KAISER PERMANENTE® **Northwest Region Utilization Review**

UR 45 Acupuncture Medical Necessity Criteria; Commercial Business Lines

Department: Complementary & Alternative Medicine	Number: UR 45
Section: KPNW Region	Effective: Sept 1999
Applies to: Acupuncture Services	Last Reviewed: 2/17, 3/18, 2/19, 2/21, 2/20/24
Review Responsibility: UROC	Last Revised: 12/18, 3/20, 2/22, 2/23
Subject Matter Expert: Lauren Kaplan, DO	

MEDICAL NECESSITY CRITERIA FOR ACUPUNCTURE

DEFINITIONS

Acupuncture: A complementary/alternative system of medical theory, oriental diagnosis and treatment used to promote health and treat organic or functional disorders. Acupuncture treats specific acupuncture points or meridians.

Maintenance Treatment/Therapy: Once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

POLICY AND CRITERIA

A. Acupuncture is covered for nausea associated with pregnancy or chemo, overactive bladder with urge incontinence and for some chronic pain conditions. A condition is considered chronic if it has been present for ≥3 month (90 days).

B. Telephonic, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral (this must be a KP clinician if the member has an HMO plan). A member request for referral without documented evaluation is generally not sufficient, however, an evaluation will not be required if:

- The condition is an acute exacerbation or recurrence of the same condition which was evaluated recently (within the previous 12 months) or recurrently over many years by a Kaiser Permanente clinician; AND
- The condition previously exhibited significant improvement after the acupuncture treatments; AND
- The previous exam and information otherwise exhibit no contraindications, as outlined below in the Contraindications section.

For all qualifying diagnoses, there must be documentation in the medical record of the intensity of the symptoms for both the initial acupuncture referral and any extensions requested. An example of documenting the intensity of symptoms may be asking the patient to rate their worst pain and their current pain on a scale from 1 to 10. It is important to note that sometimes the intensity of symptoms will be modest but will significantly interfere with a particular activity of importance to the patient. Reviewers need to consider that those making the referral consider it implicit that the condition is of sufficient concern to warrant intervention.

C. Significant, sustainable and measurable improvement must be evident after the initial course of treatments. If objective improvements are documented, additional treatments may be clinically indicated. Services are not provided for on-going chronic conditions or maintenance therapy lacking improvement. In the situation of chronic pain, when the patient's condition is not expected to completely resolve, there must be an expectation of some functional or other improvement for therapy to be continued.

D. Approved Diagnoses:

i. Nausea of pregnancy
ii. Nausea associated with chemotherapy
iii. Overactive bladder with urge incontinence
iv. Migraine and tension headache (episodic or chronic, with symptom onset ≥3 months ago)
v. Chronic pain syndromes, when due to
    1. musculoskeletal pain, including myofascial neck pain
    2. osteoarthritis
    3. fibromyalgia
    4. TMJ disorder/pain (NOTE: TMJ services may be a benefit exclusion)
    5. rotator cuff tendonitis
    6. neuropathic pain
    7. cancer pain

E. Patients actively participating in the KP Pain Clinic program may be considered for other diagnoses if:

1. Patient has intractable chronic pain (lasting greater than 3 months); AND,
2. The pain syndrome has been unresponsive to other reasonable traditional therapies or side effects or side effect/concerns have prevented the patient from using traditional therapies; AND,
3. Patient has tried acupuncture therapy and there is documented evidence of efficacy (i.e., increased function; reduced utilization of services such as prescription drugs; and/or subjective reports of reduced pain).

CONTRAINDICATIONS

Medical contraindications include:

1. Bleeding dyscrasia
2. Acupuncture at sites of active infection
3. Electro-acupuncture is contraindicated in patients with pacemakers

OTHER CONSIDERATIONS

**A maximum of 2 units of acupuncture will be authorized per visit.

Acupuncture is not covered for other conditions, including but not limited to tinnitus, epilepsy, psoriasis, smoking cessation, weight reduction or stroke. CMI (Care Management Institute) does not recommend acupuncture for the treatment of persistent asthma.

SPECIAL GROUP CONSIDERATIONS

Commercial: Covered for all Washington groups as a mandate; Oregon contracts vary, check CM.
Medicare: See MCG A-0329 "Acupuncture".
Washington Medicaid: Acupuncture is not covered.
Oregon Medicaid: Covered for certain conditions, check Linefinder

RATIONALE

EVIDENCE BASIS

A 2018 Agency for Healthcare Research and Quality (AHRQ) systematic review of noninvasive nonpharmacological interventions for chronic pain reports that acupuncture improved function and/or pain for at least 1 month when used for chronic low back pain, chronic neck pain, and fibromyalgia.[1] This review notes that effects across included studies were mostly small and that there was a paucity of long term evidence.[1] Additionally, no evidence suggested serious harms from acupuncture, but data on harms was limited in the included studies.[1] 2021 National Institute for Health and Care Excellence (NICE) guidance addressing the management of chronic primary pain includes a recommendation for a single course of acupuncture or dry needling to manage chronic primary pain.[2] The basis for this recommendation included an evidence review that found that several (k=27) studies showed a reduction in pain and improvement in quality of life in the short term (up to 3 months) following acupuncture compared to usual care or sham acupuncture.[2] The guideline notes substantial variation in the type and intensity of acupuncture interventions used.[2]

Chronic Migraine and Chronic Tension-Type Headache

A 2022 Health Technology Assessment commissioned by the Washington State Health Care Authority reports that acupuncture was associated with reductions in the number and severity of headache days compared with sham and active treatments for individuals with chronic migraine.[3] Strength of evidence was generally low and included studies had a high risk for bias.[3] A 2018 Hayes health technology assessment of the effectiveness of acupuncture for episodic and chronic tension-type headache and episodic migraine reports that a large body of evidence suggests that acupuncture may offer a modest benefit for improving rates of response and reducing frequency in patients with episodic or chronic tension-type headaches or episodic migraines and that acupuncture may aide in a near-term reduction in analgesic use among patients.[4] The report notes that the evidence is of low-quality and thus uncertainty about the true effect remains.[4]

Knee Osteoarthritis

A 2018 Hayes health technology assessment of the efficacy and safety of acupuncture for the treatment of osteoarthritis of the knee reports that a moderate-sized body of evidence shows short-term ($\leq$3 months) benefits for pain and function in patients with osteoarthritis of the knee who received acupuncture compared to sham acupuncture or no intervention.[5] The overall quality of the evidence for acupuncture for osteoarthritis of the knee was low and inconsistencies in the evidence yield uncertainty in the effect of acupuncture compared to conventional drug treatment.[5]

PTSD

Per MCG, 25th Edition (2022)
For posttraumatic stress disorder (PTSD), evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A systematic review of 7 randomized controlled trials with 709 patients with PTSD found low-quality evidence favoring acupuncture over control interventions (eg, sham acupuncture, paroxetine, cognitive behavioral therapy, or usual care) for improving PTSD symptoms and depression 1 to 6 months after treatment. The authors noted a need for additional sufficiently powered trials to increase the confidence in these findings.

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2. NICE. Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain. NICE Guideline No. 163. United Kingdom: National Institute for Health and Care Excellence; April 2021.
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KAISER PERMANENTE®

Northwest Region Utilization Review

UR 61: Applied Behavior Analysis (ABA) Medical Necessity Criteria

Department: Behavioral Health
Section: KPNW Region
Applies to: KPNW Region
Review Responsibility: UROC
Subject Matter Expert: Sara Cuthill, MD; Brandon Duft, MD; Kristen Morris, BCBA

Number: UR 61
Effective: 10/24/12
Last Reviewed: 3/19, 3/21, 3/22
Last Revised: 3/18, 5/20, 3/23

DEFINITIONS

Applied Behavior Analysis- the science of behavior, with a history extending back to the early 20th century. Its guiding philosophy is behaviorism, which is based on the premise that attempts to improve the human condition through behavior change (e.g., education, behavioral health treatment) will be most effective if behavior itself is the primary focus.

BACB- The Behavior Analyst Certification Board, Inc.® (BACB®) is a corporation established in 1998 to meet professional credentialing needs identified by behavior analysts, governments, and consumers of behavior analysis services. The BACB's certification requirements, examination content, and procedures undergo regular review according to established standards for organizations that grant professional credentials. All BACB requirements and examination content are developed by experts in the discipline

BCBA- The Board-Certified Behavior Analyst® (BCBA®) is a graduate-level certification in behavior analysis. Professionals certified at the BCBA level are independent practitioners who provide behavior analysis services.

BCaBA- The Board-Certified Assistant Behavior Analyst® (BCaBA®) is an undergraduate-level certification in behavior analysis. Professionals certified at the BCaBA level provide behavior analysis services under the supervision of Board-Certified Behavior Analyst® (BCBA®).

Mid-Level Provider- Mid-Level Providers assist in the supervision and deliver of behavior analytic services and practice under the direction of the BCBA.

Mid-Level Providers must meet the follow criteria:

(A) Possesses a Bachelor of Arts or Science Degree and has either:

1. Twelve semester units in applied behavior analysis and one year of experience in designing and/or implementing behavior modification intervention services; or

2. Two years of experience in designing and/or implementing behavior modification intervention services.

(B) Is registered appropriately with the state in which services are provided

Technician- Technicians assist in delivering behavior analysis services and practice under the direction and close supervision of a BCBA Supervisor, who is responsible for all work technicians perform. Technicians must meet state guidelines of where they provide services.

POLICY AND CRITERIA

POLICY

Kaiser Foundation Health Plan of the NW (KFHPNW) has reviewed the best available literature related to Applied Behavior Analysis (ABA) and consulted with internal Licensed Behavior Analysts. The literature points to potential evidence supporting ABA as an effective treatment modality for behaviors associated with autism. ABA is the most empirically validated and clinically endorsed intervention for autism spectrum disorders. ABA will be covered when patients, providers and programs meet the following conditions:

CRITERIA TO RECEIVE MEDICALLY NECESSARY BEHAVIOR ANALYTIC SERVICES:

1. The member has had a documented diagnostic assessment and final diagnosis of an Autism Spectrum Disorder (ASD) by:
   a) a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; or
   b) a qualified non-Kaiser Permanente provider whose evaluation and diagnosis has been reviewed and confirmed by a qualified Kaiser Permanente provider or multi-disciplinary team appropriately licensed and trained in the diagnosis and treatment of autism; AND
2. There is documentation of a severe challenging behavior and/or communication and social interaction issues, clearly related to characteristics of ASD that:
   a) presents a health or safety risk to self or others (such as self-injury, aggression toward others, destruction of property, elopement, severe disruptive behavior); **OR**
   b) presents a significant functional interference within the home and/or community; AND
   c) demonstrates behaviors that are developmentally inappropriate and pose a significant obstacle to the member's performance of developmentally appropriate daily functioning including self-help and communication
3. There is a reasonable expectation on the part of a qualified treating practitioner or multi-disciplinary team that the individual's behavior will improve significantly with ABA therapy.

<u>ABA Assessment</u>

1) Assessment for the development of the behavior analytic treatment plan will be completed by the external ABA provider.
2) Assessment will be completed of skill deficits, maladaptive behavior, and restrictive behaviors.
3) Direct assessment is required of the member to identify appropriate treatment interventions.

ABA Treatment

1. After assessment is completed by the external ABA Provider, a treatment plan outlining appropriate interventions will be sent to KP ABA department for review.
2. Treatment plans must be reviewed at a minimum of every 6 months, unless more frequent submission is requested by KP to ensure the health and safety of the member.
3. Treatment plans will include data supporting that behavior analytic services remain appropriate for the member and is making progress on the identified reason for referral.
4. The services offered cannot be a duplicative of service offered by or required of the school/ educational system; AND
5. The treatment plan will only include identified evidence-based behavior analytic interventions
6. The presence and participation of an adult caregiver or parent/foster parent/legal guardian is addressed in the child's treatment plan, including, as appropriate, family education, support and training.

Both assessment methods and treatment interventions, must meet BACB treatment and ethical guidelines.

Continuation Criteria

ALL of the following must be reviewed and approved (or denied) by the utilization management MD:

1. The criteria for treatment must continue to be met. The patient will need to be reassessed by external ABA Provider upon the appearance of new maladaptive behaviors that meet the medical necessity criteria.
2. The external ABA Provider will submit an updated treatment plan no more than 10 days before the authorization expiration date, to ensure the most up to date data is presented within the report.
3. The treatment plan should include the data identifying progress or regression for each goal from the previous authorization period and the identified goals for the next authorization period. If data identifies regression on a goal, a rationale should be provided to identify adjustments in the intervention package or barriers to treatment.

