eye showed that the accommodating CrystalensTM AT-45 provided good uncorrected near and distance visual acuity with minimal adverse effects. In a substudy the authors compared contrast sensitivity under mesopic conditions with and without glare in a subgroup of patients who received the Crystalens versus a matched population of 64 patients who received standard IOL. The results of this substudy showed that the difference in contrast sensitivity between the two groups of patients was clinically irrelevant.
ICU (Human Optics) Several randomized and nonrandomized trials compared the performance of 1CU with monofocal and multifocal intraocular lenses (IOLs) (Evidence tables 2-4). The results of the studies showed that distance corrected near vision was significantly better in the 1CU group versus other groups receiving non-accommodating IOLs. Two small studies showed that the accommodative ability of the lens may decrease by time (8 months in Sauder and colleagues' trial and 12 months in Dogru and colleagues' study) leading to a reduction in the near vision acuity. The studies had some limitations and long-term follow-up is needed to determine the long-term safety and efficacy of the lens. In a large prospective, controlled, but non-randomized trial with potential biases (Evidence table 3), Uthoff and colleagues found that 1CU had a minor statistical advantage of half a reading step towards monofocal IOLs measured with subjective methods in near point, defocusing curve, and near visual acuity with BSCVA. They explained that this could be due to the pseudophakic accommodation by the

Back to Top

optic shift or as a result of the additional pseudophakic pseudoaccommodation. The accommodative effect differed between patients and was unpredictable. *Tetraflex*: The prospective nonrandomized US Food and Drug Administration trial (Sanders 2010) on Tetraflex accommodative IOL is ongoing. In this study 255 patients received Tetraflex IOLs and 101 received monofocal IOLs. Interim results of 12 months follow-up of 239 patients in the Tetraflex arm and 96 controls show that the Tetraflex patients read better than the controls at print sizes of 20/80 (P=.04), 20/63 (P=.01), 20/50 (P<.001), 20/40 (P=.001), 20/32 (P<.001), and 20/25 (P=.001). The proportion of patients reading at a speed of ≥80 words per minute was significantly higher with the Tetraflex IOL (P=.003). Ninety-six percent of Tetraflex patients reported never wearing glasses for distance compared with 80% of control patients (P<.001). Seventy-five percent of the Tetraflex patients reported that they did not or occasionally needed to wear glasses for near reading small print and/or dim light compared with 46% of control patients (P<.001). The trial had its limitations and the study groups were not randomly assigned to type the IOL implanted which is a source of selection bias. They were also not blinded to the IOL received, which is another source of bias especially with subjective outcomes as self-reporting of use of spectacles. Moreover, the reading ability and speed is dependent on many factors in addition to visual acuity. In conclusion, large randomized, controlled, and blinded trials with long-term follow-up are needed to determine the long-term efficacy, durability of benefit, and safety of the accommodative intraocular lenses.

Multifocal Intraocular Lens: A Cochrane meta-analysis with valid methodology (Leyland et al, 2008, evidence table 1) pooled the results of ten randomized controlled trials that compared visual outcomes of multifocal IOLs versus monofocal IOL implantation after cataract surgery. There were variations between the studies in population sizes, measures and outcomes reported, as well as follow-up durations. The main pooled results of the analysis showed no significant differences between multifocal and monofocal IOLs in uncorrected distance visual acuity or the proportion of patients achieving distance 6/6 best-corrected distance visual acuity. The uncorrected near vision was improved with the multifocal IOLs, and the rate of freedom from use of glasses was also higher with the multifocal IOLs. Contrast sensitivity was lower among participants receiving multifocal IOL implants who also experienced significantly higher rates of glare and halos. The results of another meta-analysis (Cochener et al 2011, Evidence table 2) that had the limitation of pooling results of observational studies together with randomized controlled trials, also showed that multifocal IOLs provided better uncorrected near visual acuity and less need for spectacles compared to monofocal IOLs. The results of the analysis also showed that diffractive multifocal lenses led to better results than the refractive IOLs, and that ReSTOR® had better uncorrected near visual acuity, uncorrected distance visual acuity, and higher spectacle independence rates compared with other multifocal IOLs. The incidence of halos was higher with multifocal lenses versus monofocal IOLs, but there was no significant difference between the different multifocal IOLs. No sensitivity analysis including only RCTs was made, and the results of the meta-analysis should be interpreted with caution. A more recent randomized controlled trial by Alió and colleagues (2011, Evidence table 3) compared the visual performance of 4 different IOLs: monofocal Acri. Smart, multifocal AcrySof ReSTOR® SN6AD3, multifocal Acri.Lisa 366D, and multifocal ReZoom refractive IOL. The same type of lens was implanted bilaterally in each of the 152 participants (304 eyes). After six months of follow up, the results showed that all patients had postoperative significant improvement in uncorrected and corrected visual acuities. Patients with the ReSTOR® and Acri.Lisa multifocal lens implants had significantly better uncorrected reading acuity than those in the monofocal or the refractive ReZoomTM groups. The monofocal group had the greatest uncorrected reading distance at 1 and 6 months postoperatively. The authors did not evaluate patient satisfaction with the different types of IOLs, nor did they assess the contrast sensitivity, or presence of glare and halos. Studies comparing ReSTOR® +3.0 D versus ReSTOR® +4.0 D were not critically appraised in this report, but their overall results showed better intermediate visual acuity, but more glares with the +3.0 D vs.+4.0 D IOLs. Conclusion: There is good evidence from the published literature that multifocal intraocular lenses improve near visual acuity when compared to monofocal lenses, without compromising distance visual acuity.

There is good evidence that patients undergoing multifocal IOLs implantation have higher rates of spectacle independence compared to those with monofocal lens implants. There is evidence that patients with multifocal IOL implants experience more halos and glare and have lower contrast sensitivity than those with monofocal implants. There is fair evidence that optical outcomes are better with diffractive versus refractive multifocal IOLs, and that improvement in near vision without use of glasses and patient satisfaction are more evident with ReSTOR® compared to other multifocal IOLs. There is insufficient evidence to determine any significant difference in contrast sensitivity, glare, or halos between multifocal IOLs.

Articles: *Accommodative Intraocular Lens* Single optic IOLs - The majority of studies published on the accommodative intraocular lenses evaluated single optic accommodative IOL, mainly the ICU (Humans Optics), and to a lesser extent the CrystalensTM AT-45. The search identified one meta-analysis of RCTs, a small number of controlled randomized and nonrandomized trials, and case series. The larger trials with more valid methodology and longer-term follow-up were selected for critical appraisal. The meta-analysis was not critically appraised as it had a low methodological quality and only included only 5 RCTs with very small sample sizes, along with other nonrandomized, and non-controlled studies published from 1996-2006. Dual optic IOLs - The literature search revealed a small pilot prospective case series with a retrospective control on the Synchrony dual-

Back to Top

optic IOL. Phase III FDA clinical trials are still ongoing. The following studies were critically appraised: Harman FE, Maling S, Kampougeris G, et al. Comparing the 1CU accommodative, multifocal, and monofocal intraocular lenses: a randomized trial. Ophthalmology. 2008; 115:993-1001. See Evidence Table. Cumming JS, Colvard DM, Dell SJ, et al. Clinical evaluation of the Crystalens AT-45 accommodating intraocular lens: results of the U.S. Food and Drug Administration clinical trial. J Cataract Refract Surg. 2006;32:812-825 See Evidence Table. Mesci C, Erbil HH, Olgun A, et al. Visual performances with monofocal, accommodating, and multifocal intraocular lenses in patients with unilateral cataract. Am J Ophthalmol. 2010; 150:609-618. See Evidence Table. Uthoff D, Gulati A, Hepper D, Potentially accommodating 1CU intraocular lens: 1-year results in 553 eyes and literature review. J Refract Surg. 2007; 23:159-171. See Evidence Table.
Multifocal Intraocular Lens The literature search revealed a large number of studies on multifocal intraocular lenses. The majority were prospective or retrospective observational studies and case series with different population sizes and follow-up durations and no comparison or control groups. There were also a number of published randomized or nonrandomized controlled trials that evaluated the visual function, and /or quality of life after the implantation of monofocal versus multifocal lenses. The search also identified three meta-analyses that pooled the results of trials comparing multifocal versus monofocal intraocular lenses, one meta-analysis of studies compared different IOLs, as well as a pooled analysis of two non-randomized trials that compared outcomes of ReSTOR vs. monofocal IOLs lenses. The most recent meta-analysis comparing outcomes of monofocal versus multifocal lenses, and the meta-analysis that compared different multifocal lenses were selected for critical appraisal. A recent RCT that compared outcomes of one monofocal and three different multifocal IOLs was also critically appraised. Alió JL, Grabner G, Plaza-Puche AB., et al. Postoperative bilateral reading performance with 4 intraocular lens models: six-month results. Cataract Refract Surg. 2011; 37:842-852. See Evidence Table**.** Cochener B, Lafuma A, Khoshnood B, et al. Comparison of outcomes with multifocal intraocular lenses: a meta-analysis. Clin Ophthalmol. 2011; 7:45-56. See Evidence Table. Leyland M, Pringle E. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database of Systematic Reviews 2008, issue 4. See Evidence Table.

The use of Accommodative Intraocular Lens in the treatment of visual correction following cataract surgery does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered not medically necessary:

HCPC Codes	Description
V2787	Astigmatism correcting function of intraocular lens
V2788	Presbyopia correcting function of intraocular lens

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
8/1/2005	5/3/2011[MDCRPC], 10/4/2011[MDCRPC], 6/5/2012[MDCRPC], 4/02/2013[MDCRPC], 02/04/2014 [MPC],12/02/2014 [MPC], 10/06/2015[MPC], 08/02/2016[MPC], 06/06/2017[MPC], 04/03/2018[MPC], 04/02/2019[MPC], 04/07/2020[MPC], 04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC]	08/02/2016

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
08/02/2016	Added criteria for Toric Intraocular Lens

Back to Top

Date Sent: 4/29/24

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Intraoperative Neurophysiological Monitoring (IONM)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Noridian retired LCD Sensory Evoked Potentials & Intraoperative Neurophysiology Monitoring (L34072). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

GENERAL CRITERIA

- Intraoperative neurophysiologic monitoring must be performed by either a licensed physician trained in clinical neurophysiology or a trained technologist who is practicing within the scope of his/her license/certification as defined by state law or appropriate authorities and is working under direct supervision of a physician trained in neurophysiology; AND

- Intraoperative neurophysiologic monitoring must be interpreted by a licensed physician trained in clinical neurophysiology, other than the operating surgeon, who is either in attendance in the operating suite or present by means of a real-time remote mechanism for neurophysiologic monitoring situations and is immediately available; AND

- Monitoring is conducted and interpreted real-time (either on-site or at a remote location) and continuously communicated to the surgical team; AND

- The physician performing, or supervising monitoring must be monitoring no more than three cases simultaneously; AND

- Charges related to intraoperative monitoring will only be reimbursed when billed on a HCFA 1500 claim form for professional charges; AND

- Any charges related to intraoperative monitoring billed on a UB form are not reimbursable.