Transition to Discharge

1. Transition Plan to discharge must be submitted to the ABA department within 3 months of the planned discharge date.
    a. Transition plan must include how services will be faded to the next level of care recommended.
2. Upon discharge the provider will submit a case closure summary signed by the parent/guardian to KP ABA Department within 30 days of discharge.
    a. This case closure summary will include:

i. Date of discharge
ii. How treatment will be maintained
iii. Any recommended support services
iv. Data indicating that member has met criteria for discharge and reason for referral has been addressed

Criteria for Discharge, ONE of the following must be met:

1. No significant, measurable improvement has been documented on the patient's targeted behavior(s) reasonably attributable to the services provided or, after a period of 6 months of appropriate treatment, there is no reasonable expectation that termination of the current treatment would put the patient at risk for decompensation or the recurrence of signs and symptoms that necessitated treatment.
    a. For changes to be "significant", they must result in improved function, be durable over time beyond the end of the actual treatment session and be generalizable outside the treatment setting.

2. Treatment is making the symptoms persistently worse.
3. The patient has achieved adequate stabilization of the challenging behavior and less-intensive modes of therapy are appropriate.
4. The patient demonstrates an inability to maintain long-term gains from the proposed plan of treatment.
5. Parent/Guardian has requested termination of treatment.

SPECIAL GROUP CONSIDERATIONS

Applies to all commercial groups and Medicare
Washington Medicaid: Does not apply to WA Medicaid members.
Oregon Medicaid: Check LineFinder

RATIONALE

EVIDENCE BASIS

A 2014 Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review evaluated behavioral interventions for children with ASD, including ABA-based early intensive behavioral and developmental intervention.[4] The review reports that young children receiving such interventions display improvements in aspects of cognitive functioning, adaptive skills, language and communication skills, and social skills, and that children in these interventions displayed more improvement than children receiving other types of interventions.[4]

A 2016 AHRQ systematic review in support of the United States Preventive Services Task Force's recommendations on screening for ASD in young children evaluated the evidence for treatment and reports similar findings to the 2014 AHRQ report – namely that studies showed statistically significantly greater cognitive improvements and language outcomes in the ABA-based intervention arms than in the comparator arms.[5]

REFERENCES

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KAISER PERMANENTE® **Northwest Region Utilization Review**

UR 68: Assisted Reproductive Technology (ART) Medical Necessity Criteria

Department: Non-Behavioral Health	Number: UR 68
Section: KPNW Region	Effective: 05/16
Applies to: KPNW Region	Last Reviewed: 05/16, 6/17, 5/18, 2/22
Review Responsibility: Peter Miksovsky, MD, OB/GYN	Last Revised: 6/19, 1/20, 1/21, 3/21, 2/23, 4/23

ASSISTED REPRODUCTIVE TECHNOLOGY MEDICAL NECESSITY CRITERIA

DEFINITIONS

ART- Assisted Reproductive Technology refers to procedures in which pregnancy is attempted through the manipulation of sperm and egg outside the body, such as in vitro fertilization (IVF) or gamete intra-fallopian transfer (GIFT).

IVF- In-vitro fertilization involves retrieving an egg from the woman, combining with sperm in a lab, observing and raising the embryos in the lab for 3 to 5 days, then transferring the resulting embryo back into her uterus.

GIFT- gamete intra-fallopian transfer is a modified version of in vitro fertilization (IVF). GIFT involves retrieving an egg from the woman, combining with sperm in a lab then immediately transferring the unfertilized egg and sperm into her fallopian tube with fertilization taking place in the fallopian tube instead of in a laboratory dish.

ZIFT- zygote intra-fallopian transfer is a modified version of in vitro fertilization (IVF). ZIFT involves retrieving an egg from the woman, combining with sperm in a lab then transferring the fertilized egg (called a zygote) into her fallopian tube before cell division takes place. The zygote is transferred the next day after fertilization occurs.

IUI- Intra-uterine insemination is the placement of washed and concentrated sperm via a catheter into a woman's uterus when she is ovulating. It is often combined with superovulation medicine to increase the number of available eggs, which can result in multiple gestation.

POLICY AND CRITERIA

Assisted reproductive technology may be indicated when A-C below are present:

A. Individual 45 years or younger with use of autologous oocytes and 1, 2 and 3 below.

1. Infertility, as defined by **1 or more** of the following:
   a) Failure to conceive after regular unprotected sexual intercourse for 1 year or more for female 34 years or younger
   b) Failure to conceive after regular unprotected sexual intercourse for 6 months or more for female 35 years old or older.
   c) Individual or partner with infertility due to medical or surgical treatment (e.g., chemotherapy, radiotherapy, gonadotoxic medication, oophorectomy, orchiectomy)

d) Individual with impending infertility due to planned cancer treatment for cure (eg, chemotherapy or oophorectomy)
e) Partner is HIV positive and **ALL** of the following:
    i. Adherent with highly active antiretroviral therapy
    ii. Washed sperm needed for insemination to prevent HIV transmission
f) Male partner with infertility due to cancer therapy (eg, orchiectomy or chemotherapy)
g) Individual with nonobstructive azoospermia or severe oligospermia
h) Partner with paraplegia, and sperm retrieval needed to achieve pregnancy (eg, electro-ejaculation or surgical sperm retrieval)
i) Prior failed cycle of in vitro fertilization or intracytoplasmic sperm injection

2. Infertility evaluation and treatment performed, as indicated by **1 or more** of the following:
    a) Individual with impending infertility due to planned cancer treatment for cure (eg, chemotherapy or oophorectomy)
    b) Individual with infertility due to medical or surgical treatment (e.g., chemotherapy, radiotherapy, gonadotoxic medication, oophorectomy) and **ALL** of the following:
        i. No evidence of tumor recurrence, as indicated by **1 or more** of the following:
            - Two years or more after completion of cancer treatment for gynecologic tumors
            - Two years or more after completion of hematopoietic stem cell transplant
            - Three years or more after initial diagnosis in individual with breast cancer without axillary lymph node involvement
            - Five years or more after initial diagnosis in individual with breast cancer with axillary lymph node involvement
            - After completion of adjuvant tamoxifen, if appropriate, for breast cancer
        ii. Patient had embryo or oocyte cryopreservation prior to treatment.
    c) Hysterosalpingogram shows absent or nonpatent fallopian tube (eg, from prior ectopic pregnancy or pelvic inflammatory disease)
    d) In vitro fertilization or intracytoplasmic sperm injection needed, as indicated by **1 or more** of the following:
        i. Cryopreserved sperm needed from partner (eg, after chemotherapy)
        ii. Prior in vitro fertilization or intracytoplasmic sperm injection cycle resulted in failed fertilization or pregnancy
        iii. Surgical sperm retrieval needed for azoospermia or severe oligospermia in male partner
    e) Treatment for infertility, including specific disorders, as indicated by **1 or more** of the following:
        i. Anovulatory female without polycystic ovary syndrome or other endocrinopathy and **1 or more** of the following:
            - For female 34 years or younger: trial of at least 4 cycles of clomiphene citrate or letrozole and intrauterine insemination
            - For female 35 to 37 years of age: trial of at least 3 cycles of clomiphene citrate or letrozole and intrauterine insemination
            - For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.

ii. Endocrinopathy in female (eg, hypothyroidism, adrenal disorders, pituitary tumor)
iii. Endometriosis
iv. Failure of 12 cycles of donor intrauterine insemination
v. Hypogonadotrophic hypogonadism in male partner
vi. Intrauterine pathology (eg, adhesions, polyps)
vii. Pelvic adhesions
viii. Polycystic ovary syndrome, treated with **ALL** of the following:
- Other causes of infertility ruled out or treated (eg, thyroid disease, hyperprolactinemia, male factor infertility)
- Treated with at least 6 cycles of clomiphene citrate or letrozole

ix. Repair of varicocele
x. Retrograde ejaculation treated with pharmacotherapy
xi. Submucosal leiomyomas
xii. Tubal anastomosis (ie, reversal of tubal ligation)

f) Unexplained infertility and **ALL** of the following:
i. Conventional treatment of unexplained infertility has failed, as indicated by **1 or more** of the following:
- For female 34 years or younger: trial of at least 4 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole) and intrauterine insemination
- For female 35 to 37 years of age: trial of at least 3 cycles of controlled ovarian stimulation (eg, clomiphene citrate or letrozole) and intrauterine insemination
- For female 38 years or older: proceed with in vitro fertilization or 2-3 cycles of intrauterine insemination without gonadotropin.

ii. Normal female serum levels of **ALL** of the following:
- Anti-Mullerian hormone
- Estradiol
- FSH
- Progesterone (in midluteal phase)
- Prolactin
- TSH

iii. Normal hysterosalpingogram and sonohysterography
iv. Normal sperm count, motility, and morphology

3. **1 or more** of the following:
a) Embryo or egg cryopreservation needed for impending infertility due to planned cancer treatment
b) Maximum number of embryos to be transferred is consistent with current evidence to limit risk of multiple-birth pregnancies, as indicated by **1 or more** of the following:
i. One fresh or frozen single-embryo transfer for individual 36 years or younger during first 3 in vitro fertilization cycles
ii. Up to 2 fresh or frozen embryos transferred for individual 36 years or younger after first 3 failed single-embryo transfer in vitro fertilization cycles
iii. One fresh or frozen single-embryo transfer for individual 37 years of age during first in vitro fertilization cycle

iv. Up to 2 fresh or frozen embryos transferred for individual37 years of age after first failed in vitro fertilization cycle
v. Up to 2 fresh or frozen embryos transferred for individual 38 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
vi. Up to 3 fresh or frozen embryos transferred for individual 38 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
vii. Up to 3 fresh or frozen embryos transferred for individual 39 to 40 years of age if prognosis is favorable and/or additional embryos are available for cryopreservation
viii. Up to 4 fresh or frozen embryos transferred for individual 39 to 40 years of age if prognosis is unfavorable and no additional embryos are available for cryopreservation
ix. Up to 5 fresh or frozen embryos transferred for individual 41 to 45 years of age

B. No hydrosalpinx or after treatment with tubal occlusion or salpingectomy
C. No prior in vitro fertilization cycle, or maximum number of prior in vitro fertilization cycles has not exceeded a total of 6 cycles without a live birth

SPECIAL GROUP CONSIDERATIONS

ART may be excluded from coverage. Check CM for exclusions or limitations.

OR PEBB- Check infertility benefit with each request as to whether females must be diagnosed as *infertile* to qualify for infertility treatment.

Cryopreservation is typically excluded from coverage unless the member has coverage for ART, in which case, the associated cryopreservation is also covered. The Exclusion is applied when cryopreservation is requested/billed as a distinct procedure aside from a covered ART procedure.
When cryopreservation is covered, procedures to obtain eggs/sperm are also covered.

RATIONALE

EVIDENCE BASIS

MCG reviewed the evidence on assisted reproductive technology (ART) in 2022. Their findings are provided below:

For infertility, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Guidelines recommend mature oocyte, embryo, or sperm cryopreservation prior to planned chemotherapy.[1-4] Multiple-embryo transfer is associated with an increased risk for multiple-gestation pregnancies and pregnancy complications, including cesarean birth, preeclampsia, premature delivery, and low-birth-weight infants.[5, 6] Additionally, analysis of a US database found a significant adverse effect on intrauterine growth for live singleton and twin births resulting from transfer of multiple embryos.[7] Guidelines on the number of embryos to transfer have been developed by professional societies in order to optimize healthy live births and minimize multiple-gestation pregnancies.[8-10] Assisted reproductive technology registries from 36 European countries for 2008 show an overall distribution of the transfer of 1, 2, 3, and 4 or more embryos as 22.4%, 53.2%, 22.3%, and 2.1%, respectively, resulting in proportions of singleton, twin, and triplet deliveries of 78.3%, 20.7%, and 1.0%, respectively.[11] A systematic review and meta-analysis of

randomized controlled trials concluded that increasing the number of single-embryo transfer attempts to 3 cycles using fresh or frozen embryos in women younger than 36 years results in a cumulative live birth rate similar to double-embryo transfer and reduces the likelihood of multiple births by 94%.[12] A meta-analysis of individual patient data from randomized trials reported that elective single-embryo transfer resulted in a lower pregnancy rate than double-embryo transfer in a fresh in vitro fertilization cycle; however, the difference was almost completely overcome by an additional frozen single-embryo transfer cycle. Additionally, the rate of multiple-gestation pregnancy and risk of preterm birth and delivery of a low-birth-weight infant were decreased with single-embryo transfer.[13] A systematic review and meta-analysis reported that elective single-embryo transfer is associated with decreased risk of preterm birth and low birth weight as compared with double-embryo transfer, but with higher risk of preterm birth as compared with spontaneously conceived singleton infants.[14] A multicenter randomized controlled trial of 1650 women with infertility found that frozen single blastocyst transfer was associated with an improved singleton live birth rate compared with fresh single blastocyst transfer (50% vs 40%, respectively). However, frozen single blastocyst transfer was also associated with a higher risk of preeclampsia (3.1% vs 1.0%, respectively) which the authors advise warrants additional evaluation.[15] A national registry study of the outcomes by number of embryos transferred (124,148 IVF cycles, 32,732 cycles with complete outcomes data available) reported that the odds of live birth were similar regardless of whether 1, 2, or 3 embryos were transferred; however, all adverse perinatal outcomes (multiple births, prematurity, small for gestational age) occurred more frequently when 3 or more embryos were transferred. The odds of live birth were higher with double-embryo transfer in all age groups; however, the association was stronger in women older than 40 years. Multiple birth risk increased with double-embryo transfer in all age groups, but was substantially lower in women age 40 years and older. The authors concluded that the findings supported restricting embryo transfer to fewer than 3.[16] A practice guideline recommends that women age 35 to 40 years be considered for elective single-embryo transfer if they have top-quality blastocyst-stage embryos available for transfer.[17] For women age 40 to 42 years, another practice guideline recommends double-embryo transfer.[2]