Back to Top

INDICATIONS

Intraoperative neuromonitoring may be indicated for a variety of spinal, intracranial, and vascular procedures. The specific type of monitoring indicated for each procedure varies, as outlined in the below criteria and summarized in the following tables. Pre-procedural baseline testing may be separately reported, but only once per operative session.

Somatosensory-evoked potentials with or without motor-evoked potentials

Intraoperative neuromonitoring using somatosensory-evoked potentials (SSEP), with or without motor-evoked potentials (using electrical stimulation), may be medically necessary during the following procedures:

- Spinal procedures
  - Dorsal rhizotomy
  - Correction of scoliosis
  - Correction of deformity involving traction on the spinal cord
  - Spinal cord tumor removal
  - Surgery due to traumatic injury to spinal cord
  - Surgery for arteriovenous (AV) malformation of spinal cord
- Intracranial procedures
  - Microvascular decompression of cranial nerves
  - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
  - Cholesteatoma, including mastoidotomy or mastoidectomy
  - Vestibular neurectomy for Meniere's
  - Removal of cranial nerve neuromas affecting any of the following nerves:
    - Abducens
    - Facial
    - Glossopharyngeal
    - Hypoglossal
    - Oculomotor
    - Recurrent laryngeal
    - Spinal accessory
    - Superior laryngeal
    - Trochlear
  - Deep brain stimulation
  - Endolymphatic shunting for Meniere's disease
  - Oval or round window graft
  - Removal of cavernous sinus tumors
  - Resection of brain tissue near primary motor cortex and requiring brain mapping
  - Resection of epileptogenic brain tissue or tumor
  - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)
- Non-cranial vascular procedures
  - Carotid artery surgery
  - Arteriography with test occlusion of carotid artery
  - Deep hypothermic circulatory arrest
  - Distal aortic procedures
  - Surgery of the aortic arch, its branch vessels, or thoracic aorta

Electroencephalographic monitoring

Intraoperative electroencephalographic (EEG) monitoring may be considered medically necessary for any of the following procedures

- Intracranial procedures
  - Microvascular decompression of cranial nerves
  - Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions

Back to Top

  - Cholesteatoma, including mastoidotomy or mastoidectomy
  - Vestibular neurectomy for Meniere's
  - Removal of cranial nerve neuromas affecting any of the following nerves:
    - Abducens
    - Facial
    - Glossopharyngeal
    - Hypoglossal
    - Oculomotor
    - Recurrent laryngeal
    - Spinal accessory
    - Superior laryngeal
    - Trochlear
  - Deep brain stimulation
  - Endolymphatic shunting for Meniere's disease
  - Oval or round window graft
  - Removal of cavernous sinus tumors
  - Resection of brain tissue near primary motor cortex and requiring brain mapping
  - Resection of epileptogenic brain tissue or tumor
  - Other intracranial procedures (e.g., aneurysm repair, intracranial AVM)
- Non-cranial vascular procedures
  - Carotid artery surgery
  - Arteriography with test occlusion of carotid artery

Electromyographic monitoring

Intraoperative electromyographic (EMG) monitoring may be considered medically necessary when monitoring is during any of the following procedures:

- Dorsal rhizotomy
- Microvascular decompression of cranial nerves
- Removal of acoustic neuroma, congenital auricular lesions, or cranial base lesions
- Cholesteatoma, including mastoidotomy or mastoidectomy
- Vestibular neurectomy for Meniere's
- Removal of cranial nerve neuromas affecting any of the following nerves:
  - Abducens
  - Facial
  - Glossopharyngeal
  - Hypoglossal
  - Oculomotor
  - Recurrent laryngeal
  - Spinal accessory
  - Superior laryngeal
  - Trochlear

SPINAL PROCEDURES	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Dorsal rhizotomy	☑		☑
Correction of scoliosis	☑		

Back to Top

Date Sent: 4/29/24

Correction of deformity involving traction on the spinal cord	☑		
Spinal cord tumor removal	☑		
Surgery due to traumatic injury to spinal cord	☑		
Surgery for AV malformation of spinal cord	☑		

NON-CRANIAL VASCULAR PROCEDURES	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Carotid artery surgery	☑	☑	
Arteriography w/ test occlusion of carotid artery	☑	☑	
Deep hypothermic circulatory arrest	☑		
Distal aortic procedures (due to risk of ischemia to spinal cord)	☑		
Surgery of aortic arch, its branch vessels, or thoracic aorta	☑		

Back to Top

INTRACRANIAL PROCEDURES*	SSEP (with or without MEP) 95925,95926, 95927,95938 With MEP – 95928, 95929, 95939	EEG 95822 95955	EMG 95860 95861 95867 95868 95870
Microvascular decompression of cranial nerves	☑	☑	☑
Removal of acoustic neuroma, congenital auricular lesions, cranial base lesions	☑	☑	☑
Cholesteatoma, including mastoidotomy or mastoidectomy	☑	☑	☑
Vestibular neurectomy for Meniere's	☑	☑	☑
Removal of cranial nerve neuromas affecting any of following nerves: *Abducens* *Facial* *Glossopharyngeal* *Hypoglossal* *Oculomotor* *Recurrent laryngeal* *Spinal accessory* *Superior laryngeal* *Trochlear*	☑	☑	☑
Deep brain stimulation	☑	☑	
Endolymphatic shunt for Meniere's disease	☑	☑	
Oval or round window graft	☑	☑	
Removal of cavernous sinus tumors	☑	☑	
Resection of brain tissue near primary motor cortex and requiring brain mapping	☑	☑	
Resection of epileptogenic brain tissue or tumor	☑	☑	
Other intracranial vascular procedures (e.g. aneurysm repair, intracranial AV malformation)	☑	☑	

*Intraoperative brainstem auditory evoked response monitoring may also be appropriate for intracranial procedures in which auditory function is at risk, such as acoustic neuroma resection or brainstem tumor resection.

EXPERIMENTAL AND INVESTIGATIONAL

IONM is considered experimental/investigational for all indications not meeting the above criteria. Examples of procedures for which there is insufficient evidence to establish net benefit of IONM include, but are not limited to, the following:

Back to Top

- Routine lumbar or cervical laminectomies and fusions
- Spinal cord stimulator implantation
- Thyroid or parathyroid surgery
- Cochlear implantation
- Vagal nerve stimulator implantation
- Spinal injections
- Hip replacement
- Parotid gland surgery

Intraoperative monitoring of visual evoked potentials is experimental and investigational for all indications.

Intraoperative monitoring of motor evoked potentials using transcranial magnetic stimulation is experimental and investigational for all indications.

Nerve conduction studies for intraoperative monitoring purposes are considered experimental and investigational for all indications.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist
- Last 6 months of radiology if applicable

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

EVIDENCE BASIS

There is moderate strength of evidence that IONM may identify patients at greater risk of adverse outcomes due to neurological injury among individuals undergoing certain spinal procedures. For surgeries that risk damaging the spinal cord (e.g., scoliosis correction, spinal cord tumor removal), the effectiveness of IONM has been assumed. As such, the evidence base for comparative studies is minimal. However, multiple retrospective and prospective cohort studies indicate that IONM may accurately identify those with postoperative neurological deficits. Less clear is whether knowledge of injury, intraoperatively, can lead to intervention which prevents or reverses said neurological deficits.

A systematic review (Fehlings 2010) concluded that IONM is sensitive and specific for detecting neurological complications during spinal surgery. That review included 14 prospective cohort studies addressing a variety of spinal indications. Across all included studies, IONM was not associated with any serious harms. Authors concluded that IONM can be a valuable tool during spinal surgery when the spinal cord or nerve roots are at risk.

IONM has also been proposed as potentially valuable during thyroid surgery as a means to prevent injury to the recurrent laryngeal nerve. A systematic review (Malik 2016) evaluated 17 studies comparing thyroid surgery with and without IONM. Using pooled data from those studies, authors found no statistically significant difference in recurrent laryngeal nerve palsy (RLNP) between those who had undergone thyroid surgery with or without IONM. Another systematic review (Yang 2017) reported a slightly lower incidence of RLNP among those who had thyroid surgery with IONM, but this difference was not statistically significant.

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) released a position statement on IONM in April 2014. The AANS/CNS concluded that there is insufficient evidence to show that the use of IONM mitigates the severity of neurological injury or reduces its incidence. However, the position statement did note that use of IONM may help to diagnose neurological injury during surgery. Later that year, an analysis of all spine surgeries performed from 2007-2011 that were included in the Nationwide Inpatient Sample database was published by James WS, et all. This study included 443,194 spine procedures in which 31,680 cases utilized IONM. Iatrogenic neurological injury was rare, occurring in less than 1% with no difference in cases where IONM was used. In 2015, Hawksworth et al, from the University of Texas Health Sciences Center, published an analysis of their department's spine surgeries completed from 2011-2013, before and after adopting a departmental policy limiting IONM use to intradural procedures and those for spinal deformity correction. While utilization of IONM dropped from 38% of spinal cases to 7%, there was no change in

Back to Top

Date Sent: 4/29/24

incidence of neurological injury. In fact, the only observed cases of injury occurred in cases utilizing IONM where the monitoring did not alert the surgeon to the injury.

In 2017, Hadley, et al published, “Guidelines for the Use of Electrophysiological Monitoring for Surgery of the Human Spinal Column and Spinal Cord” which was approved by both the American Association for Neurological Surgeons and he Congress f Neurological Surgeons. This Guideline was based on review of relevant published literature from 1966-2017. Similar to the aforementioned 2014 position statement, this new Guideline found that IONM “has not been shown to be successful in reducing the rate or perioperative neurological deterioration or to improve neurological outcome during spinal surgery procedures.” The authors later conclude that because use of IONM during spina surgery has not been correlated with improvements in neurological outcome that its expense does not appear justified.

In a systematic review on IONM for cervical degenerative myelopathy and radiculopathy, authors concluded that altering of the surgical plan or intraoperative steroid administration based upon IONM monitoring was not shown to decrease the incidence of neurological injury. However, the review concluded that IONM may be sensitive for assessing neurological injury for diagnostic information.

The American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) released a position statement in 2014 supporting the use of intraoperative SSEP for certain spinal surgeries, particularly those with increased risk for nerve root or spinal cord injury (including complex, extensive, or lengthy procedures). Authors also stated that intraoperative SSEP was not indicated for routine lumbar or cervical root decompression.

In 2012, the American Academy of Neurology (AAN) and the American Clinical Neurophysiology Society (ACNS) identified 11 studies as part of their evidence-based guidelines process, from which they concluded the IONM is safe and effective for identifying increased risk of adverse outcomes, including paraparesis, paraplegia, and quadriplegia during spinal surgery (Nuwer 2012).

Medical Technology Assessment Committee (MTAC)

Intraoperative Neurophysiologic Monitoring (IONM)

08/17/2015: MTAC REVIEW

Evidence Conclusion: The selected studies offer a small sample of the extensive literature currently available relating to IONM. For the most part, the available evidence is descriptive and details the experience of IONM in various surgical settings. In the selected studies, IONM is using to support surgeries in various specialties including neurosurgery (brain and spine), cardiac, and vascular. Population sizes range from 62 to 119 and assessed pre- and post- surgical outcomes such as neurophysiologic alerts during surgery and post-operative neurological deficits. Conclusions from the selected studies conflict with some asserting the utility of IONM technology and others finding minimal utility due to the inability to predict post-operative complications (Schramm, Koht et al. 1990; Linstedt, Maier et al. 1998; Ghariani, Liard et al. 1999; Bose, Sestokas et al. 2004). Surgical procedures and interventions are not always based on scientific evidence and instead, tend to evolve over time. Today, IONM is considered to be a standard of care limiting the ability to carry out methodologically sound comparative studies due to equipoise. Beyond that, the existing literature base is extremely heterogeneous addressing various surgical procedures in different populations with varying and conflicting conclusions. As a result, the evidence is insufficient to be able to determine if IONM is truly effective at detecting and preventing neurologic complications.
Conclusions: There is insufficient evidence to establish that IONM, either on-site or remote, reduces the risk of neurologic injuries during surgical procedures. There is insufficient evidence to support the safety of IONM.
Articles: The literature search revealed a large number of publications relating to IONM. There were no randomized controlled trials (RCTs) comparing the outcomes of surgeries that employed the use of IONM (either remote or on-site) with those not utilizing the monitoring technique nor where there any studies making a comparison between remote and onsite monitoring. The search yielded a wide variety of observational studies the majority of which had no comparison group. Due to the extensive amount of literature identified, the following studies are a small sample of the available evidence: Bose B, Sestokas AK, Schwartz DM. Neurophysiological monitoring of spinal cord function during instrumented anterior cervical fusion. *The Spine Journal*. 2004;4(2):202-207. See Evidence Table 1. Schramm J, Koht A, Schmidt G, et al. Surgical and electrophysiological observations during clipping of 134 aneurysms with evoked potential monitoring. *Neurosurgery*. 1990;26(1):61-70. See Evidence Table 1. Ghariani S, Liard L, Spaey J, et al. Retrospective study of somatosensory evoked potential monitoring in deep hypothermic circulatory arrest. *The Society of Thoracic Surgeons*. 1999; 67:1915-1918. See Evidence Table 1. Linstedt

Back to Top

U, Maier C, Petry A. Intraoperative monitoring with somatosensory evoked potentials in carotid artery surgery – less reliable in patients with preoperative neurologic deficiency? *Acta Anaesthesiol Scand*. 1998;42(1):13-16. See Evidence Table 1.

The use of Intraoperative Neurophysiologic Monitoring (IONM) does not meet *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

General Neuromonitoring:

CPT® or HCPC Codes	Description
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)
G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)

Somatosensory-evoked potentials (SSEP):
NOTE: CPTs 95925 and 95926 should not be billed during the same procedure if both upper and lower limbs are monitored; instead, CPT 95938 should be used. CPT 95938 should not be coded in conjunction with either 95925 or 95926. Similarly, 95928 and 95929 should not be billed together; instead 95939 should be used if both upper and lower limbs are monitored.

CPT® or HCPC Codes	Description
95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs

Motor evoked potentials (MEP):

CPT® or HCPC Codes	Description
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs
95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs

Electroencephalography:

CPT® or HCPC Codes	Description
95822	Electroencephalogram (EEG); recording in coma or sleep only
95955	Electroencephalogram (EEG) during nonintracranial surgery (eg, carotid surgery)

Electromyography:

CPT® or HCPC	Description

Back to Top

Codes	
95860	Needle electromyography; 1 extremity with or without related paraspinal areas
95861	Needle electromyography; 2 extremities with or without related paraspinal areas
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95870	Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters

Considered not medically necessary:

CPT® or HCPC Codes	Description
95907	Nerve conduction studies; 1-2 studies
95908	Nerve conduction studies; 3-4 studies
95909	Nerve conduction studies; 5-6 studies
95910	Nerve conduction studies; 7-8 studies
95911	Nerve conduction studies; 9-10 studies
95912	Nerve conduction studies; 11-12 studies
95913	Nerve conduction studies; 13 or more studies
95930	Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/27/2015	07/05/2016[MPC], 05/02/2017[MPC], 03/06/2018[MPC], 03/05/2019[MPC], 03/03/2020[MPC], 03/02/2021[MPC], 03/01/2022[MPC], 03/07/2023[MPC], 04/02/2024[MPC]	05/07/2019

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
05/07/2019	MPC approved to adopt KP National criteria for IONM.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Iontophoresis
Phonophoresis

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Iontophoresis"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Treatment	Criteria Used
Iontophoresis	Kaiser Permanente has elected to use the Iontophoresis (KP-0617) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
Phonophoresis	Kaiser Permanente has elected to use the MCG Phonophoresis guideline (A-0616): this is not covered per MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.
For Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction and Joint Pain or Devices for use in the member's home	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

***MCG are proprietary and cannot be published and/or distributed**. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

Back to Top

Date Sent: 4/29/24

These criteria do not imply or guarantee approval. Please check with your plan to ensure coverage.
Preauthorization requirements are only valid for the month published. They may have changed from previous months and may change in future months.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices
Iontophoresis for Joint Pain
Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

Background

Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis may include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug). Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication.

Medical Technology Assessment Committee (MTAC)

Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices

BACKGROUND

Hyperhidrosis or excessive sweating may be classified into primary or essential hyperhidrosis with an unknown cause, and secondary hyperhidrosis which is due to an underlying condition as hyperthyroidism, menopause, obesity, psychiatric disorder, and others. It may be localized in one or several locations of the body, most often in the hands (palmer hyperhidrosis) but may also be planter, axillary, facial, or general. Several methods are used to treat patients with primary hyperhidrosis, or secondary cases with heavy sweating or untreatable conditions. These include the use of antiperspirants, drugs, psychotherapy, surgery, iontophoresis, use of botulinum toxin, alternative medicine, and others. Iontophoresis can be defined as a means of delivering medication to a localized tissue area by applying electrical current to a solution of the medication. It consists of applying low intensity current (15-18 mA) supplied by a D/C generator to the palms and/or soles immersed in an electrolyte solution. The procedure has to be repeated regularly, and the results may vary among patients. The Drionic and Idrostar devices are battery- operated methods of inducing tap water iontophoresis.

06/12/2002: MTAC REVIEW
Iontophoresis for Hyperhidrosis using Drionic or Idrostar Devices
Evidence Conclusion: There is not enough evidence to permit conclusions on the use of either the Drionic or Idrostar device for treating hyperhidrosis.
Articles: The search yielded three articles, two of which were reviews, and the third was a small case series with 22 patients with hyperhidrosis treated with the Drionic unit.

The use of Idrostar in the treatment of hyperhidrosis via iontophoresis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/03/2009: MTAC REVIEW
Iontophoresis in the Treatment of Hyperhidrosis
Evidence Conclusion: There is insufficient evidence to draw conclusions on the safety and efficacy of iontophoresis for treating hyperhidrosis. No published comparative studies were identified. The literature base consists of case series, mostly with fewer than 25 patients and one case series with 112 patients. The larger series reported that about 81% of participants responded to treatment. The criteria provided for response was not clearly defined and there was no long-term follow-up.

Back to Top

Articles: Four empirical studies specifically evaluating iontophoresis for hyperhidrosis were identified. There were no randomized or non-randomized controlled studies. All of the empirical studies were case series. Three had fewer than 25 patients and were excluded from further review. The fourth (Karakoc et al., 2002) included 112 patients and was critically appraised. See Evidence Table.

The use of iontophoresis in the treatment of hyperhidrosis does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Iontophoresis for Joint Pain

BACKGROUND

Iontophoresis is proposed as a treatment for joint pain. It has been used for various types of tendonitis including epicondylitis, patellar tendonitis, biceps tendonitis, rotator cuff tendonitis and Achilles tendonitis (Winn, unpublished manuscript). Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Dexamethasone sodium phosphate, a negative ion, is a commonly used drug used for iontophoresis treatment of joint pain. Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication. Common treatments for joint pain include rest, ice after exercise, stretching, bracing and immobilization; medications such as analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) and injection of corticosteroids. A well-done randomized controlled trial (Hay et al., 1999) found that local injection of corticosteroid was more effective for treating lateral epicondylitis than NSAID treatment, but that more than 80% of patients were improved at 12 months regardless of treatment.