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KAISER PERMANENTE®

Northwest Region Utilization Review

UR 10.A Bariatric Surgery Medical Necessity Criteria for Commercial Members

Department: Surgery	Number: UR 10.A
Section: KPNW Region	Effective: 3/2000
Applies to: Bariatric Surgery	Last Reviewed: 8/18, 7/19, 3/23
Review Responsibility:	Last Revised: 1/20, 10/20, 1/21, 3/22
Dr Nathan Bronson, Bariatric Surgery;	
Terri Graven, RN, Obesity Program	

POLICY AND CRITERIA

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR THE BARIATRIC SURGERY PREPARATION PROGRAM (NOTE: admission into the Program, also known as the Severe Obesity Program, is required prior to consideration of bariatric surgery) FOR COMMERCIAL LINES OF BUSINESS

CRITERIA

Patients will be eligible to participate in the preparation process and may be a candidate for bariatric surgery if:

1. Body Mass Index (BMI) is >35 Kg/m2 with one or more of the following serious co-morbid conditions at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program:

    a. Sleep apnea requiring treatment with Continuous Positive Airway Pressure (CPAP) or inability to use CPAP with an Apnea/Hypopnea Index (AHI) >15 on sleep study *or* inability to use CPAP with an AHI >5 and documentation of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, hypertension, ischemic heart disease, or history of stroke;

    b. Congestive heart failure (CHF) or cardiomyopathy with a NW Permanente Cardiologist recommendation for bariatric surgery;

    c. Obesity hypoventilation and PC02 $\geq$45 and a NW Permanente Pulmonologist recommendation for bariatric surgery;

    d. Diabetes mellitus requiring medical therapy that includes insulin or an insulin sensitizing oral agent *i.e.* metformin or pioglitazone (or documented intolerance to insulin or insulin sensitizing oral agents) or >15 pound weight gain within 2 years of starting insulin therapy or endocrinologist recommendation for bariatric surgery;

    e. Severe hypertriglyceridemia (>1000 mg/dl) requiring medical therapy, which includes fibrate drugs and therapeutic doses of omega-3 fatty acid (6 grams daily), or a NW Permanente Endocrinologist recommendation for bariatric surgery;

    f. Hypertension with blood pressure >140/90 (130/80 in the presence of diabetes or renal disease) documented on two consecutive visits requiring the use of antihypertensive medications, including a diuretic, unless contraindicated;

    g. Extremity edema with ulceration documented by a NW Permanente Primary Care Provider;

h. Gastroesophageal reflux requiring prolonged medical management documented by a NW Permanente Physician;

i. Stress incontinence related to obesity and a NW Permanente Urologist or uro-gynecologist recommendation for bariatric surgery;

j. Pseudotumor cerebri documented by a NW Permanente Neurologist.

OR

2. BMI is ≥40 Kg/m2 with no co-morbid condition at the time of initiation of physician-directed therapy for obesity and/or referral to the Severe Obesity Program;

AND

3. Be ≥18 years old and general health adequate to tolerate surgery;

AND,

4. Members with a history of tobacco products* use must have a documented "quit" date ≥6 months prior to referral for consultation.

   *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

5. Have documentation in the medical record or referral that the member has been previously unsuccessful with medical treatment for obesity. The general expectation is bariatric surgery will not be done until a prior effort to lose weight is made as an adult. Programs attempted prior to adult years do not qualify.

   Practitioner documentation in the medical record of one of the following must occur:

   a. Minimum of 6-month participation (does not need to be continuous or uninterrupted for 6 months) in a recognized commercial behavioral weight management program. For example, 4 months with Weight Watchers and 2 months with Jenny Craig would meet criteria. The treatment program must include hypocaloric diet changes, nutrition education, physical activity, and behavior change strategies. Acceptable programs include but are not limited to: Weight Watchers or similar behavioral-based programs such as Medifast, Nutrisystem, and/or Jenny Craig. Non-commercial, book-based programs, such as Atkins and Dr. Phil, do not qualify.

   b. Minimum of 6-month participation in a Physician, Nurse Practitioner, Physician Assistant, Registered Dietician, or Licensed Behavioral Therapist supervised weight loss program, with or without obesity pharmacotherapy.

   c. Three or more primary care visits over a minimum of 6 months with weight management treatment and follow-up plan in the progress note.

   d. Participation in and completion of all sessions of Kaiser Permanente NW Health Engagement and Wellness Service weight management course.

NOTE: Currently, the bariatric surgical procedures offered are limited to laparoscopic Roux-en-Y Gastric Bypass (RNYGB) and laparoscopic sleeve gastrectomy. The type of surgical procedure performed is up to the clinical discretion of the surgeon.

Roux-en-Y Gastric Bypass (RYGBP) is a procedure that restricts the size of the stomach by stapling shut 90% of the lower stomach and bypassing the nearby intestine.

Laparoscopic Sleeve Gastrectomy is an irreversible surgical removal of a large portion of the stomach along the greater curvature in which the stomach is reduced to about 25% of its original size.

OTHER REQUIREMENTS

After the bariatric surgery referral, but prior to bariatric surgery, the member must complete **all** program requirements. Surgical clearance must be received.

OTHER CONSIDERATIONS

1. Surgical risk determinations: Individuals with BMI >60 and/or age >60 years are at higher surgical risk. Decisions regarding the appropriateness of surgery will be made individually based on rehabilitation potential and the physician and surgeon's judgment regarding surgical risk and likelihood of benefit.

2. Revisional bariatric surgery: Patients who have previously had bariatric surgery requesting re-operation for weight loss or severe reflux will be managed individually but will need to meet BMI and co-morbidity requirements. There is no evidence suggesting that performing more aggressive bariatric procedures is indicated for weight regain after procedures with both restrictive and malabsorptive components or impaired absorption of nutrients, such as roux-en-y gastric bypass.

3. Because the most common reason for surgical failure (weight regain) is inappropriate eating behaviors and lack of physical activity, patients will need to have their current behaviors carefully assessed and surgery will not be recommended unless current behaviors are conducive to post-operative success.

CONTRAINDICATIONS TO BE DETERMINED PRE-OPERATIVELY BY THE SURGEON

1. Current pregnancy or desire for pregnancy in the next 18 months
2. Alcohol or substance abuse within the last year
3. Nicotine use, including *tobacco products and nicotine replacement therapy (NRT) **products within 6 months prior to surgery

   *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

   **NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

4. Uncontrolled major psychiatric disorder. If you suspect the presence of uncontrolled depression, suicidal ideation, paranoid ideation, psychotic disorder, multiple personality disorder or active/untreated eating disorder i.e. bulimia, a NW Permanente Psychiatrist must be consulted pre-referral to ascertain control.

5. Endogenous reasons for obesity i.e. Cushing's disease

6. Clinical cirrhosis or advanced liver disease is a contraindication to bariatric surgery due to excessive operative mortality. Patients with hepatitis C or chronic active hepatitis B, prior jejunoileal bypass, or chronically abnormal liver tests of any cause should be evaluated with further testing including transaminase levels, tests of hepatic synthetic function (albumin and PT/INR), CBC, and abdominal ultrasound with doppler. If significant abnormalities are found (i.e., ascites, hepatofugal blood flow, splenomegaly, thrombocytopenia, albumin < 3, coagulopathy despite vitamin K replacement, referral to gastroenterology is recommended for further evaluation prior to consideration of bariatric surgery. Although fatty infiltration of the liver and NASH (non-alcoholic steatohepatitis) are the most common causes of abnormal transaminase levels in severely obese patients, persistently abnormal liver tests should have serologic evaluation for chronic viral hepatitis as well as other causes of transaminase elevation.
7. Other conditions that the primary care provider, bariatric surgeon, KPNW consultant, or Severe Obesity Team members feel would raise the risk of surgery to unacceptable levels.

SPECIAL GROUP CONSIDERATIONS

Commercial (UR10A): Applies to all commercial groups, including Federal, OEBB and PEBB members
Medicare: See UR 10B Medicare MNC for bariatric surgery
Washington Medicaid: Not covered
Oregon Medicaid: See UR 10C OHP MNC

NOTE

Patients requesting repeat bariatric procedures need to have their prior operative records obtained to define post-surgical anatomy. If this is not possible, an upper GI x-ray may be useful. If metabolic, renal, or hepatic complications are present from prior jejunoileal bypass, general surgery referral is recommended regardless of the BMI status to discuss revision of this operation unless clinical cirrhosis or other conditions are present that would increase operative risk to unacceptable levels.

Patients with mechanical complications stemming from previous bariatric surgeries (i.e. vomiting, obstruction) should be referred to general surgery or gastroenterology for further evaluation.

Patients with intact post bariatric surgical anatomy from previous procedures with both malabsorbtive and restrictive components will not be offered revisional operative procedures (ie stomal narrowing, band over bypass or pouch reductions) because of inadequate weight loss or weight regain. Those whose operative anatomy have broken down (ie gastric-gastric fistulae) will be considered for revisions as indicated by risk/benefit ratios.

RATIONALE

EVIDENCE BASIS

The KP National Guideline Program clinical practice guideline recommendations include a summary of the evidence relevant to selecting patients for bariatric surgery. Brief excerpts from that evidence summary are included here:

“Efficacy:

- Weight loss: In obese adults, bariatric surgery produces greater weight loss and maintenance of lost weight than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight.

- Weight loss at 2 to 3 years following a variety of surgical procedures in adults with presurgical BMI ≥30 varies from a mean of 20% to 35% of initial weight and a mean difference from nonsurgical comparators of 14% to 37% depending on procedure. (SOE: High)
- Mean weight loss at 10 years following a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) is approximately 16% of initial weight, representing a mean weight regain of 7%. (SOE: Low)

- Comorbidities: In obese adults, bariatric surgery generally results in more favorable impact on obesity-related comorbid conditions than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss.
  - Glycemic control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve a mean weight loss of 20% to 35%, there is a ↓in FPG, insulin and incidence of T2DM and there is a greater likelihood of diabetes remission among those with T2DM at baseline. Remission was defined variously depending on the study. (SOE: high)
    - At 10 years, incidence and prevalence of T2DM are lower in those who have undergone surgery. However, among those in whom T2DM remits after surgery, diabetes may recur over time. (SOE: low)
  - Blood pressure control
    - At 2 to 3 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, blood pressure or use of blood pressure medication is reduced compared with nonsurgical management. Blood pressure tends to increase over time, and at 10 years post-surgery, there is no difference in mean SBP or the incidence of new cases of hypertension in those who underwent bariatric surgery compared to those who did not undergo surgery. (SOE: low)
    - Among obese adults with baseline hypertension, a greater percentage is in remission at 2 to 3 years and 10 years following bariatric surgery compared with nonsurgical management. (SOE: low)
  - Cholesterol and lipid control
    - At 2 to 3 years and 10 years following a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, serum TG levels are lower, HDL-C levels are higher, TC-to-HDL-C ratio is lower, and changes in TC or LDL-C levels are inconsistent compared with nonsurgical management. (SOE: low)
  - Quality of life
    - Most measures of health-related quality of life (HRQOL) are improved at 2 and 10 years following bariatric surgery. (SOE: moderate)
  - Total mortality
    - Total mortality is decreased compared with nonsurgical management at mean follow-up of 11 years after undergoing a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) in patients with mean BMI >40 who achieve a mean long-term weight loss of 16% (SOE: low)
  - CVD risk
    - There are insufficient data on the efficacy of bariatric surgical procedures for weight loss and maintenance or CVD risk factors 2 or more years post-surgery in patients with a BMI <35.

Complications:
Perioperative (≤30 days) and longer term (>30 days) complications following bariatric surgery vary by procedure and patient-derived risk factors.

- Roux-en-Y Gastric Bypass.
    - When performed by an experienced surgeon, perioperative complications following laparoscopic gastric bypass:
        - Consist of a major adverse outcome in approximately 4% to 5%, including mortality (0.2%), DVT and/or pulmonary embolism (PE) (0.4%), and a requirement for reoperation (3% to 5%). Rates of any complication, major or minor, range from 2% to 18%. (SOE: moderate)
        - Are less frequent for the laparoscopic approach than for open incision. (SOE: moderate)
        - When performed by an experienced surgeon, perioperative complications following open gastric bypass:
            - Consist of a major adverse outcome in approximately 8%, including mortality (2%), DVT/PE (1%), and reoperation (5%). (SOE: low)
        - When performed by an experienced surgeon, perioperative complications following gastric bypass (laparoscopic or open):
            - Are associated with extremely high BMI, inability to walk 200 feet, history of DVT/PE, and history of obstructive sleep apnea. (SOE: low)
- Laparoscopic Sleeve Gastrectomy
    - There is insufficient evidence to establish the incidence of perioperative and longer-term complications."