10/08/2003: MTAC REVIEW

Iontophoresis for Joint Pain

Evidence Conclusion: There is insufficient evidence to conclude that iontophoresis for joint pain is effective compared to the accepted alternatives, corticosteroid injection and NSAID treatment. No studies compared iontophoresis with one of these established treatments. There is some evidence that iontophoresis is not more effective than placebo treatment, although the data are limited. The highest quality study identified was an RCT comparing active iontophoresis with placebo iontophoresis in patients with epicondylitis (Nirschl). This study found a greater effect with active iontophoresis two-days after treatment, but no difference in efficacy after one-month. The study was powered to detect a 20% difference between groups. Another RCT conducted with patients with epicondylitis (Runeson) found no difference in the efficacy of active or placebo iontophoresis 3- and 6-months after treatment. Neither RCT had an intention to treat analysis, but follow-up was much higher in the Nirschl study (90% compared to 64% in the Runeson study). Statistical power was not discussed in the Runeson study. The quality of evidence for conditions other than epicondylitis was low.

Articles: The search yielded 12 articles. None of the studies compared iontophoresis to corticosteroid injection or oral medication treatment. There were four RCTs conducted with patients who had epicondylitis. Two studies compared active iontophoresis treatment to placebo treatment and were critically appraised. The two other studies had irrelevant comparison groups and were not reviewed: one compared iontophoresis with two types of active substances and one compared iontophoresis to an experimental treatment, phonophoresis. In addition, there were three controlled studies conducted among patients with other types of tendonitis. All three had weaker methodology than the placebo-controlled epicondylitis studies and were not reviewed. Two did not compare the different treatment groups in analysis and one had a sample size of only 22 patients. *The following studies were critically appraised:*

Nirschl RP, Rodin DM, Ochiai et al. Iontophoretic administration of dexamethasone sodium phosphate for acute epicondylitis. *Am J Sports Med* 2003; 31: 189-195. See Evidence Table. Runeson L, Haker E. Iontophoresis with cortisone in the treatment of lateral epicondylalgia (tennis elbow)- a double blind study. *Scand J Med Sci Sports* 2002; 12: 136-142. See Evidence Table.

The use of iontophoresis in the treatment of joint pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

BACKGROUND

Temporomandibular joint (TMJ) dysfunction is a common condition and involves pain, particularly in the chewing muscles and jaw joint, radiating pain in the face, neck or shoulders, painful clicking sounds in the jaw joint, and restricted jaw movement. Drug therapies for TMJ dysfunction include analgesics, minor tranquilizers or muscle relaxants at bedtime, antidepressants, injections of a local anesthetic and cortisone injections.

Back to Top

Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis to treat TMJ include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug) (Lark & Gangarosa). Iontophoresis is proposed as an alternative to local anesthetic injections for the treatment of TMJ dysfunction. Possible advantages are less discomfort than interarterial injection and fewer side effects than systemic medications.

02/13/2002: MTAC REVIEW
Iontophoresis in the Treatment of Temporomandibular Joint Syndrome
Evidence Conclusion: There is insufficient published scientific evidence on which to base conclusions about the effect of medication delivery with iontophoresis on health outcomes in patients with temporomandibular joint syndrome. Two small RCTs were reviewed, both of which may have had insufficient statistical power to detect clinically important differences between groups; neither of the study discussed statistical power calculations. Shiffman did not compare the randomized groups in analysis. Reid did not find that iontophoresis was more effective than placebo.
Articles: The search yielded eight articles. The majority were review articles/opinion pieces. There were two small randomized controlled trials (RCTs) with clinical outcomes. These two articles were critically appraised: Shiffman EL, Braun BL, Lindgren BR. Temporomandibular joint iontophoresis: A double-blind randomized clinical trial. J Orofacial Pain 1996; 10: 157-65. See Evidence Table. Reid KJ, Dionne RA, Sicard-Rosenbaum L, Lord D, Dubner RA. Evaluation of iontophoretically applied dexamethasone for painful pathologic temporomandibular joints. Oral Surg Oral Med Oral Pathol 1994; 77: 605-9. See Evidence Table.

The use of Iontophoresis in the treatment of temporomandibular joint syndrome does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Iontophoresis -

Considered Medically Necessary when criteria in the applicable policy statements listed above are met

CPT® Codes	Description
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes

Phonophoresis - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
No specific codes	

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Review Date	Date Revised
02/13/2002	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC], 06/04/2013[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC],	08/03/2021

Back to Top

	08/01/2023[MPC], 04/02/2024[MPC]	

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/13/2017	Added home unit language
09/03/2019	MPC approved to add clinical indication for Palmar/Plantar Hyperhidrosis
11/05/2019	MPC approved to adopt non coverage criteria for Phonophoresis; adopting MCG A-0616
06/15/2020	60-day notice required for non-coverage of phonophoresis, updated effective date to 10/1/2020
08/04/2020	Added Medicare LCA A57642
08/03/2021	Removed LCD L35008 and LCA A57642; added KPWA medical policy statement under Medicare section.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intraoperative Radiation Therapy (IORT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	4/01/2016 Noridian retired LCD Brachytherapy: Non-Intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for “medical judgment” which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

Intraoperative radiation therapy (IORT) may be considered medically necessary in the following situation:

- Rectal cancer with positive or close margins with T4 lesions or recurrent disease.

IORT is considered investigational when used for all other oncologic applications, including but not limited to:

- Breast cancer
- Fibromatosis
- Gastric cancer
- Glioma
- Gynecologic cancers
- Head and neck cancers
- Neuroblastoma
- Pancreatic cancer
- Renal cell cancer
- Soft tissue sarcoma

Some requests may be approved on a case-by-case basis by the Medical Director.

Back to Top

Date Sent: 4/29/24

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage

Background

The usual method for delivering radiation is external beam with high-energy photons. However, the external beam doses required to achieve local tumor control can exceed the radiation tolerance of some normal organs and other structures of the body.

Intra-operative radiation therapy (IORT) is being investigated as a technique to deliver a high dose of radiation to a locally advanced tumor while attempting to protect adjacent normal tissues at the time of surgery. It is delivered with applicators and cones attached to the treatment head of high-energy medical linear accelerators. After all or most of the cancer is surgically removed, a large, single-dose of high-energy radiation is aimed directly at the tumor site. Nearby healthy tissue is protected with special shields.

The goal of IORT is to enhance local tumor control. Most patients receiving IORT are concurrently treated with high-dose external beam photon irradiation. The term “intraoperative radiation therapy” may also refer to intra-operative brachytherapy, the temporary or permanent implantation of radioactive seeds. Intra-operative radiation therapy is usually a component of a multi-disciplinary treatment approach for localized cancers that cannot be completely removed or that have a high risk of recurring in nearby tissues.

Medical Technology Assessment Committee (MTAC)

Intraoperative Radiation Therapy (IORT) for Breast Cancer

BACKGROUND

Breast cancer is the most common cancer in women of all races and ethnicities (not counting skin cancer), and the second most common cause of death from cancer among white, black, Asian/Pacific Islander, and American Indian/Alaska Native women. The American Cancer Society (ACS) estimated that in 2015, 231,840 new cases of invasive breast cancer and 62,570 breast carcinoma in-situ, will be diagnosed among women in the U.S. and that 40,290 will die from breast cancer. The reported five-year relative survival rate is 98.5% for women diagnosed with localized breast cancer. This drops to 84% among women with cancer that has spread to nearby lymph nodes (regional stage) and to 24% in those with metastases in distant lymph nodes and/or other organs (CDC and ACS web pages accessed October 27, 2015). The widespread screening programs and new developments in early detection of cancer have led to an increase in the incidence of early stage breast cancer. Surgical treatment has thus shifted from radical mastectomy to personalized local treatment that preserves the breast and axillary lymph nodes, together with adjuvant therapy. Breast conserving surgery (BCS) followed by postoperative whole breast external beam radiotherapy (EBRT or WBRT) is currently considered the standard treatment for patients with early-stage breast cancer. This approach has been shown to reduce local recurrence (LR) and improve the overall survival. Traditional whole breast EBRT is administered in the postoperative setting as 45-50 Gy in daily fractions for 5 consecutive weeks. An additional external beam boost of 10-16 Gy is often delivered to the tumor bed to improve local control and reduce local recurrence. It is reported that almost one third of the patients undergoing BCS in North America do not receive post-BCS breast radiation therapy and many others choose mastectomy instead, for several reasons including the long course of treatment, comorbidities, advanced age, distance from the radiation therapy facility, inconvenience, and cost (Vaidya, 2010, Esposito 2014, Abbott 2015, Zhang 2015). Accelerated partial breast irradiation (APBI), is a radiation technique that targets partial breast tissue around the tumor cavity with fewer fractions. APBI has emerged in the last 2 decades and is increasingly being accepted as an alternative to whole breast EBRT. It is based on the observation that more than 90% of local recurrences occur at /or near the tumor bed after BCS. There are several techniques for delivering APBI, including multi-catheter interstitial brachytherapy, balloon catheter brachytherapy, 3D- conformal radiation therapy, and intraoperative radiation therapy (IORT). These techniques differ widely in regard to the degree of invasiveness, radiation delivery, operator proficiency, acceptance between radiation oncologists, and length of treatment (Njeh 2010, Vaidya 2010, Abbott 2015, Esposito 2015, Zhang 2015). IORT is an APBI approach that delivers a single dose of irradiation directly to the tumor bed at the time of surgery. Unlike other APBI techniques

Back to Top

that target the index quadrant, IORT specifically targets the tumor cavity. The index quadrant is not demarcated anatomically, whereas the tumor cavity is easily located by the operating surgeon. IORT can be delivered by using low-energy X-rays, electron beam radiation therapy, brachytherapy, high-dose-rate (HDR) after loaders, and other hybrid devices (Esposito 2015). The intrabeam® device (Carl Zeiss, Oberkochen, Germany) is a device used to deliver IORT during surgery after removal of the tumor. It comprises a miniature low-energy X -ray source (50 kVp) that delivers a dose of 20 Gy at the surface of the applicator and 5-5 Gy at 1 cm deep, in 20-40 minutes treatment time. Tungsten-impregnated sheets are used to shield the wound before treatment. Access to the operating room should be controlled and the medical personnel shielded during treatment. The intraoperative electron radiation therapy (IOERT) is another method for delivering IORT that involves the application of electron radiation directly to the tumor bed at the time of surgery. Compared to the X-ray beams, the electron beams have limited penetration into the tissue and faster delivery of the required radiation dose. The IOERT systems are designed to deliver radiation in non-shielded operating theaters. Currently there are three mobile linear accelerators that can be moved easily into an operating room and deliver IOERT (Novac 7®, Liac®, and the Mobetron®). The radiation procedure is completed in 2 minutes delivering a dose of 21 Gy with the depth of 90% isodose ranging from 13-24 mm (Esposito 2015). The advantages of IORT include the reduced treatment visits by delivering a single radiotherapy fraction during surgery, immediate visualization of the operative bed before delivering the radiotherapy, minimizing the possibility of missing the target, shielding the surrounding organs, avoiding treatment delay for patients who may also need to undergo chemotherapy, and reducing healthcare costs. Disadvantages of IORT on the other hand, include longer operating time, reported increased local recurrence compared to EBRT, and lack of final pathological results before delivering the IORT. In patients with positive margins that require re-excision, an IORT boost may be ineffective and may cause complications in re-excision of the margins and difficulty in interpreting the pathology. In addition, IORT requires training of staff, operating room equipment efforts, and expensive devices (Hanna 2014, Esposito 2015).

12/21/2015: MTAC REVIEW
IROT for breast cancer
Evidence Conclusion: There are two large published intraoperative radiation therapy (IORT) trials that investigated whether IORT is equivalent (ELIOT) or noninferior (TARGIT-A) to standard EBRT for the treatment of women with early stage breast cancer undergoing breast conservative surgery, The ELIOT trial used electron IORT (using 2 linear accelerators; NOVAC 7 and Liac) and the TARGIT-A trial used a point source low- energy x-rays (50kV maximum) using the Intrabeam device. TARGIT-A trial (Vaidya et al, 2010, 2014), Evidence Table 1 This was a large multicenter trial that examined the noninferiority of IORT to EBRT (within a specified margin of 2.5%) after breast conserving surgery (BCS). 2,232 women 48-75 years of age, with invasive ductal breast cancer undergoing BCS were randomly assigned to receive either a standard regimen of 25-25 fractions (40-56 Gy) EBRT or a single fraction low energy IORT. Randomization was performed either before surgery (pre-pathology entry) or after surgery (post-pathology entry). In the latter group IORT was given after surgery by reopening the wound. 15% of the patients in the IORT group received additional EBRT (the trial protocol allowed recipients of IORT to receive additional EBRT based on unfavorable features found in the pathology [risk adapted policy]). The primary outcome of the trial was pathologically confirmed ipsilateral breast tumor recurrence (IBTR). The initial results of the trial were published in 2010 when only less than one fifth of the participants were followed-up for at least 4 years (median 25 months for all subjects). These results showed that the IBTR rate was 1.2% in the IORT arm and 0.95% the EBRT arm (p=0.41). More recent results were published in 2014 after the addition of 1,219 participants, and longer follow-up for the initial cohort. The estimated 5-year risk of local recurrence was 3.3% in the IORT group and 1.3% in the EBRT group (p=0.042) (median follow-up was 29 months due to the short follow-up of the additional patients; only 18% of the patients had 5 years of follow-up). The results published in the first report indicate that rate of ipsilateral local recurrence in the IORT group IORT met the noninferiority margin of 2.5% (prespecified by the investigators) for the overall patient population, and for the pre-pathology subgroup, but not for the post-pathology group. However, the incidence of the local recurrence was significantly higher with IORT vs. EBRT. This higher rate was observed at a median follow-up of 29 months which is below the median time when local recurrences are expected, especially when 90% of the women had estrogen receptor positive tumors that tend to recur later. In addition, almost two thirds of the women received adjuvant hormonal therapy which delays recurrence in estrogen receptor positive cases (Silverstein 2014). The results also show that the women who received IORT alone had 3 times the recurrence rate vs. those who received IORT+EBRT (2.7 vs. 0.9%). The authors indicated that the difference was not statistically significant, but no p value was provided. The trial was multicenter, randomized, and controlled. However, it had several methodological limitations, mainly the inadequacy of follow-up duration needed to provide conclusive evidence on the noninferiority of IORT to EBRT. The prespecified non-inferiority margin of 2.5% required a 5-year follow-up for all patients, which was only fulfilled by 20% of the study cohort. Other limitations of the trial include the open-label design (due to the nature of the intervention), and the multiple amendments made to the protocol along the course of the study such as the addition of more participating countries, increasing the population size, changing the start and ending date of the trial, and changing the funding source. In addition, each center participating in the trial managed the EBRT group

Back to Top

according to its institutional guidelines and determined its own criteria for treating patients with IORT given alone or as a boost therapy. ELIOT trial (Veronesi, et al 2013), Evidence Table 2 This was a prospective single-center trial that randomized 1,305 women 48-75 year of age with clinically invasive T1-T2, ≤2.5 cm breast cancer suitable for breast conservative surgery (BCS), to undergo whole breast EBRT delivered over 6 weeks, or receive a single dose of electron beam IORT. The primary outcome of the trial was ipsilateral breast tumor recurrence (IBTR). The results of the analysis show that after a median follow-up of 5.8 years the IBTR fell within the pre-defined equivalence margin of 4.5%, but the rate was significantly higher in the IORT group (4.4% vs. 0.4% in the EBRT group, p<0.0001, NNH of 25). The significantly higher rates of IBTR in the IORT group were observed for both the true local recurrence in the index quadrant, and for new ipsilateral breast tumors in other quadrants. The author indicated that the difference may be attributable to the very low recurrence rates in the EBRT group because of the high experience and quality of management. Some investigators raised the question on whether the 4-cm applicator size used in the trial might have been too small to adequately treat microscopic disease that extended beyond the existed tumor. Axillary or other regional lymph node metastasis and locoregional tumor recurrence were also significantly higher in the IORT group (NNH=143 and 22 and respectively). There were no significant differences between the two study arms in the development of contralateral breast metastasis, distant metastasis, or in the 5-year overall survival rate. Subgroup analysis according to patients' risk based on tumor size, grade, receptor status, and nodal positivity, showed that low risk women (69.4% of the study participants) had a 5-year IBTR rate of only 1.5% compared to 11.3% of those with one or more high-risk factors. A multivariate analysis showed that tumors size >2 cm, ≥4 positive lymph nodes, poorly differentiated tumors, and tumors with triple negative subtypes doubled the risk of IBTR. The rate of adverse skin effects (erythema, dryness and hyperpigmentation) was significantly higher in the EBRT group, and the rate of fat necrosis was significantly higher in the IORT group. There were no significant differences between the groups in mammary retraction, pain, or burning. Conclusion: The results of the two large published RCTs show that the rate of local recurrence with IORT was non-inferior (TARGIT-A trial) or equivalent (ELIOT trial) to EBRT. However, these results were based on margins prespecified by the investigators of the trials. The results of both TARGIT-A and ELIOT trials show that the risk of ipsilateral tumor recurrence was significantly higher with the IORT compared to EBRT. The published trials had relatively short follow-up duration and do not provide sufficient evidence to determine the long-term risk of delayed cancer recurrence inside or outside the index quadrant, as well as the long-term efficacy and safety of the therapy. There was significant heterogeneity between the published studies as regards to the study design, patients' ages, tumor size, threshold values, radiation sources and techniques used for delivering the IORT, as well as the follow-up duration. Multivariate analysis of the ELIOT trial results showed that the risk of ipsilateral local recurrence in women receiving IORT was almost double in patients with tumors size >2 cm, ≥4 positive lymph nodes, poorly differentiated tumors, or with triple negative subtypes.
Articles: The literature search revealed two large RCTs on IORT (TARGIT-A trial and ELIOT trial) as well a systematic review and meta-analysis of published studies, and a large number of single institution cohort studies. The two large RCTs and the meta-analysis were selected for critical appraisal. Vaidya JS, Joseph DJ, Tobias JS, et al. Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): an international, prospective, randomised, non-inferiority phase 3 trial. *Lancet*. 2010 Jul 10; 376 (9735):91-102. See Evidence Table 1**.** Vaidya JS, Wenz F, Bulsara M, et al. Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial. *Lancet.* 2014 Feb 15; 383 (9917):603-613. See Evidence Table 1**.** Veronesi U, Orecchia R, Maisonneuve P, et al. Intraoperative radiotherapy versus external radiotherapy for early breast cancer (ELIOT): A randomized controlled equivalence trial. *Lancet Oncol*. 2013 Dec; 14 (13):1269-1277. See Evidence Table 2**.** Zhang L, Zhou Z, Mei X, et al. Intraoperative Radiotherapy versus Whole-Breast External Beam Radiotherapy in Early-Stage Breast Cancer: A Systematic Review and Meta-Analysis. *Medicine (Baltimore)*. 2015 Jul; 94(27):e1143. See Evidence Table 3**.**

The use of IORT for breast cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
19294	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with partial mastectomy (List separately in addition to code for primary procedure)
77424	Intraoperative radiation treatment delivery, x-ray, single treatment session

Back to Top

77425	Intraoperative radiation treatment delivery, electrons, single treatment session
77469	Intraoperative radiation treatment management
HCPC Codes	**Description**
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

Date Created	Date Reviewed	Date Last Revised
12/01/2015	12/01/2015[MPC], 10/04/2016[MPC], 08/01/2017[MPC], 06/05/2018[MPC], 06/04/2019[MPC], 06/02/2020[MPC], 06/01/2021[MPC], 06/07/2022[MPC], 06/06/2023[MPC], 04/02/2024[MPC]	04/20/2016

[MPC] Medical Policy Committee

Revision History	Description
01/06/2016	MPC approved the MTAC recommendation of insufficient evidence for IORT for breast cancer
04/20/2016	Changed Medicare language as LCD 34065 was retired.