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KAISER PERMANENTE®

Northwest Region Utilization Review
UR 50: Biofeedback Medical Necessity Criteria

Department: Non-Behavioral Health
Section: KPNW Region
Applies to: KPNW Region
Review Responsibility: Aaron Bayne, MD (Peds Uro), Waleed Lutfiyya, MD (Colorectal Surgery)

Number: UR 50
Effective: 12/08
Last Reviewed: 9/19, 10/22
Last Revised: 2/20, 9/20, 9/21, 9/23

DEFINITIONS

Biofeedback (BFB) is a form of complementary or alternative medicine that measures a person's bodily processes and conveys such information in real time in order to raise the person's awareness and conscious control of the related physiological activities.

CRITERIA FOR THE *INITIATION* OF BIOFEEDBACK

Biofeedback may be indicated for **1 or more** of the following:

1) Tension or migraine headache AND pharmacologic treatment is inadequate or not indicated by reason of **1 or more** of the following:
    a) insufficient or no response to multiple pharmacological (medication) treatment attempts
    b) intolerance of multiple pharmacologic treatment attempts
    c) patient has a preference for nonpharmacologic interventions
    d) history of long-term, frequent, or excessive use of analgesic (pain medication) or medications that can aggravate headache
    e) deficient stress-coping skills that remain a significant contributor to headache onset despite counseling of the patient by a qualified professional
    f) pregnant patient
    g) breast-feeding patient
    h) patient attempting to become pregnant

2) Dyssynergic (muscle incoordination) constipation in adults as indicated by **ALL** of the following:
    a) evidence of dyssynergic constipation as indicated by **ONE or more** of the following:
        i) anorectal manometry shows dyssynergic motor pattern
        ii) non-relaxing puborectalis muscle (responsible for controlling bowel movements) while straining to expel the index finger during a rectal digital examination or paradoxic movement of pelvic floor on digital examination
        iii) proctography evidence of non-relaxing puborectalis
        iv) prolonged delay in transit time (greater than 20% retention of radiopaque markers 5 days after ingestion)
        v) prolonged expulsion of simulated stool (i.e. balloon expulsion test greater than one minute)
        vi) internal prolapse
        vii)levator spasm/proctalgia fugax
    b) inadequate response to diet, laxatives, exercise, or hydration therapy for constipation

c) no finding of significant obstruction or partial obstruction on colonoscopy or barium enema
d) no evidence of hypothyroidism
e) no use of drugs known to be constipating (i.e. narcotic pain medications)

3) Stress and/or urge urinary incontinence (inability to control urination) in females and males as indicated by **ALL** of the following:
   a) the patient is cognitively (mentally) intact
   b) the patient has failed a trial of pelvic muscle exercise (PME) training. A failed trial is defined as one in which there is no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of PMEs to increase periurethral muscle strength (responsible for controlling urination).

4) Voiding dysfunction/dyssynergia (muscle incoordination) in children, 5-18 years old, when indicated by **ALL** of the following:
   a) the patient is cognitively intact
   b) the patient has no spinal cord abnormalities that would interfere with normal voiding
   c) the patient has been evaluated by a Kaiser Permanente pediatric urologist who is recommending biofeedback based on **ALL** of the following:
      i) a failed trial of timed voiding
      ii) if patient is $\geq$12 years of age, a failed trial of proper relaxation techniques during voiding.
      iii) if patient is $\geq$16 years of age, a failed trial of pelvic floor exercises.
      iv) evidence of significant dyssynergia based on pelvic floor EMG during the active phase of voiding (EMG/electromyography tests the electrical activity of muscles).

   Examples of voiding dysfunction/dyssynergia include: dysfunctional elimination syndrome (DES), detrusor/sphincter dyssynergia, vesicoureteric reflux, pelvic floor dysfunction.

5) Fecal incontinence when **ALL** of the following exist:
   a) documentation of a treatment plan including goals and frequency of treatment
   b) the patient is motivated to actively participate in the treatment plan and is responsive to care plan requirements
   c) the patient is cognitively intact and deemed capable of participating in the treatment plan by the consulting physician
   d) the patient has some degree of rectal sensation and can voluntarily contract the external anal sphincter as determined by either manometry OR physical exam findings
   e) the patient does not have existing pathology that would prevent treatment completion.

6) The following pain related conditions when at least two appropriate treatment modalities have been tried and failed:
   a) temporo-mandibular joint syndrome (NOTE: TMJ services may be a benefit exclusion)
   b) cancer pain
   c) cervical (neck) strain

7) Muscle re-education of specific muscle groups when **ALL** of the following are met:
    a) the patient has one or more of the following:
        i. pathological muscle abnormalities of spasticity
        ii. incapacitating muscle spasm
        iii. muscle weakness
    b) conventional treatments (heat, cold, massage, exercise, support) have not been successful

CRITERIA FOR THE *CONTINUATION* OF BIOFEEDBACK

Treatment progress must be clearly documented in an updated plan of care/current progress summary at the end of each authorization period and/or when additional visits are being requested. Progress Note Documentation must include the following:

1. Current and previous level of functioning, including:
    - Objective tests or measurements of physical function
    - A description of the member's current level of functioning or impairment
2. Identification of any health conditions which could impede the member's ability to benefit from treatment
3. Objective measures of the member's functional progress relative to each treatment goal, and a comparison to the previous progress report
4. Summary of member's response to biofeedback, with documentation of any issues which have limited progress
5. Documentation of member's participation in treatment as well as member/caregiver participation or adherence with a home exercise program (HEP), when applicable
6. Brief prognosis statement with clearly established discharge criteria
7. An explanation of any significant changes to the member's plan of care and the clinical rationale for revising the plan of care
8. Recommended treatment techniques and/or modalities, their anticipated frequency and duration

CRITERIA FOR *DISCHARGE*

A member will be discharged from therapy when **any** of the following occurs:

1. Member no longer demonstrates functional impairment or has achieved goals set forth in the POC or has returned to their prior level of function
2. Member has adapted to impairment with assistive/adaptive equipment or devices
3. Member has been receiving services over an extended period of time and it cannot be determined whether the progress is due to therapeutic intervention or natural development, services can be discontinued.
4. Member is unable to participate in the plan of care due to medical, psychological, or social, complications
5. Member (and/or family/caregiver) is non-compliant with Home Exercise Program and/or lacks participation in scheduled therapy appointments

SPECIAL GROUP CONSIDERATIONS

Medicare: The Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual. Chapter 1, part 1.30.1- requires Biofeedback Therapy (done as outpatient PT) coverage for the Treatment of Urinary Incontinence if the provider deems biofeedback the desired treatment option. It is the decision of Kaiser Permanente to cover conditions in addition to urinary incontinence, in accord with the provisions of the Biofeedback medical necessity criteria. NOT COVERED: treatment of ordinary muscle tension, psychosomatic conditions and home biofeedback are not covered.

Also see KPNW **BEAM Policy**

NOTE:

This policy is informed by CMS coverage requirements for biofeedback and internal clinical expert opinion.

CLINICAL

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BOTULINUM TOXIN INJECTION FOR CHRONIC MIGRAINE PROPHYLAXIS

Policy Number: 0005
Effective Date: May 1, 2015
Reviewed Date: July 2023
Next Review: July 2024
Clinical Reviewer: Michael Zatt, DO

BACKGROUND

CLINICAL BACKGROUND

Chronic migraine (CM) is a type of chronic daily headache that can be severely disabling. Individuals diagnosed with CM must have experienced headaches for at least 15 days per month for more than three months, with headaches on at least eight days that possessed migrainous features (HIS 2018). Approximately three million adults in the United States (1.3% of the population) are estimated to be affected by CM (Natoli 2010). One in five of these individuals are occupationally disabled. Research has also shown that CM is associated with reduced quality of life (Bigal 2008, Dodick 2006).

Treatment for chronic migraine typically includes pharmacotherapy, but may include complementary treatments such as changes in diet, sleep, and exercise. Acute pharmacotherapy includes options such as simple analgesics, non-steroidal anti-inflammatory drugs, triptans, CGRP antagonists, and ergotamines. Preventive pharmacotherapy options include antidepressants, anticonvulsants, beta-blockers, calcium channel blockers and botulinum type A (e.g., BTA or Botox) injections (Chawla 2011), and CGRP antagonists. The use of BTA for chronic migraine involves injections into the muscles of the head and neck approximately every 12 weeks.

POLICY AND CRITERIA

Injection of onobotulinumtoxinA (Botox) may be considered medically necessary for chronic migraine prophylaxis when both of the following criteria are met:

- Diagnosis of chronic migraine as described by the International Headache Society Classification with attacks occurring for 15 or more days per month for more than 3 months, of which at least 8 days per month are migraine headache; AND
- Member has documented failure of (or intolerance to) prophylactic migraine medications from at least 3 different drug classes. Each trial must have lasted at least 2 months. Classes include:
    - Anti-depressants
    - Anti-convulsive medications
    - Beta blockers
    - Angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers

Members meeting the above criteria may receive no more than 5 (five) treatments in a 12 month period.

If a previous trial of botulinum toxin injection for chronic migraine prophylaxis has NOT produced at least a 7-day reduction in monthly number of migraines, or severity of headaches by 3/10 points, or reduced total headaches duration by at least 100 hours per month, additional injections are considered NOT medically necessary.

RATIONALE

EVIDENCE BASIS

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on botulinum toxin for migraine prophylaxis in 2015. Findings and conclusions were as follows:

Aurora 2010 (n = 679) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy I (PREEMPT I) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. PREEMPT I consisted of a 24-week, double-blind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Investigators assessed the frequency of headache episodes (the primary outcome of interest), as well as numerous secondary outcomes, including the frequency of headache days, the frequency of migraine days, and the frequency of migraine episodes. The study reports no improvement in reduction of headache episodes over placebo (p = 0.344). However, the study does report that BTA produced a 7% reduction in headache days over placebo, meaning that patients receiving BTA injections had, on average, 1.4 fewer headache days per month than those receiving placebo (p = 0.006, 95% CI: -2.40, -0.40).

Diener 2010 (good-quality RCT): Diener et al. (n = 705) reported results from the Phase III Research Evaluating Migraine Prophylaxis Therapy II (PREEMPT II) study, assessing the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Like PREEMPT I, PREEMPT II consisted of a 24-week, doubleblind, parallel-group, placebo-controlled phase followed by a 32-week, open-label phase. Whereas the primary outcome of interest in PREEMPT I was the frequency of headache episodes, PREEMPT II focused instead on the frequency of headache days. Investigators also measured numerous secondary outcomes, including the frequency of headache episodes, the frequency of migraine days, and the frequency of migraine episodes. The study reports that BTA produced an 11.5% reduction in headache days over placebo, i.e., 2.3 fewer headache days per month (p < 0.001, 95% CI: -3.25, -1.31).
Dodick 2010 (pooled data from two good-quality RCTs detailed above): Dodick et al. (n = 1384) pooled data from the PREEMPT I and PREEMPT II studies to address again the efficacy, safety and tolerability of BTA as chronic migraine prophylaxis. Again, investigators focused on the mean change from baseline in frequency of headache days, and reported that BTA produced a 9% decrease in mean headache days over placebo, i.e., 1.8 fewer headache days per month (-8.4 BTA vs -6.6 placebo, p < 0.001, 95% CI: -2.52, -1.13; Number Needed to Treat [NNT] = 9 for one person to experience at least a 50% reduction in the frequency of headache days).

Within both PREEMPT I and PREEMPT II, there is a potential for “unblinding” of the study participants to their treatment group allocation. Because BTA produces a numbing sensation and physical differences in facial appearance following injection, it is possible that participants were able to determine whether they were receiving BTA or placebo. This has the potential to result in ascertainment bias that may bias these studies’ results. However, investigators did expend rigorous effort to conduct a double-blind study, and we do not see room for methodological improvement to overcome this potential issue with subject masking to the receipt of active drug versus placebo.

In both trials, more than 60% of participants reported acute headache pain medication overuse. The International Classification of Headache Disorders 2nd edition (ICHD-2) does not classify patients with acute head pain medication overuse as having chronic migraine: “*migraine headache occurring on 15 or more days per month for more than three months in the absence of medication overuse.” If practitioners are using the ICHD-2 criteria for chronic migraine, their patient population would differ from the PREEMPT I study population. It is important to take this difference into consideration when attempting to generalize these findings.

There were significant differences between the treatment and placebo groups at baseline in both PREEMPT I (Aurora 2010) and in the pooled analysis of PREEMPT I and PREEMPT II (Dodick 2010). The placebo group had significantly more baseline headache episodes (Aurora 2010: placebo = 13.4, BTA = 12.3, p = 0.023; Dodick 2010: placebo = 13.0, BTA = 12.2, p = 0.004) and migraine episodes (Aurora 2010: placebo = 12.7, BTA = 11.5, p = 0.006; Dodick 2010: placebo = 12.2, BTA = 11.4, p =

0.004) than the treatment group. The treatment group reported significantly more cumulative headache hours (Aurora 2010: placebo = 274.9, BTA = 295.7, p = 0.022; Dodick 2010: placebo = 281.22, BTA = 295.93, p = 0.021) at baseline. If there is a differential in the magnitude of the placebo response among individuals with more or less frequent headaches or among individuals reporting more or less headache hours these imbalances in baseline characteristics might act as confounders. Because the placebo response is particularly relevant when measuring patient-reported outcomes (Hróbjartsson 2010) as was done in these trials, these possible confounders should be considered when interpreting study findings.

All studies report that treatment with 155 Units (U) to 195 U of BTA every 12 weeks over 24 weeks was well-tolerated. Pooled results from PREEMPT I and PREEMPT II showed that 62.4% of individuals receiving BTA reported adverse events, compared to 51.7% receiving placebo. Serious adverse events were reported by 4.8% of individuals receiving BTA compared to 2.3% receiving placebo. Additionally, 3.8% of those receiving BTA discontinued because of adverse events, compared to 1.2% of those receiving placebo. Adverse events most frequently cited for discontinuation of the study were neck pain (0.6%), muscular weakness (0.4%), headache (0.4%) and migraine (0.4%). No deaths were reported within either group. Both PREEMPT I and PREEMPT II had 32-week open label phases following the 24-week randomized, double-blind phases to study adverse events further.

Additional literature published between 2015 and 2016 identified only reports of new analyses of previously reported data, including 4 subgroup analyses, 1 pooled analysis, 1 systematic review, 1 meta-analysis, and 1 cost-effectiveness analysis. None of the reported analyses alter the conclusions of the previous review.

Authors of a more recent Cochrane review did not identify any additional literature (Herd 2018). In that review, authors also performed a meta-analysis combining results of the relevant RCTs. The pooled mean difference between botulinum toxin and placebo showed a benefit of approximately three fewer migraine-days per month in the treatment group (-3.1, 95% CI -4.7 to -1.4). In another meta-analysis, the authors excluded trials at high risk of bias, leaving the PREEMPT 1 and PREEMPT 2 trials (Aurora 2010 and Diener 2010, respectively). While there was still a significant benefit in favor of the treatment group, the estimate was somewhat smaller, with a mean reduction of two fewer migraine-days per month.

RELEVANT GUIDELINES

The American Academy of Neurology (AAN) reviewed evidence related to BTA for various indications, including migraine prophylaxis, in their 2008 guideline (Naumann 2008). An updated literature search in 2016 informed the following guidelines regarding chronic migraine:

> **Strong Evidence** OnaBoNT-A should be offered as a treatment option to patients with CM to increase the number of headache-free days (Level A).
>
> **Moderate Evidence** OnaBoNT-A should be considered to reduce headache impact on health-related quality of life (Level B).

The AAN 2016 guideline was reaffirmed in 2019 with no changes.

In guidelines issued by the National Institutes for Clinical Excellence (NICE), botulinum toxin type A is recommended as a treatment option for chronic migraine. NICE states the following:

1.1 Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):

- That has not responded to at least three prior pharmacological prophylaxis therapies and
- Whose condition is appropriately managed for medication overuse

1.2 Treatment with botulinum toxin type A that is recommended according to 1.1 should be stopped in people whose condition:

- Is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles) or
- Has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months

1.3 People currently receiving botulinum toxin type A that is not recommended according to 1.1 and 1.2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

CODES

CPT or HCPCS Code	Description
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Botulinum toxin type A, per unit [Botox]

ICD-10 Code	Description
G43.001 - G43.919	Migraine headache

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POLICY HISTORY

Date	Action
May 1, 2015	New policy
June 27, 2017	Calcium channel blockers removed as a class of prophylactic medication as suggested by clinician reviewer due to lack of efficacy
April 24, 2018	Definition of chronic migraine updated to reflect 3rd edition of ICHD
May 29, 2019	No policy changes; literature and guideline updates with no substantive changes.
May 15, 2020	No policy changes; literature and guideline updates with no substantive changes.
June 23, 2022	CGRP antagonists added as a class of prophylactic medication as suggested by clinician reviewer due to FDA approval of a CGRP antagonist for migraine prevention in 2021; policy amended to permit up to 5 treatments in a 12-month period as suggested by clinician reviewer based on clinical experience; literature and guideline updates with no substantive changes.

KAISER PERMANENTE® Northwest Region Utilization Review

UR 20.6 Breast Reconstruction Surgery Medical Necessity Criteria: Commercial Members

Department: Surgery	Number: UR 20.6
Section: Plastic Surgery	Effective: 9/14
Applies to: KPNW Region	Last Reviewed: 2/20, 2/20/24
Review Responsibility: UROC	Last Revised: 2/21, 2/22, 3/22, 2/23
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; H. Jonathan Chong, MD (Plastic Surgery)	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR BREAST RECONSTRUCTION SURGERY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* may vary within the Exclusions section of the EOC documents (this exclusion does not apply to 'Reconstructive Surgical Services' or services that are medically necessary).

POLICY AND CRITERIA

Patients will be eligible for breast reconstructive surgery under these criteria only 1) after medically necessary mastectomy or lumpectomy related to breast cancer or 2) to correct significant disfigurement resulting from an injury or from medically necessary surgery.

- Reconstructive surgery of the affected side may include any or all of the following:
  - Tissue reconstruction (e.g., flaps)
  - Use of tissue expanders
  - Implantation of FDA-approved internal breast prosthesis. Augmentation may be appropriate only when one of the following conditions is met:
    - Patient has undergone lumpectomy but NOT radiation therapy; OR
    - Patient has undergone mastectomy, with or without radiation therapy
  - Areolar and nipple reconstruction
  - Areolar and nipple tattooing
  - Autologous fat grafting
  - Liposuction
  - Mastopexy or reduction (e.g. oncoplastic reduction)
  - Capsule revision (capsulotomy, capsulectomy, capsulorrhaphy)
  - Dermal rearrangement (i.e. "Goldilocks" flaps)

- Reconstructive procedures may be performed on the contralateral (unaffected) side to restore the appearance of the breasts to the level of symmetry present prior to mastectomy or lumpectomy ONLY when mastectomy or lumpectomy has produced significant asymmetry.
    - The patient qualifies as having significant asymmetry when the following criteria are met:
        - There is an absence of breast tissue unilaterally where there is no ability to maintain a normal breast shape using non-surgical methods; AND
        - At least 250 g of tissue were removed OR there is a difference of at least 1 cup size.
    - Reconstructive surgery of the contralateral (unaffected) side may include any of the following when the above criteria are met:
        - Breast reduction by mammoplasty or mastopexy
        - Augmentation mammoplasty
        - Areolar and nipple reconstruction
        - Areolar and nipple tattooing
        - Capsulotomy
        - Capsulectomy
        - Breast implant removal and subsequent re-implantation when original implant was in the unaffected breast prior to disease in the affected breast
        - Liposuction
        - Autologous fat grafting

- Reconstructive procedures are considered medically necessary when performed either at the time of mastectomy (immediate reconstruction) or in a staged manner following mastectomy (delayed reconstruction). Contraindications to immediate reconstruction are:
    - Severe obesity (BMI >40)
    - Uncontrolled diabetes (HbA1c >8.0)
    - Inflammatory breast cancer
    - Members who decline or are non-compliant with standard of care cancer treatment
    - Active or recent use of tobacco and/or tobacco products* (members with a history of tobacco products* use must have a documented "quit" date >6 months prior to referral for consultation OR a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit $\leq$6 months prior to referral for consultation. *tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff))

- Reconstructive surgical revisions may be performed as deemed necessary by a physician board-certified in plastic surgery.
    - Revisions will not be covered when performed to correct changes in form or symmetry due to natural processes, such as aging or changes in weight.
    - Once the initial sequence of tattoo sessions has been completed, further touch-ups will be considered cosmetic (see Special Group Considerations).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)
**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher. Members with a HbA1c in the 7-8 range may be assessed for relative contraindications on a case-by-case basis.
3. Obesity is also a risk factor for poor surgical outcome. Members who are obese but otherwise meet the above medical necessity criteria will be assessed on a case-by-case basis.
4. Any other surgical contraindications will be determined by the surgeon.

SPECIAL GROUP CONSIDERATIONS

Medicare- This policy does not apply to Medicare. See NCD 140.2: Breast Reconstruction Following Mastectomy and LCD 37020: Plastic Surgery.

Senior Advantage EOC states:

- We cover reconstructive surgery to correct or repair abnormal structures of the body caused by congenital defect, developmental abnormalities, accidental injury, trauma, infection, tumors, or disease, if a network physician determines that it is necessary to improve function, or create a normal appearance, to the extent possible. However, reconstructive surgery that offers only a minimal improvement in appearance or is performed to alter or reshape normal structures of the body in order to improve appearance are not covered.
- Cosmetic Surgery or Procedures are covered in cases of an accidental injury or for improvement of the functioning of a malformed body member; and for all stages of reconstruction for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.

Tattooing is covered when performed in conjunction with breast reconstruction. If the tattooing is done by the operating surgeon and within the 90-days after the reconstruction surgery, it is included in the global fee for breast reconstruction CPT codes (19350, 19357-19369) and not separately reported. If the tattooing is not done by the operating surgeon and/or not done within the 90-days after the reconstruction surgery, it may be billed separately.

The touch up tattooing after one year is separately reportable and is covered indefinitely for Medicare members when associated with a covered breast reconstruction (Medicare does not have a NCD (National Coverage Determination) for tattooing to correct color defects of the skin nor does Noridian have a LCD (Local Coverage Determination)).

RATIONALE

EVIDENCE BASIS

A 2021 Agency for Healthcare Research and Quality (AHRQ) systematic review of surgical breast reconstruction options after mastectomy for breast cancer compared implant-based reconstruction (IBR) vs. autologous reconstruction (AR), assessed evidence about the timing of IBR and AR in relation to chemotherapy and radiation therapy, compared implant materials for IBR, compared anatomic planes of implant placement during IBR, evaluated the used of acellular dermal matrices (ADMs) during IBR, and compared flap types for AR.[1] The overall conclusions of this review are as follows:

"Our analysis of all surgical choices examined as KQs in this review finds no clear winners when all outcomes are considered. We encourage clinicians to inform patients about the limitations of existing research and to help patients make decisions regarding options for breast reconstruction based on their values and preferences, together with the clinician's expertise and experience. Research is needed to address various

questions related to breast reconstruction, particularly the timing of IBR and AR in relation to chemotherapy and radiation therapy, and the choices of implant materials, anatomic planes of implant placement during IBR, and flaps used for AR. Future studies should either randomize patients or adequately account for important confounders and evaluate key outcomes, especially those in the existing core outcome set for breast reconstruction after mastectomy."[1]

Tobacco Use:

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following breast reconstruction.[2] These complications include donor site complications, infection, and fat necrosis, all of which were significantly more common among smokers compared to non-smokers.[2] A 2015 systematic review of the association between smoking status and outcomes of plastic surgery reports significantly increased odds of surgical site infections, delayed wound healing, and cutaneous necrosis among patients who were smokers compared to non-smokers.[3]

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KAISER PERMANENTE®

Northwest Utilization Review

UR 12.1: Cardiac Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review
Applies to: KPNW Region
Review Responsibility: UROC
SME: Tim Jacobson, MD; Siobhan Gray, MD (Cardiology)

Number: UR 12.1
Issued: 04/03
Last Reviewed/Approved: 2/23, 1/30/24

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Requests from KP clinicians for Cardiac Rehabilitation Programs and Intensive Cardiac Rehabilitation Programs are submitted through the HealthConnect referral process for non-Kaiser services. Select patients, per cardiology discretion, might be offered *virtual* cardiac rehab but can always opt for center-based rehab instead.

DEFINITIONS

Cardiac Rehabilitation is a coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post acute cardiovascular disease may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviors, slow or reverse progression of disease. It is a complex, individualized program intended to modify cardiac risk factors through prescribed exercise, education, counseling, and behavioral intervention.

POLICY AND CRITERIA

MEDICAL NECESSITY CRITERIA (APPLICABLE TO COMMERCIAL AND MEDICARE MEMBERS)

Members will have been diagnosed with ONE of the following cardiac diagnoses or had ONE of the following cardiac procedures:

a. coronary artery bypass surgery
b. stable, chronic heart failure with left ventricular ejection fraction of ≤35% and New York Heart Association Class II to IV symptoms (including patients with a ventricular assist device). Stable patients are defined as those who have not had recent (≤6 weeks) major cardiovascular hospitalizations or procedures AND do not have signs or symptoms of volume overload on examination or by history (no orthopnea, paroxysmal nocturnal dyspnea, lower extremity edema) AND the diuretic dose has not been increased within the last 4 weeks (the only relevant diuretics are: furosemide (lasix), torsemide (demadex), bumetanide (bumex), chlorthalidone, metolazone (zaroxolyn, mykrox)).
   Placement of automated implantable cardioverter defibrillators (AICD), pacemakers (all kinds), loop recorders, left or right heart catheterizations with or without a percutaneous transluminal coronary angioplasty (PTCA), cardioversions and cardiovascular hospitalizations of less than 24 hours duration should not be considered a major cardiovascular hospitalization or procedure.
c. acute myocardial infarction (MI) within the preceding 12 months
d. current stable angina pectoris
e. heart valve repair or replacement

f. percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
g. heart or heart-lung transplant
h. left ventricular assist device (LVAD)

OTHER REQUIREMENTS

Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Programs must include the following components:

a. Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
b. Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients' individual needs;
c. Psychosocial assessment;
d. Outcomes assessment; and
e. An individualized treatment plan detailing how components are utilized for each patient.