Back to Top

KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Artificial Spinal Discs for Lumbar or Cervical Disc Disease

- Bryan™
- Charité™
- Prestige™ Artificial Discs
- ProDisc-C™
- ProDisc-L™
- Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Lumbar Artificial Disc Replacement (LADR) (150.10) Per NCD - this service is not covered for Medicare beneficiaries over 60 years of age.
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance for lumbar artificial disc replacement for Medicare members under 60 years of age or for cervical artificial disc replacement, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Artificial Spinal Discs for Lumbar or Cervical Disc Disease"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

I. Artificial cervical discs may be considered medically necessary for the following:
   A. For treatment in adults with symptomatic cervical degenerative disc disease when **ALL** of the following are met:
      1. FDA-approved prosthetic intervertebral discs are used;
      2. Performed at one level or two contiguous levels from C3-C7;
      3. Objective evidence in the clinical record documents cervical radiculopathy and/or myelopathy; and
      4. Patients have failed at least six weeks of conservative management (which may include rest, application of heat/ice, physical therapy, exercise, pain and/or anti-inflammatory medications).
   B. A subsequent, second-level, anterior total cervical disc replacement using an artificial intervertebral disc following complete decompression may be considered medically necessary in skeletally mature patients with symptomatic cervical disc degeneration when **ALL** of the following are met:
      1. The planned subsequent procedure is at a different cervical level then the initial cervical artificial disc replacement; and
      2. Clinical documentation that the initial cervical artificial disc replacement is fully healed; and
      3. Criteria A, 1-4 are met

II. Prosthetic intervertebral discs are considered investigational for **ALL** of the following:

Back to Top

- In patients with isolated axial neck pain without cervical radiculopathy or myelopathy;
- When requested adjacent to a prior fusion; or
- At a level of prior surgery
- When more than two levels are requested

III. Lumbar Disc
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Specific procedures requested with related procedure/diagnosis codes and identification of disc level(s) for surgery and device to be implanted
- Clinical notes from requesting provider &/or specialist that include a current history and physical exam
- Detailed documentation of extent and response to non-operative conservative therapy or procedural interventions
- Copy of radiologist's report(s) for diagnostic imaging (MRIs, CTs, etc.) completed within the past 12 months

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Degeneration of the intervertebral disc, also known as degenerative disc disease (DDD) is the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration can occur at any level of the spine but is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment, however the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels (Lee 2004, Mobbs et al, 2007, Sasso 2008, Yang 2008, Heidecke 2008).

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear (Yang 2008, Burkus 2010, Cepoiu-Martin 2011).

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), and Prestige Cervical Disc (Medtronic Sofamor Danek). ProDisc-C

Back to Top

has a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and PRESTIGE has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. FDA clearing of the artificial disc systems required post-approval studies to evaluate the long-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate 3, 5, 7, and 10-year data for cervical discs.

Lumbar

The Charité ® (DePuy) and ProDisc®-L (Synthes Spine) have received approval from the US Food and Drug Administration. The approval was contingent on completion of post-marketing studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to demonstrate the 5-year data for lumbar discs. The Charité ® and ProDisc®-L devices are indicated for:

1. Spinal arthroplasty in skeletally mature patients, with pain from degenerative disc disease (DDD).
2. One level of the spine (L3-S1 for the ProDisc-L, L4-S1 for the Charité).
3. Patient may have no more than a grade 1 spondylolisthesis.
4. Patients must have failed to find pain relief after at least 6 months of non-surgical therapies.

Contraindications to total lumbar disc replacement include active infection, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and DDD at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Cervical

The cervical artificial discs are FDA approved for the following:

1. Reconstruction of cervical disc from C3-C7 following single-level discectomy for intractable.
2. Symptomatic cervical disc disease confirmed by imaging.
3. Patient is skeletally mature.
4. Cervical disc disease should have failed at least six weeks of non-operative treatment prior to implantation.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

Several other contraindications are listed for each of the disc systems. Multilevel total disc replacement and disc replacement with prior spinal fusion are considered off-label uses.

Medical Technology Assessment Committee (MTAC)

Artificial Disc in the Treatment of Back Pain

02/07/2005: MTAC REVIEW

Evidence Conclusion: The trial reviewed on Charité artificial spinal disc was randomized, controlled, and multicenter, but had some limitations. Authors concluded that the clinical outcomes and incidence if major neurological complications at 2 years of follow-up were equivalent to those of BAK fusion. The trial, however, was not designed as an equivalence study. Equivalence trials are planned and analyzed differently from superiority studies, and generally require larger sample sizes. Lack of significant superiority is not necessarily the same as equivalence, and the absence of statistical significance may be due to insufficient power to detect differences between the study groups. The comparison group in this trial was the BAK fusion technique, which was the preferred fusion procedure at the time, but might not be the current up-to-date procedure. Moreover, the 24-months follow-up period might not sufficient to determine the long-term safety and effectiveness of the implant as well as its impact on other discs and on the bony structures on the back of the spine.

Articles: The search yielded 56 articles. The majority were review articles, or reports that dealt with the design, technical aspects and/or evolution of the technology. The search revealed four articles published by the same group of authors reporting on the Charité artificial disc evaluated in a multicenter RCT in the US. The article that reported the results of the trial in all centers was selected for critical appraisal.

Back to Top

The search also revealed a report on the early 6 months results for the first 53 patients randomized in an ongoing multicenter RCT of ProDisc in the United States. The system is not currently FDA approved.
Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in the literature: Results of a multicenter, prospective, randomized investigational device exemption study of Charité intervertebral disc. *L Neurosurg (Spine 2)2004;1:143-154.* See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain
10/04/2006: MTAC REVIEW
Evidence Conclusion: There is insufficient evidence that artificial discs approved by the FDA or pending approval are effective, particularly in the long-term. There is only one completed RCT and this is on the Charité device. There are no completed published RCTs on the Prestige or ProDisc devices. The Charité RCT may not have used appropriate equivalence trial methods, including failure to compare the new device to an intervention with proven effectiveness. The safety of the artificial discs after a minimum of 2 years appears similar to that of surgical fusion. Authors of the Charité had financial links to the manufacturer, which could introduce bias.
Articles: An April 2005 Blue Cross BlueShield TEC report was identified. In their literature search, they found one completed RCT, the same study included in the first MTAC review. There was also a systematic review (Freeman & Davenport, 2006) that searched the literature through April 2006 and also identified the same single completed RCT. *Literature on individual devices identified through Medline search:*
Charité device: Several additional publications on the RCT previously reviewed by MTAC (Geisler et al., 2004) were identified: Blumenthal et al. (2005) reported updated data on primary outcomes (more patients had reached 24-month follow-up). McAfee et al. (2005) reported on radiographic outcomes e.g. restoration of disc height. Regan et al. (2006) examined outcomes in the treatment group according to centers' surgical volume. McAfee et al. (2006) reported on the re-operation rate of patients in the RCT as well as other patients, for a total sample size of 688. The updated study on the primary outcomes (Blumenthal et al., 2005) and the study on re-operation rates (McAfee et al., 2006) were critically appraised. The other publications were not evaluated further because they do not add substantially to our ability to evaluate the long-term safety and efficacy of the Charité device. ProDisc device: The RCT identified in the previous MTAC search comparing ProDisc to surgical fusion is still ongoing. The study is taking place at 19 centers and has an enrollment goal of 500 patients. At the time of the first MTAC review, an article reporting initial findings for 53 patients at one center was identified. A 2005 article was identified that reported additional preliminary findings from the same center, this time for 78 patients. This study was not critically appraised because results from all centers are not yet available. Prestige device (not included in 2005 MTAC review): There was a 2004 publication reporting on preliminary findings from a randomized controlled trial on Prestige II conducted at four sites in Europe. This study was critically appraised. The article appears to report on all randomized patients, although not all patients had completed the final follow-up. No subsequent publications on outcomes of this RCT were identified. In addition, an older case series with 17 patients using the Prestige I device was identified, but not evaluated further due to the small size and the availability of higher-grade evidence. Blumenthal S et al. A prospective, randomized, multicenter food and drug administration investigational device exemptions study of lumbar total disc replacement with the Charité artificial disc versus lumbar fusion. Spine 2005; 30: 1568-1575. See Evidence Table. McAfee PC et al. Revisability of the Charité artificial disc replacement. Spine 2006; 31: 1217-1226. See Evidence Table. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. Neurosurgery Focus 2004; 17: 36-43. See Evidence Table.

The use of artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain
10/01/2007: MTAC REVIEW
Evidence Conclusion: The Prestige cervical disc system was first reviewed by MTAC before final FDA approval. At that time, there was one relatively small published RCT reporting preliminary findings (Porchet & Metcalf, 2004). At the time of data analysis, the investigators did not find a significant difference in pain and disability outcomes at 12 months for patients who underwent either artificial disc replacement or anterior cervical fusion. Limitations of this RCT included insufficient follow-up (only about two-thirds of participants had completed the 12-month follow-up and about 15% had completed the 24-month follow-up), unclear equivalence study methods, and funding from the device manufacturer. A larger multicenter RCT among patients with symptomatic single-level

 Back to Top

cervical degenerative disc disease (DDD) was identified for the evidence update (Mummanemi et al., 2007). Mummanemi and colleagues randomized 541 patients to receive either the Prestige cervical disc system or anterior cervical discectomy and fusion. Using a composite success measure developed by the investigators that considered efficacy and safety, the Prestige artificial disc system was found to be superior to ACDF in a completer analysis. In an intention to treat analysis with a "worst case scenario" analysis, Prestige was found to be non-inferior to ACDF. Advantages of the Mummanemi study were that it was randomized and there was a high follow-up rate. Disadvantages are that the study was non-blinded, and the authors have financial links with the manufacturer. In conclusion, there is fair evidence from one reasonably valid multicenter RCT that use of the Prestige artificial disc in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety. The evidence would be strengthened by longer-term follow-up data and studies conducted by impartial researchers. The Porchet & Metcalf, 2004 study does not add substantially to the body of evidence, especially since only preliminary findings were reported in the published literature.