OTHER REQUIREMENTS- APPLICABLE TO MEDICARE MEMBERS ONLY

Cardiac rehabilitation and intensive cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

a. Unmonitored exercise programs are not considered to be medically indicated and are not authorized.
b. The program must be a graded exercise program, incorporating some educational components and monitored by a healthcare professional.
c. The facility meets the definition of a hospital outpatient department or a physician directed clinic i.e., a physician is on the premises available to perform medical duties at all times the facility is open, and each patient is under the care of a hospital or clinic physician.
d. The facility has available for immediate use the necessary cardio-pulmonary, emergency, diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.
e. The program is conducted in an area set aside for the exclusive use of the program while it is in session.
f. The program is staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary (heart) disease. Services of non-physician personnel must be furnished under the direct supervision of a physician. Direct supervision means that a physician must be in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted.

CONTRAINDICATIONS

NOTE: Coverage for cardiac rehabilitation cannot be denied for a **Medicare** member based on the existence of a contraindicated condition. When medical necessity criteria and the facility/program requirements are met, coverage for Medicare members must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of cardiac rehabilitation.

Cardiac rehabilitation should not be used when the following conditions exist (for review of Commercial members only):

a. unstable angina defined as chest, neck, intrascapular or bilateral or unilateral arm discomfort felt to represent angina that occurs at rest or awakens a patient from sleep, or that is occurring on a more frequent basis than the patient's baseline frequency.
b. uncontrolled hypertension:
    - resting systolic blood pressure ≥200 mm Hg
    - resting diastolic blood pressure ≥110 mm Hg
c. symptomatic aortic stenosis- severe aortic stenosis w chest pain (angina) or tightness with activity; feeling faint or dizzy or fainting with activity; symptoms of congestive heart failure.
d. acute systemic illness or fever
e. uncontrolled atrial arrhythmia defined as a ventricular response over 130 beats per minute at rest, lasting more than 36 hours, within the last 30 days.
f. uncontrolled ventricular arrhythmia defined as 1) a ventricular rhythm associated with symptoms of chest pain, dizziness, light-headedness, presyncope, syncope or shortness of breath, within the last 30 days OR 2) a ventricular rhythm detected by an automatic implantable cardioverter-defibrillator (AICD) that required anti-tachycardia pacing (ATP) or AICD discharge, within the last 30 days.

   The exception is if patients undergoing angiogram or PCI who have ventricular arrhythmias at the time of the intervention; if no other ventricular rhythms, then patient may enroll in cardiac rehab.
g. uncompensated heart failure- a sudden worsening of the signs and symptoms of heart failure, which typically includes difficulty breathing (dyspnea), leg or feet swelling, and fatigue.
h. third degree atrioventricular block (without a functioning pacemaker)
i. active pericarditis or myocarditis

SPECIAL GROUP CONSIDERATIONS

OR/WA Medicaid: These criteria do not apply, refer to the specific criteria for these populations.

Medicare: These criteria do not apply, see Medicare NCD Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1).

RATIONALE

EVIDENCE BASIS

Several recent Cochrane systematic reviews have assessed the evidence for the use of exercise-based cardiac rehabilitation for adult patients, including: following heart valve surgery, in heart transplant recipients, in those with stable angina, in those with heart failure, and in those with an implantable cardioverter defibrillator. Overall, the findings of these reviews are mixed and summarized individually below:

Heart Failure

A 2019 review to determine the effects of exercise-based cardiac rehabilitation in people with heart failure (k=44 trials) reports that compared to no exercise control conditions, cardiac rehabilitation had no impact on mortality in the short term (<12 months follow-up), likely reduces the risk of all-cause hospital admissions and may reduce heart failure-specific hospital admissions in the short term (up to 12 months), and some evidence suggests that cardiac rehabilitation may yield a clinically important improvement in health-related quality of life.[1]

Stable Angina

A 2018 review to assess the effects of exercise-based cardiac rehabilitation in adults with stable angina (k=7 trials) determined that the effects of this therapy compared to control were uncertain for mortality, morbidity, cardiovascular hospital admissions, adverse events, and health-related quality of life. This is due to the small number of available trials and the overall low quality of the evidence for these outcomes.[2] The report indicates that exercise-based cardiac rehabilitation may result in a small increase in exercise capacity compared to usual care.[2]

Heart Valve Surgery

A 2021 review to assess the benefits and harms of exercise-based cardiac rehabilitation compared to no exercise training in adults following heart valve surgery or repair (k=6 trials) reports that the impact of exercise-based cardiac rehabilitation on mortality, hospitalization, and health-related quality of life is unclear in this population.[3] The overall body of evidence is of very low quality and available trials are heterogenous in terms of the outcomes reported, outcome measurement, and length of follow-up, making it difficult to draw firm conclusions about the effect of the intervention.[3]

Heart Transplant

A 2017 review to determine the effectiveness and safety of exercise-based cardiac rehabilitation for people after heart transplantation (k=10 RCTs) reports that exercise-based cardiac rehabilitation increased exercise capacity in this population compared to no exercise.[4] The review reports inconclusive results for health-related quality of life in the short-term (median 12 weeks of follow-up) following interventions, due primarily to the variation in outcomes and methods of reporting across studies examining HRQoL.[4]

Implantable Cardioverter Defibrillator

A 2019 review to assess the benefits and harms of exercise-based cardiac rehabilitation programs compared to control in people with an implantable cardioverter defibrillator (ICD) (k=8 RCTS) reports that exercise capacity was higher among those in exercised-based cardiac rehabilitation programs compared to those in control conditions.[5] The review indicates a lack of evidence to adequately assess the impact of exercise-based cardiac rehabilitation on mortality, serious adverse events, or health-related quality of life.[5]

Implantable Ventricular Assist Devices

A 2018 review to determine the benefits and harms of exercise-based cardiac rehabilitation programs for people with implantable ventricular assist devices (VADs) (k=2) reports improvements in scored assessments of quality of life in participants in exercise-based cardiac rehabilitation groups compared to usual care groups.[6] The review notes a lack of evidence for the effectiveness of exercised-based cardiac rehabilitation because of small sample sizes in the included studies, wide confidence intervals, high risk of performance bias, and young age of participants. Additionally, it was not possible to determine the effect of exercise-based cardiac rehabilitation on mortality, rehospitalization, heart transplantation, or cost as these outcomes were not reported in the included studies.[6]

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LVEF threshold of $\leq$45% is based on the *Heart Failure Reduced Ejection Fraction* used by the American College of Cardiology and the American Heart Association (clarification: while this is accurate, current Medicare guidelines for cardiac rehab cover EF $\leq$35%).

PEDIATRIC CARDIAC REHABILITATION (NON-MEDICARE MEMBERS ONLY)

Policy Number: 0014
Effective Date: September 2020
Reviewed Date: August 2023
Next Review: August/September 2024
Clinical Reviewer: Jeanne A. Mowry, MD, pediatrics

BACKGROUND

CLINICAL BACKGROUND

Pediatric cardiac rehabilitation is aimed to improve a child's functional capacity, improve quality of life, increase lean mass relative to fat mass, increase overall physical activity, educate a family to adopt a healthy lifestyle, and ultimately decrease risk of future cardiovascular disease. Cardiac rehabilitation typically is composed of three separate components, including aerobic training, resistance training, and flexibility training.

POLICY AND CRITERIA

Pediatric cardiac rehabilitation may be medically indicated for patients aged 8 to 17 years when ONE of the following are true:

1. Patient has at least one of the following diagnoses:
    a. Cardiomyopathy; OR
    b. Single ventricle; OR
    c. Coronary artery anomalies

    OR

2. Patient is status post valve repair or replacement

Pediatric cardiac rehabilitation is not considered to be medically indicated for pulmonary hypertension, atrial septal defect, or ventricular septal defect.

For patients meeting criteria for pediatric cardiac rehabilitation, treatment is limited to 15 visits over 6 months, to include initial consult (with cardiopulmonary exercise testing and 6-minute walk tests). Twelve weekly visits may also be authorized.

NOTE: These criteria do NOT apply to Medicare members. See UR 12.1 for Medicare members.

RATIONALE

EVIDENCE BASIS

Wittekind (2018) reported outcomes among 8 young patients with nonischemic dilated cardiomyopathy who underwent cardiac rehabilitation. Patients ranged in age from 10 years to 31 years, and half of patients were male. Average BMI was 38.2 kg/m2 at baseline, with a mean waist circumference of 46.8 inches. Of the 8 subjects included in this study, 3 were under age 18 (a 10-year old boy, a 14-year old boy, and a 17-year old girl). Subjects attended two 45-minute sessions per week for up to 16 weeks. Authors reported that patients attended, on average, 85% of possible sessions. Overall, there were no statistically significant differences in mean left ventricular ejection fraction or in body mass index.

However, waist circumference was significantly decreased by approximately 1.4 inches at one-year follow-up, and 6-minute walk distance increased by roughly 111 meters. Findings from this study are limited by the extremely small sample size, and the failure to control for medications used.

Rhodes (2005) reported on 19 children with serious congenital heart disease who were referred for cardiac rehabilitation. Of the patients who completed the study (n=16), 11 were Fontan patients and 5 had other congenital heart disease. Patients were only eligible if they were between ages 8 and 17 years, had nontrivial congenital heart disease of severity sufficient to have activity restriction, had undergone at least 1 surgical or interventional procedure and/or had significant residual hemodynamic defect, have abnormal exercise function (peak VO_2 less than 80%) measured within the prior 6 months, and a commitment to attend and participate in rehabilitation. The treatment program consisted of 1-hour sessions twice weekly for 12 weeks. On average, patients attended 18 of 24 sessions. Authors reported that 15 of 16 patients had statistically significant improvements in at least one measure. On average, peak VO_2 increased from 26.4 to 30.7 mL/kg, and peak work rate increased from 93 to 106 W. There were no statistically significant changes in body mass index, resting oxygen saturation, FEV1/FVC, or blood pressure. No adverse events were reported, and authors concluded that the study was inadequately powered to identify adverse events due to small sample size.

While findings from the initial Rhodes study support use of cardiac rehabilitation in this highly selected population, the duration of treatment effect remains unclear. The same authors published a follow-up study of the same population, reporting outcomes on average 7 months after completion of the rehabilitation program (Rhodes 2006). In that analysis, authors reported that exercise function did not significantly decrease from completion of the program to follow-up and remained significantly elevated relative to baseline. Authors also reported improved quality of life measures, such as self-esteem, behavior, and emotional state. A group of 18 control subjects with similar diagnoses who had not undergone cardiac rehabilitation were found to have no statistically significant changes in exercise function over the same period.

Dulfer (2014) evaluated the effects of an exercise program in terms of health-related quality of life among children and adolescents with congenital heart disease. Patients included those who had undergone surgical repair for tetralogy of Fallot or those with a Fontan circulation for single-ventricle defects. Authors randomized subjects to a control group or to a cardiac rehabilitation program consisting of 3 weekly visits for 12 weeks. Authors reported that the younger patients (aged 10-15) had significantly improved cognitive functioning (self-reported) and social functioning (parent-reported). Subjects who were older (16 to 25 years) had no significant changes in health-related quality of life.

Kroll (2021) examined the impacts of a multidisciplinary cardiac rehabilitation program on exercise capacity, patient functioning (social, emotional, school, psychological), and quality of life in 25 patients with CHD between the ages of 7 and 24 years old. The program was a home-based year-long program based out of a children's hospital that included 4 in-person visits with multiple providers (e.g., cardiologist, physical therapist, occupational therapist, psychologist, registered nutritionist) every 3 to 6 months. Participants were provided an activity monitor and personalized physical activity prescription and had the option of being paired with a mentor who would contact them between in-person visits to assess progress with the physical activity recommendations. Between baseline and the final session, a significant improvement in exercise capacity was observed. Parents of participants reported improvements in the patients' emotional, social, school, psychosocial, cognitive functioning, communication, and overall QoL, whereas patients did not report improvements in these areas. Patients reported improvements in perceived cardiac-related QoL and self-concept.

Ferrer-Sargues (2021) reported on the effect of a cardiopulmonary rehabilitation program on peripheral musculature function of 15 children (ages 12-16 years) with CHD. The intervention consisted of twice weekly exercise sessions of 70 minutes each, including both endurance and resistance training components, for a total of 24 sessions. Peripheral muscle function was measured at baseline, upon completion of the 24 sessions, and 6 months after program completion via hand grip strength, biceps brachii strength, quadriceps femoris strength, and single heel-rise tests. Improvements in peripheral muscle function were observed across all measures of strength from baseline and were maintained at 6

months post-intervention. Findings from this study are limited by the small sample size, lack of comparison group, and lack of data collection about physical activity during the 6-month follow-up period.