Articles: At the time of the previous MTAC review of artificial discs (October 2006), there was one published randomized controlled trial on the Prestige disc with 55 patients from 4 sites in Europe. The article reported preliminary findings of the RCT (Porchet & Metcalf, 2004). No follow-up publication was identified that reported final results of this RCT. The updated literature search identified a new, larger RCT. This study randomized 541 patients at 32 sites in the United States to discectomy with artificial disc replacement or ACDF (Mummaneni et al., 2007). This was the key study submitted to the FDA for device approval. The Mummaneni et al. RCT was critically appraised: Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table.

The use of Prestige artificial disc in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Artificial Disc in the Treatment of Back Pain

02/01/2010: MTAC REVIEW

Evidence Conclusion: The published randomized controlled trials on lumbar and cervical artificial disc replacement, reviewed for this report, were all US FDA investigational device exemption (IDE) studies designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD, or ACDF for cervical disc disease (non -inferiority design). Lumbar total disc replacement with artificial intervertebral discs (Charité, and ProDisc-L). The trials on artificial total lumbar disc replacement compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the CHARITE IDE trial had a maximum study duration of two years which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration.

CHARITE IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with non-blinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated.

In conclusion, there is insufficient evidence to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration. Cervical total disc replacement with artificial intervertebral discs (ProDisc-C, Bryan, and PRESTIGE). The trials on artificial total cervical disc replacement compared the procedure in conjunction with discectomy to anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with radiculopathy or myelopathy from a single-level cervical disc disease From C3 to C7, that failed conservative treatment of at least 6 weeks. The trials were randomized, controlled and multicenter, but were not blinded, the postoperative care was not standardized and left to the

 Back to Top

discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturer, all of which are sources of bias. Moreover the 2-year follow-up duration insufficient to examine the long-term efficacy, safety, and durability of the artificial disc replacement, or to determine whether it is associated with the risk of adjacent risk degeneration. In conclusion, the short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or PRESTIGE artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease.

Articles: *Lumbar artificial disc replacement* the updated literature search identified two randomized controlled trials that compared total lumbar disc replacement with Charité (Guyer 2009) or ProDisc-L (Zigler 2007) systems versus lumbar fusion. Guyer et al reported on 5-year follow up of patients enrolled in the Charité IDE trial that was the key study submitted to the FDA for device approval. Zigler et al's trial was also the key trial for FDA approval for ProDisc-L. Both RCTs was critically appraised. Guyer RD, McAfee PC, Banco RJ, et al. Prospective, randomized multicenter Food and drug Administration investigational device exemption study of lumbar total disc replacement with the Charité artificial disc and versus lumbar fusion: Five-year follow-up. Spine J. 2009; 9:374-386. See Evidence Table. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine. 2007; 22:1155-1162. See Evidence Table *Cervical artificial disc replacement:* The literature search revealed two RCTs on ProDisc-C total disc replacement as well as two trials on Bryan cervical disc arthroplasty (conducted by the same principle investigators, and published in 5 articles). Two studies, one for each system (Murrey 2009 for ProDisc-C, and Heller 2009 for Bryan cervical disc arthroplasty), were selected for critical appraisal based on the methodological quality of the trial, population size and duration of follow-up. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine. 2009; 9:275-286. See Evidence Table. Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:107-107. See Evidence Table.

The use of artificial spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Artificial Disc in the Treatment of Back Pain

02/13/2012: MTAC REVIEW

Evidence Conclusion: *CERVICAL* The three large published trials on cervical arthroplasty were industry sponsored studies submitted to the U.S. Food and Drug Administration for premarket approval of the devices: Prestige, ProDisc-C, and Bryan cervical disc. All three trials were designed as noninferiority trials i.e. attempting to show that cervical artificial disc replacement is at least as good as ACDF for cervical disc disease. They had similar inclusion and exclusion criteria, similar follow-up schedules, and similar outcome measures and success criteria defined by the FDA. The three trials are still ongoing as the FDA required that the investigators conduct post-approval studies to evaluate the longer-term safety and effectiveness of the devices. The post-approval studies are expected to provide 3, 5, 7, and 10-year data for cervical discs. Each of the three studies compared total replacement with an artificial disc (Prestige, ProDisc-C, or Bryan) in conjunction with discectomy to a single-level anterior cervical decompression and fusion (ACDF) among patients between 18 and 60 years of age (>21 years in Bryan disc trial) with a single level cervical radiculopathy or myelopathy between C- 3 and C-7 that had failed conservative treatment of at least 6 weeks. The trials were relatively large, randomized, controlled, and multicenter, but were not blinded, the postoperative care was not standardized and left to the discretion of the surgeon, and the majority of the investigators had financial ties to the manufacturers who supported the trials, all of which are sources of bias. The 24 months interim analyses of the three trials were previously reviewed by MTAC. The conclusion of the last 2010 MTAC assessment of the technology was as follows, "The short-term results of the trials provide fair evidence that the use of the ProDisc-C, Bryan, or Prestige artificial cervical disc systems in conjunction with discectomy is at least non-inferior to ACDF in "clinical success" defined as a composite outcome incorporating efficacy and safety, among patients with symptomatic single-level cervical disc disease. There is insufficient evidence however, to make any conclusion on whether total intervertebral cervical disc would need revision, would deteriorate with time, or would increase the risk of adjacent segment degenerative disc disease." After the last MTAC review of 2010, mid-term follow-up data were published for all three trials: 48 months postoperative data for ProDisc and Bryan artificial discs and 60 months postoperative data for Prestige cervical disc. These mid-term follow-up data were only available for just over two thirds of the

 Back to Top

population in the Bryan disc trails, and around 50% for each of the 60 months follow-up data for the Prestige disc trials and the 48 months follow-up for ProDisc-C trial. The published results of all three studies show that the one level cervical disc arthroplasty appears to be at least as effective as cervical fusion in up to 2 years of follow-up. The results the extended, mid-term analyses suggest that the outcomes the artificial disc arthroplasty continues to be noninferior to those of fusion. However, the follow-up rates are poor, and the results on sustained effect and durability should be interpreted with caution. The 48 and even 60 months follow-up duration is still insufficient to determine the long-term efficacy, durability, and safety of the system, and the potential risk on adjacent risk degeneration. The trials are still ongoing and long-term results for up to 10 years follow-up are expected. In conclusion, the additional information does not change the conclusions of the previous reports; data on long-term safety and efficacy is still lacking, and there is no evidence to date to determine if one of these three FDA approved artificial discs is superior to the others. A recent update of the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) (November 2011) concluded that artificial intervertebral disc arthroplasty for the treatment of patients with cervical degenerative disc disease does not meet their criteria. The TEC update however did not include Sasso et al's 2011 article that reports on the 48 months outcomes of all participating centers in the Bryan cervical disc trial. At the time of the TEC review only one center had published the 48-month follow-up results (BCBS 2011). *LUMBAR* As indicated in the last 2010 MTAC review, the published randomized controlled trials on lumbar artificial disc replacement were U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) studies that were designed to show that artificial disc replacement is at least as good as fusion for lumbar DDD. The studies (reviewed in earlier reports) compared the procedure with interbody fusion among patients 18 to 60 years of age, who had a single level DDD at L4-5 or L5-S1 (Charité) or L3-S1 (ProDisc-L) confirmed radiographically and failed conservative treatment of at least six months. The trials were randomized, controlled and multicenter, but were not blinded and sponsored by the manufacturer which are sources of bias. All trials except the Charite IDE trial had a maximum study duration of two years, which does not allow determining the long-term efficacy, durability, or safety of total disc replacement or its impact on adjacent risk degeneration. Charite IDE trial (Guyer et al 2009) was the only published RCT with long-term follow-up. However, the five-year outcomes were reported for only 35% of the randomized participants in the original two-year trial (6 of the initial 14 investigational sites refused to participate in the five-year continuation study, and a number of patients were lost to follow-up). This reduces the statistical power of the study which was based on the initial population size. Moreover, the investigational procedure was compared to interbody fusion using the BAK cage technique, which currently is not the best-accepted fusion technique. These, together with nonblinding and other limitations of the original trial make it hard to interpret or generalize the results of the long-term follow-up. The trial on ProDisc-L (Zigler 2007) was also randomized, controlled, and multicenter. However, it had only 2-year follow-up duration which does not allow determining the long-term effectiveness, harms, or durability of the device. Moreover 11.5% of fusion patients and 9% of ProDisc-L patients were not included in the analysis, which was not based on intention to treat. There is also a concern that the investigators used a revised version of the ODI score that had not been validated. Yajun, et al's meta-analysis, 2010 (Evidence table 1) pooled the results of five studies involving 837 patients. The meta-analysis had valid methodology and analysis, and according to its reviewers, four of the five trials had good methodological quality. They indicated however, that the studies had limited population sizes and did not indicate that the assessors of the outcomes were blinded. The pooled results of the analysis showed that at 2 years of follow-up the patient functioning ability as measured by the Oswestry Disability Index (ODI) in the total disc replacement (TDR) group was better than the fusion group but, according to the authors a mean difference of 4 Oswestry points is not clinically relevant. There was also a statistically significant but clinically irrelevant difference in the pain score in favor of the TDR. After performing a sensitivity analysis excluding one large study that compared TDR with BAK cages, the difference in ODI, pain, and patient satisfaction were no longer significant. The authors concluded that TDR is not superior to fusion in treating lumbar degenerative disc disease. In conclusion, there is still insufficient published evidence to date, to determine the long-term efficacy, durability, or safety of artificial disc replacement for patients with lumbar degenerative disc disease, or to determine whether it is associated with the risk of adjacent risk degeneration.

Articles: *CERVICAL DISC* The literature search revealed four articles reporting on long-term outcomes of three pivotal clinical trials on Prestige ST, ProDisc-C, and Bryan artificial discs (one in a single center, and the other on the entire population studied). The search also identified an RCT on KineflexIC artificial disc with 2-year follow-up, and a recent meta-analysis (Cheerag, et al. 2011) that pooled the 2-year follow-up results of the three first trials. No trials comparing the three FDA approved artificial disc systems to one another were identified.