Balfour (1991) reported on 16 patients who participated in a pediatric/young adult cardiac rehabilitation program. Less than half of patients completed the program (7 of 16), and outcome data were only available for 6 patients. The treatment program included 3 supervised sessions of 30-40 minutes each week for 3-6 months. Diagnoses among the patients included: dilated cardiomyopathy, aortic stenosis, tetralogy of Fallot, idiopathic hypertrophic subaortic stenosis, aortic valve replacement, ventricular septal defect, mitral valve prolapse, Fontan circulation, premature ventricular contractions, and pulmonary stenosis. Overall, there were statistically significant decreases in resting blood pressure, as well as significant increases in peak oxygen consumption and exercise treadmill time. The study was limited by very small sample size and high loss to follow-up.

EXPLANATION AND RATIONALE

There is very low strength of evidence that pediatric cardiac rehabilitation may yield short-term improvements in VO_2 among patients with severe congenital heart disease. There is insufficient evidence to determine whether cardiac rehabilitation is effective among other pediatric populations. Additionally, there is insufficient evidence regarding long-term outcomes following pediatric cardiac rehabilitation, as the longest follow-up was roughly nine months after program completion. However, Northwest Permanente clinical expert consensus supports pediatric cardiac rehabilitation as being valuable for select populations despite the limited evidence base.

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KAISER PERMANENTE® **Northwest Utilization Review**

UR 46 Chiropractic Medical Necessity Criteria for Medicare and Commercial Business Lines

Department: Utilization Review	Number: UR 46
Applies to: Kaiser Permanente Northwest Region	Effective: 1/11
Review Responsibility: UROC	Last Reviewed/Approved: 1/23, 1/30/24
Subject Matter Expert: Medicare criteria	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS

DEFINITIONS

Manual Manipulation- treatment by use of hands or with manual devices i.e. those that are hand-held with the thrust of the force of the device being controlled manually.

Subluxation- a partial or incomplete dislocation; displacement; or misalignment of a joint. It is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact. This may be demonstrated by x-ray or by physical examination.

Common examples of acceptable descriptive terms include:

-off centered,
-malpositioning,
-spacing- abnormal, altered, decreased, increased,
-rotation,
-listhesis- antero, postero, retro, lateral, spondylo,
-motion- limited, lost, restricted, flexion, extension, hyper/hypo mobility, aberrant

Acute Subluxation: a condition is considered acute when the patient is being treated for a new injury identified by an x-ray or physical examination. Result of chiropractic treatment is expected to be an improvement in, or arrest of progression, of the condition.

Chronic subluxation: a condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as in the case with an acute condition) but where continued therapy can be expected to result in some functional improvement. When the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

Exacerbation: an exacerbation is a temporary marked deterioration of the patient's condition due to a flare-up of the condition being treated.

Recurrence: A return of symptoms of a previously treated condition that has been quiescent for 30 days or more. This may require reinstitution of therapy.

Maintenance Treatment/Therapy is a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. (Chiropractic maintenance therapy is not considered to be medically reasonable

or necessary and is therefore not covered. When chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy.)

POLICY AND 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)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Billing and Coding: Chiropractor Services (A57914)
Kaiser Permanente Medical Policy	Due to the absence of a NCD or LCD, Kaiser Permanente has chosen to use this document, "Chiropractic", based on the Medicare Benefit Policy Manual, for medical necessity determinations. Use the criteria below.

There must be subluxation of the spine**.**

- Subluxation of the spine must have resulted in a neuromusculoskeletal condition for which manual manipulation is appropriate treatment. The result of chiropractic manipulation is expected to be an improvement in, arrest or retardation of the patient's condition and treatment must have a direct therapeutic relationship to the patient's level of subluxation and diagnosed condition.

  Demonstrated by X-ray

  To demonstrate a subluxation *(see definition above)* with an x-ray the following applies:

  a. X-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment (i.e., no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment).
  b. In certain chronic subluxation cases (e.g., scoliosis) an older x-ray may be accepted if health record indicates condition has lasted longer than 12 months and there is a reasonable basis for concluding condition is permanent.
  c. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

  Demonstrated by Physical Examination

  To demonstrate a subluxation based on physical examination, **two of the four following criteria must be present, one of which must be a.) asymmetry/ misalignment or c.) range of motion abnormality:**

  a. Asymmetry/misalignment identified on a sectional or segmental level;
  b. Pain/tenderness evaluated in terms of location, quality and intensity;
  c. Range of motion abnormality (changes in active, passive and accessory joint movements resulting in an increase or decrease of sectional or segmental mobility);
  d. Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia (connective tissue), muscle and ligament.

- Telephonic, video, email or face-to-face evaluation by the referring clinician is required prior to requesting a referral.

- If there is chronic subluxation of the spine, and the patient's condition is not expected to completely resolve, there must be an expectation of some functional improvement for therapy to be continued. **When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is considered maintenance therapy and is not covered.**
- Symptoms must bear a direct relationship to the level of subluxation. The subluxation must be causal. A statement that there is "pain" is insufficient. The location of the pain must be described and whether particular vertebra listed is capable of producing pain in the area determined.

OTHER REQUIREMENTS FOR APPROVING SERVICE CONTINUATION

- The clinical condition must be evaluated by a chiropractic physician who will evaluate for appropriateness when/if asking for the continuation to determine that this condition is appropriate for manipulation modalities. Patient record should include the following and it should be provided with the request for the continuation:

    1. Symptoms causing patient to seek treatment
    2. Family history if relevant
    3. Past health history
    4. Mechanism of trauma
    5. Quality and character of symptoms/problem
    6. Onset, duration, intensity, frequency, location and radiation of symptoms
    7. Aggravating or relieving factors
    8. Prior interventions, treatments, medications, secondary complaints

- Chiropractic treatment may not be medically indicated for a condition that adds significant risk of injury to the patient from dynamic thrust but does not rule out the use of dynamic thrust. The doctor should discuss the risks of such **relative contraindications** with the patient and record this in the chart. Such conditions include:

    1. Articular hypermobility and circumstances where the stability of the joint is uncertain;
    2. Severe demineralization of the bone
    3. Benign bone tumors of the spine
    4. Bleeding disorders and anticoagulant therapy (this does *not* include antiplatelet medications)
    5. Radiculopathy with progressive neurological signs

ABSOLUTE CONTRAINDICATIONS

Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

1. Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis
2. Acute fractures and dislocations or healed fractures and dislocations with signs of instability
3. Unstable os odontoideum
4. Malignancies that involve the vertebral column

5. Infections of bones or joints of the vertebral column
6. Signs and symptoms of myelopathy or cauda equine syndrome
7. For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and
8. A significant major artery aneurysm near the proposed manipulation.

SPECIAL GROUP CONSIDERATIONS:

Medicare: 2013 Noridian published guidance for chiropractic that states, "Under the Medicare program chiropractic maintenance therapy is not considered to be medically reasonable or necessary and is not payable" and "When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The chiropractor should be afforded the opportunity to affect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time.
Medicare does not make separate payment for any device used during spinal manipulation.

RATIONALE

EVIDENCE BASIS

In 2020, the Agency for Healthcare Research and Quality (AHRQ) published an updated report on noninvasive nonpharmacologic treatment for selected chronic pain conditions that includes an assessment of the effectiveness of spinal manipulation for these conditions.[1] For patients with chronic back pain, evidence from 3 RCTs was pooled and showed that spinal manipulation resulted in function improvement over the short and/or intermediate term and improved pain at intermediate term.[1] AHRQ produced surveillance reports to identify more recent evidence published between December 2021 and March 2022 and assess how any more recent evidence impacts the findings of the 2020 report.[2] One additional RCT examining spinal manipulation for chronic low back pain was identified that did not impact the overall conclusions from the 2020 report.[2]

In 2017, the Evidence-based Synthesis Program of the Department of Veterans Affairs (VA) published a systematic review on the effectiveness and harms of spinal manipulative therapy for acute neck and lower back pain compared to usual care or other forms of acute pain management.[3] The review reports overall statistically significant evidence of clinical benefit of spinal manipulation treatments for acute lower back pain (moderate quality of evidence), with improvement to the outcomes of pain and function. The review found very few studies examining spinal manipulation therapy for acute neck pain and rated the evidence as “low” that this form of therapy improves outcomes in patients with acute neck pain. The review found insufficient evidence to determine the relationship between spinal manipulation therapy and the use of opiate medication for either acute low back pain or acute neck pain. There was a high degree of heterogeneity across the results of the included studies which is unexplained and suggests a need for more research to better understand what contributes to patient selection and intervention to improve the consistency of results across studies.[3]

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MEDICARE REFERENCES

- Medicare Benefit Policy Manual, Chapter 15, 30.5 and 240.1.1 re no coverage for x-rays and any other diagnostic test**.**
- 42 CFR 410.21 re manual subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.2 re criteria needed for manual manipulation for a subluxation
- Medicare Benefit Policy Manual, Chapter 15, 240.1.3 re maintenance

KAISER PERMANENTE®

Northwest Utilization Review

UR 41: Cochlear Implants Medical Necessity Criteria

Department: KPNW Utilization Review
Applies to: KPNW Region
Review Responsibility: UROC
SME: John Goddard, MD (ENT)

Number: UR 41
Issued: 4/07
Last Reviewed: 4/16, 4/19, 6/20, 5/21, 5/22
Last Revised: 4/17, 4/18, 6/23

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage are determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR COCLEAR IMPLANT

DEFINITIONS

A. Cochlea: a spirally wound, tube-like structure that forms part of the inner ear and is essential for hearing. It is composed of a network of liquid filled tubing and tiny hairs. When sound is sent to the cochlea, it causes ripples in the liquid and the hairs to bend. This movement triggers electrical impulses which are transmitted to the auditory nerve.

B. Cochlear implant device: an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. The purpose is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired. A cochlear implant consists of two (2) main components:
   1. The implant package and electrode array (or receiver-stimulator) – this controls the flow of electrical pulses into the ear and is inserted into the shell-like structure in the inner ear known as the cochlea; and
   2. The external speech processor and headset – a coil is held in position against the skin by a magnet and the microphone is worn behind the ear; the body-worn speech processor can be worn in a pocket, in a belt pouch, or in a harness (the other option is an ear-level speech processor).

C. dB: decibel, unit for expressing loudness of sound

D. Hz: hertz, unit for expressing frequency of sound

E. The Lexical Neighborhood Test and the Multi-syllabic Lexical Neighborhood Test, designed for children who may be cochlear implant candidates, assess recognition of words and individual sounds. The results are used as a benchmark for children with hearing impairment.

F. Middle ear: the hollow portion of the ear behind the eardrum. The middle ear contains one or more ossicles, which amplify vibration of the eardrum into pressure waves in the fluid in the inner ear.

POLICY AND CRITERIA

MEDICAL NECESSITY CRITERIA

A. Adults (age 18 or older) with 1 or 2 below in addition to 3 through 5:
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing aids.
      a. Limited benefit from binaural amplification: defined by test scores of ≤50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and ≤60% in the opposite ear (See Special Group Considerations below for Medicare criteria).
      b. Profound sensorineural hearing loss: for individuals older than 24 months, the pure tone average for both ears should equal or exceed 70dB at 500Hz, 1000Hz, and 2000Hz.
   2. Single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.
   5. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.

B. Children (age 9 months through 17 years) with 1 or 2 below in addition to 3 through 9:
   1. Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from binaural amplification, defined by test scores of ≤50% correct in the best-aided listening condition on tape recorded tests of open set sentence cognition in the ear to be implanted and ≤60% in the opposite ear.
   2. For patients 5 years and older with single sided deafness (SSD) and asymmetric hearing loss (AHL) who have profound sensorineural hearing loss in the ear to be implanted and normal hearing or mild to moderate sensorineural hearing loss in the other ear.
   3. For single sided deafness, cochlear implant is not recommended if profound hearing loss for over 10 years.
   4. For children age 12-24 months, profound sensorineural hearing loss: thresholds of 90dB or greater at 1000Hz.
   5. For children age 24 months to 17 years, pure tone average of 70dB or greater at 500Hz, 1000Hz, and 2000Hz.
   6. In younger children, little or no benefit is defined by lack of progress in the development of simple auditory skills in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six-month period.
      In older children, lack of aided benefit is defined as ≤30% correct on the Multi-syllabic Lexical Neighborhood Test (MLNT) or Lexical Neighborhood Test (LNT), depending upon the child's cognitive ability and linguistic skills.
   7. A three to six-month hearing aid trial is required for children without previous experience with hearing aids. Radiographic evidence of labyrinthine fibrosis that would lead to ossification will justify implantation without a trial of amplification.
   8. Medical evaluation to determine there is adequate access to auditory nerve fibers to merit implantation.
   9. Freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

OTHER REQUIREMENTS or CONSIDERATIONS

Replacement of battery charger is not covered; replacement of batteries is covered for all members. Replacement of a cochlear implant and/or its external components is considered medically necessary when the existing device cannot be repaired or when replacement is required because a change in the member's condition makes the present unit non-functional and improvement is expected with a replacement unit. Must be performed in an ambulatory surgery center (ASC) or an inpatient or outpatient hospital facility.