All three initial studies on Bryan, ProDisc, and Prestige cervical discs initial trials with 2-year outcomes that were submitted to the FDA for premarket approval were previously reviewed by MTAC. The reports on long-term follow-up outcomes of the studies were reviewed and their results added to the last MTAC report to update the findings and conclusions. The meta-analysis was not critically appraised as it does not add more evidence to 24 months interim results of the individual trials. Pooling these results still provide 2-year results when long-term safety, durability, and efficacy are needed. The recent RCT on KineflexIC was also not selected for appraisal as it only provides 24 months data. The following initial trials and more recent publications were critically appraised:

 Back to Top

Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with The Prestige disc: results from a prospective randomized controlled trial. J Neurosurg Spine 2010; 13:308-318. See Evidence Table. Delamarter, RB, Murrey D. Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients SAS Journal. 2010; 4:122–128. See Evidence Table**.** Heller JG, Sasso RC, Papadopoulos SM, et al. Comparison of Bryan cervical disc arthroplasty with anterior cervical decompression and fusion. Clinical and radiographic results of a randomized, controlled, clinical trial. Spine. 2009; 34:101-107. See Evidence Table**.** Mummanemi PV, Burkus JK, Haid RW et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled trial. J Neurosurg Spine 2007; 6: 198-207. See Evidence Table. Murrey D, Janssen M, Delamarter R, et al. Results of a prospective, randomized, controlled, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. 2009; 9:275-286. See Evidence Table**.** Sasso RC, Anderson PA, Riew D, et al. Results of cervical arthroplasty compared with anterior discectomy and fusion: Four-year clinical outcomes in a prospective randomized, controlled, trial. J Bone Joint Surg A. 2011; 93:1684-1692. See Evidence Table**.** *LUMBAR* The literature search for studies published after the MTAC 2010 re-review of the technology, did not identify more recent reports on extended follow-up of the key trials on the Charité IDE or ProDisc-L used for the treatment of a single level generative disc disease (DDD). There was a recently published RCT (Delamarter et al 2011) conducted by the same investigators of Pro-disc-L total replacement, but for the treatment of two-level lumbar DDD which the focus of the current review is not. The search also revealed one meta-analysis of studies on artificial lumbar disc replacement for single level DDD, a systematic review, and once case series on with a 2-7 years follow-up of 57 patients who received an artificial Charite III total disc arthroplasty. The meta-analysis was selected for critical appraisal: Yajun W, Yue Z, Xiuxin H. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease*. Eur Spine J.* 2010; 19:1250-1261. See Evidence Table.

The use of cervical artificial disc in the treatment of back pain meeting the *Kaiser Permanente Medical Technology Assessment Criteria* is inconclusive.

The use of artificial lumbar spinal discs in the treatment of back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease

BACKGROUND

Degenerative disc disease (DDD) is defined as any changes that occur at any level of the spine. It's the leading cause of pain and disability among adults in the United States as well as other parts of the world. Disc degeneration is most common in the lower neck (cervical disc disease) and in the low back (lumbar disc degeneration). DDD may cause pain in the affected area and may also radiate along the nerves emerging from the spinal canal at that level.

Most DDDs can be treated nonoperatively to relieve the pain. Conservative treatments include physical therapy, nonsteroidal anti-inflammatory medications, and analgesics. Acupuncture, spinal manipulations, axial traction, and muscle relaxants are other alternative therapies that may be used to alleviate the pain and discomfort. A number of patients may not benefit from the non-invasive therapy and resort to surgical treatment. Spinal interbody fusion, a procedure that involves the fusion of two or more vertebrae to eliminate the pain caused by their abnormal motion, has been the surgical standard of care for lumbar DDD for decades. Anterior cervical discectomy combined with fusion (ACDF) is also a well-established treatment for cervical degenerative disc disorders. Interbody fusion reduces the pain caused by the treated segment. However, the rigid fusion also leads to a reduction in normal spine motion, and an increase in the biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [1-4].

Recently arthroplasty performed with artificial discs have emerged as a surgical alternative to interbody fusion. The technology is rapidly developing and offers the promise to restore the normal spinal movement without the kinematic and biochemical issues of fusion. Potential benefits of disc arthroplasty include maintenance of a range of motion, avoidance of adjacent segment degeneration, restoring disc height, correcting spinal misalignment, greater maintenance of maneuverability, and earlier return to previous level of function. In addition, many trials [5, 6] have shown that cervical disc arthroplasty (CDA) is as safe and effective as ACDF for the treatment of CDD at a single level. On the other hand, potential disadvantages of the artificial disc may include implant migration and material wear [3, 7, 8].

Back to Top

The Charité, the first artificial intervertebral disc used, was developed Germany in the 1950s, but was not commercially available until 1987 after undergoing major design modifications. The third generation Charité ™ (DePuy Spine) consists of two chromium alloy endplates and a sliding ultra-high molecular weight polyethylene core. The ProDisc-L (Synthes Spine, West Chester, PA) is another disc implant, also developed in Europe, for disc replacement at one level from L3-S1. It has a ball and socket design and is composed of three components; two metal endplates and a plastic inlay. More recently researchers developed artificial disc devices to replace cervical intervertebral discs. These include ProDisc-C (Synthes Spine, West Chester, PA), Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN), Prestige Cervical Disc (Medtronic Sofamor Danek), Mobi-C Cervical Disc (LDR Spine USA), and Kineflex|C Spinal System (SpinalMotion Inc.). ProDisc-C have a similar design to the ProDisc-L, Bryan disc prosthesis has two metal endplates and a polyethylene core, and Prestige has two main pieces of stainless steel that articulate against one another with a ball and trough.

The Prestige ST, ProDisc-C and Bryan artificial disc systems have received the US Food and Drug Administration (FDA) premarket application approval as Class III devices in July 2007, December 2007, and May 2009 respectively. The Mobi-C has received the US Food and Drug Administration (FDA) premarket application approval on August 2013.

Contraindications to total cervical disc replacement include systemic infection, infection at the operating site, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and symptomatic cervical disc disease (SCDD) at more than one level.

09/21/2016: MTAC REVIEW
Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease
Evidence Conclusion: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) (evidence table 1) This meta-analysis of RCT aimed to determine the safety and efficacy of cervical disc arthroplasty (CDA) at two contiguous levels cervical disc degeneration. The search was performed between January 2000 and July 2015. Evaluation of study quality was performed using the Cochrane Collaboration's tool for assessing risk of bias. Mean follow-up of included studies ranged from 20-48 months. CDA group patients showed fewer blood loss, lower post-operative complications, lower reoperation rate and better range of motion at all angles and levels. No significant difference was identified in mean surgical time, neck disability index and neck and arm pain VAS scores. Limitations remain in the variety of artificial intervertebral disc types. Furthermore, there is limited number of articles on artificial cervical disc for 2 levels.
Overall, CDA is more effective; the study has valid methodology with some limitations.

Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) (evidence Table 2) This multicenter RCT, FDA investigational device exemption pivotal trial aimed to compare the Mobi-C cervical artificial disc to anterior discectomy and fusion (ACDF) for treatment of cervical DDD at 2 contiguous levels of the cervical spine. This study shows that the overall study success rates met the non-inferiority margin and provided statistical superiority of the total disc replacement (TDR) treatment over ACDF. Results should be interpreted with caution since several authors had received clinical or research support for this study from LDR, the sponsor. In addition, many other authors had financial ties with LDR.

Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) (evidence Table 3) This is a 4-year follow-up result of the study performed by the same author in 2013. The follow up in the 2013 study presented earlier is 24 months. The current study follow-up is 48 months. At 48 months, total disc replacement (TDR) had greater improvement than ACDF in: neck disability index scores, 12-Item Short Form Health Survey Physical Component Summary scores, patient satisfaction, and overall success. In addition, TDR patients had lower subsequent surgery rates and showed a lower rate of adjacent-segment degeneration; TDR also maintained segmental range of motion. The study shows that TDR continue to be safe, effective and superior to ACDF at 48 months for the treatment of degenerative disc disease at 2 contiguous cervical levels.

A systematic review and meta-analysis of RCTs [9] indicated that CDA is more effective and safer than ACDF for the treatment of symptomatic cervical disc disease in mid- to long-term follow-up. However, only one study

 Back to Top

including 2-level was included in the review. A prospective, randomized study [10] compared the safety and effectiveness of the Bryan Cervical Disc in patients with myelopathy caused by two-level cervical disc disease in Han Nationality. The authors found that the Bryan Cervical Disc replacement was shown to be reliable and safe for the treatment of patients with two-level cervical disc disease.

Conclusion:

- Two-level cervical artificial disc replacement shows positive outcomes on the short-term
- There is low evidence to support the effectiveness and safety of two-level cervical artificial disc replacement over anterior cervical discectomy and fusion (ACDF) on the short-term for the treatment of cervical degenerative disc disease
- Studies with longer term follow-up are needed to confirm these findings

Articles: The literature revealed a number of articles; the following articles were selected for critical appraisal: Anterior cervical discectomy and fusion (ACDF) versus cervical disc arthroplasty (CDA) for two contiguous levels cervical disc degenerative disease: a meta-analysis of randomized controlled trials (Zou et al., 2016) See Evidence Table 1. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial (Davis et al., 2013) See Evidence Table 2. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results (Davis et al., 2015) See Evidence Table 3.

The use of Two-level cervical artificial disc replacement for the treatment of cervical degenerative disc disease does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:
Cervical:

CPT® or HCPC Codes	Description
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

Considered Not Medically Necessary:
Lumbar:

CPT® or HCPC Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

 Back to Top

0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/07/2005	04/06/2010[MDCRPC], 02/10/2011[MDCRPC], 12/06/2011[MDCRPC], 03/06/2012[MDCRPC], 04/03/2012[MDCRPC], 02/05/2013[MDCRPC], 12/03/2013[MPC], 10/07/2014[MPC], 08/04/2015[MPC], 06/07/2016[MPC], 04/04/2017[MPC], 02/06/2018[MPC], 01/08/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC]	01/04/2022

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34866 and L35008
10/04/2016	Added MTAC review
11/01/2016	MPC approved criteria for two contiguous levels from C3-C7
06/04/2020	Removed deleted and inaccurate CPT code 0357T
01/04/2022	Defer to KPWA policy for Medicare members for lumbar disc replacement if younger than 60 years old and for cervical disc replacement for all ages.

Back to Top