CONTRAINDICATIONS

A. Agenesis of the 8th cranial nerve
B. Complete CN aplasia
C. Pathologies of the central auditory pathway
D. Michel deformity (complete labyrinthine aplasia/non-development) present
E. Known intolerance to materials used in the implant
F. Perforated tympanic membrane
G. Deafness attributed to central damage of the acoustic nerve or central auditory pathway
H. External or middle ear infection present

SPECIAL GROUP CONSIDERATIONS

Medicare: Cochlear implants for Medicare members with open-set sentence recognition tests of scores between 40% and 60% correct are covered if the device is implanted in an acceptable clinical trial or study. Otherwise, open-set sentence recognition tests of scores must be less than 40%.

Oregon Medicaid: See Prioritized List

OREGON: Senate Bill 491 requires that bilateral cochlear implants be provided when medically necessary.

RATIONALE

EVIDENCE BASIS

MCG reviewed the evidence on cochlear implants in 2022. Their findings are provided below:

For adults with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review and meta-analysis of 14 studies (679 adult patients) evaluating quality of life improvement after cochlear implantation found that cochlear implantation was associated with significant improvement in quality of life measured by hearing-specific or cochlear implant-specific quality of life patient-reported outcomes.[1] A systematic review of 3 randomized controlled trials and 7 observational studies (308 adult patients) with severe to profound sensorineural hearing loss found that compared with unilateral cochlear implantation, bilateral cochlear implantation was associated with improved speech perception in noise, sound localization, and subjective improvements in speech and spatial hearing.[2] A systematic review of unilateral vs bilateral cochlear implantation in adults concluded that unilateral implantation with or without the use of hearing aids was effective for improving speech perception in adults with severe to profound sensorineural hearing loss; both simultaneous and sequential bilateral cochlear implantation provided additional improvement in speech perception.[3] A systematic review of 14 studies comparing unilateral cochlear implant with or without hearing aid

on the non-implant ear vs bilateral cochlear implant found benefit for bilateral implants in noise conditions and in several self-reported outcome measures.[4] A systematic review of sequential cochlear implants in adults and children found that although the quality of the studies was poor, the evidence suggested that a second implant can be beneficial even if there is a substantial interval between implants.[5] An industry-sponsored randomized controlled trial of 38 adults with postlingual, severe to profound hearing loss compared simultaneous and sequential (2 years between procedures) bilateral cochlear implants and found, 1 year after both implants were in place, comparable results between the groups in terms of speech intelligibility in noise from straight ahead, from spatially separated sources, and in silence. The authors concluded that patients who receive sequential implants derive the same benefit as those who receive them simultaneously.[6] A national guideline recommends simultaneous bilateral cochlear implantation only for adults with severe to profound deafness who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism of spatial awareness.[7] Most adult patients who receive a cochlear implant have improvement in both hearing threshold and ability to lip-read. Postlingual deaf adults attain scores of 90% to 100% for speech-reading capabilities on everyday sentence material and above 80% for high-content sentences after cochlear implant. Over half of postlingual deaf adults can achieve some degree of telephone conversational ability after cochlear implant.[8] A prospective study of 94 postlingual deaf patients (65 to 85 years of age) who were treated with cochlear implants for sensorineural hearing loss found a mean improvement in speech perception scores of 52% at 6 months, with continued improvement at 12 months; there was also significant improvement in quality of life. Patients with depression, as assessed by the Geriatric Depression Scale-4 (GDS-4), decreased from 41% to 24% at 12 months after implantation.[9] A literature review of patients 65 years and older who were treated with cochlear implants found that patients showed improvement in speech outcomes and quality of life and had similar device complication rates as compared with younger patients. The authors concluded that elderly age should not exclude appropriate candidates for a cochlear implant.[10] A prospective study of 20 patients with asymmetric hearing loss found, at 1-month follow-up, that cochlear implantation in the affected ear was associated with decreased tinnitus severity and improved sound localization and hearing-specific quality of life, as compared with preoperative measurements; the improvements were sustained at 12-month follow-up.[11] A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, and quality of life in adults and children with single-sided deafness or asymmetric hearing loss.[12]

For infants or children with hearing loss, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review of prognostic factors for cochlear implant in children found that improved outcomes were associated with early implant, congenital deafness due to GJB-2 gene mutation, less severe inner ear malformations, and early implant of postmeningitic or congenitally deaf children.[13] Multiple studies of unilateral cochlear implant in children demonstrate that functional outcomes are improved when the surgery is performed at a younger age. Eligible children should receive a cochlear implant as soon as bilateral profound hearing impairment is diagnosed to maximize speech and language achievement and integration into an oral communication environment. Children who are implanted when younger than 2 years can experience normal or near-normal rates of auditory skill and oral language development. However, even in older children, the oral language and speech benefits of implant are substantial for those who have some residual hearing because they are able to hear more speech and sound information with the cochlear implant than with a hearing aid.[14-18] A systematic review of 14 studies evaluating the effect of early (before 12 months) cochlear implantation found better scores on speech production, auditory performance, and some receptive language tests in children

implanted before 12 months compared with those implanted later. However, the authors noted that the available evidence consisted of cohort studies with moderate to high risk of bias, and recommended long-term follow-up studies.[19] A systematic review of 4 studies with a total of 103 pediatric patients found that simultaneous bilateral implantation, as compared with sequential bilateral implantation, resulted in statistically significant higher speech and language development scores 3 years after the first cochlear implantation.[20] Children with bilateral cochlear implants that are activated at earlier ages and with shorter gaps between surgeries appear to receive greater benefit than those implanted later and with longer gaps between surgeries.[21] Other systematic reviews that compared bilateral cochlear implant with unilateral implant in children found that, although the data are limited, bilateral cochlear implant appeared to be more effective in terms of sound localization and improved speech perception in quiet and noise.[22-24] A systematic review and meta-analysis of 12 observational studies with 119 pediatric patients (mean age 6.6 years) with single-sided deafness (unaided pure-tone average of 90 dB or greater in one ear) found that cochlear implants improved speech perception in noise in 79.6% of patients and speech perception in quiet in 81% of patients; cochlear implants were also associated with improved sound localization.[25] A technology assessment found moderate-quality evidence that cochlear implants improve sound localization, speech perception in noise, tinnitus symptoms, speech and language development, and quality of life in children with single-sided deafness or asymmetric hearing loss.[12] A systematic review of 13 studies with a total of 1073 pediatric patients compared the outcome of cochlear implantation in children with normal development to those with mild to severe developmental disability; children with mild developmental delay had similar receptive and expressive language outcomes as compared with children without developmental delay, but children with severe developmental delay had worse outcomes. Careful preoperative and postoperative counseling may be particularly important in this patient population.[26] A retrospective study of factors associated with limited use and nonuse of cochlear implants in children found that disabilities (eg, cerebral palsy, autism, moderate mental retardation, attention-deficit hyperactivity disorder, learning disability) and lack of family interest were factors that required more support to ensure adequate use.[27]

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Northwest Region Utilization Review

UR 72: CPAP Titration in a Sleep Center Medical Necessity Criteria

Department: Non-Behavioral Health
Section: KPNW Region
Applies to: KPNW Region
Review Responsibility: Yanina Benikova, MD

Number: UR 72
Effective: 01/2020
Last Reviewed/Approved: 1/23, 1/30/24

CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) TITRATION IN A SLEEP CENTER MEDICAL NECESSITY CRITERIA

POLICY AND CRITERIA

CPAP sleep center titration may be indicated for **1 or more** of the following:

1) Adult with central sleep apnea syndrome due to congestive heart failure
2) Adult with obesity hypoventilation (shallow breathing) syndrome, as indicated by **ALL** of the following
   A. BMI (body mass index) greater than 30
   B. Daytime hypercapnia (excess carbon dioxide in the blood) with $PaCO_2$ (partial pressure of carbon dioxide) greater than 45 mm Hg/ 6.0 kPa (kPa is a unit of pressure) without other etiology (eg, kyphoscoliosis, lung parenchymal disease, myopathy, severe hypothyroidism)
   C. Sleep-disordered breathing or hypoventilation on polysomnography (sleep study), as indicated by **1 or more** of the following:
      i. Apnea-hypopnea index of 5 or greater
      ii. Increase in $PaCO_2$ during sleep by more than 10 mm Hg/ 1.3 kPa above value while awake
      iii. Significant oxygen desaturation (ie, less than 90%) not explained by obstructive apneas or hypopneas
   D. TSH level does not demonstrate hypothyroidism.
3) Adult with obstructive sleep apnea, as indicated by **ALL** of the following:
   A. Appropriate testing situation, as indicated by **1 or more** of the following:
      i. Initial full-night CPAP titration study
      ii. Repeat full-night CPAP titration study, as indicated by **1 or more** of the following:
         a. Greater than 10% body weight gain or loss, and need to adjust pressure settings
         b. Inadequate initial CPAP titration study, and need to perform further pressure titration
         c. Insufficient response to CPAP therapy due to inadequate pressure or pressure leaks
         d. Return of symptoms after initial adequate response to CPAP therapy, and need to adjust pressure settings
   B. Obstructive sleep apnea, as indicated by **1 or more** of the following:

i. Mild obstructive sleep apnea (ie, apnea-hypopnea index or respiratory disturbance index between 5 and 15, determined with polysomnography) and **1 or more** of the following:
    a. Cardiovascular disease documented (eg, hypertension, ischemic heart disease, heart failure, stroke)
    b. Excessive daytime sleepiness (eg, Epworth Sleepiness Scale score of 10 or greater in adult patient)
    c. Fibromyalgia-like symptoms
    d. Headaches upon awakening
    e. Heartburn and reflux
    f. Impaired cognition
    g. Mood disorder
    h. Night sweats
    i. Nocturia or nocturnal enuresis
    j. Observed apnea or choking episodes
    k. Patient is commercial vehicle driver
    l. Snoring
ii. Moderate or severe obstructive sleep apnea (ie, apnea-hypopnea index or respiratory disturbance index 15 or greater, determined with polysomnography)
iii. Upper airway resistance syndrome associated with unexplained excessive daytime sleepiness

C. Performed as full-night CPAP titration study

4) Child, infant, or adolescent with obstructive sleep apnea and **ALL** of the following:

A. Appropriate testing situation, as indicated by **1 or more** of the following:
    i. Initial full-night CPAP titration study
    ii. Repeat full-night CPAP titration study, as indicated by **1 or more** of the following:
        a. Greater than 10% body weight gain or loss, and need to adjust pressure settings
        b. Inadequate initial CPAP titration study, and need to perform further pressure titration
        c. Insufficient response to CPAP therapy due to inadequate pressure or pressure leaks
        d. Return of symptoms after initial adequate response to CPAP therapy, and need to adjust pressure settings

B. Polysomnography demonstrates obstructive sleep apnea (ie, apnea-hypopnea index of 1 or greater in child younger than 18 years)

C. Signs and symptoms consistent with obstructive sleep apnea, including **1 or more** of the following:
    i. Daytime sleepiness
    ii. Enuresis
    iii. Failure to thrive (weight less than fifth percentile for age)
    iv. Hyponasal speech
    v. Mouth breathing
    vi. Nocturnal pauses in breathing
    vii. Nonspecific behavioral problems (eg, hyperactivity, developmental delay, aggression, poor school performance)
    viii. Pulmonary hypertension

ix. Signs of increased respiratory effort (ie, nasal flaring)
x. Snoring

D. No tonsillar or adenoid enlargement (or tonsillar or adenoid enlargement and contraindication to surgical intervention), or failure of tonsil or adenoid removal to change symptoms

E. Performed as full-night CPAP titration study

RATIONALE

EVIDENCE BASIS

MCG reviewed the evidence on CPAP in 2022.[1] Their findings are provided below:

"For adults with central sleep apnea due to congestive heart failure, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review identified 16 articles that studied treatment of central sleep apnea syndromes related to congestive heart failure and concluded that CPAP therapy can normalize the apnea-hypopnea index and improve left ventricular ejection fraction.[2]

For adults with obesity hypoventilation syndrome, evidence demonstrates at least moderate certainty of at least moderate net benefit. CPAP has been shown to be effective for the treatment of the majority of patients with obesity hypoventilation syndrome, particularly in the subgroup with severe obstructive sleep apnea.[3]

For adults with obstructive sleep apnea, evidence demonstrates at least moderate certainty of at least moderate net benefit. In adults, mild obstructive sleep apnea is defined as an apnea-hypopnea index or respiratory disturbance index of 5 to 15, moderate as 15 to 30, and severe as greater than 30.[4] Systematic reviews, prospective cohort studies, and randomized trials have concluded that CPAP is an effective treatment, with improvement in objective and subjective sleepiness, quality of life, and clinical measures such as blood pressure (in patients who are hypertensive) and cardiovascular mortality.[5-9] A randomized trial evaluating the effects of CPAP on prehypertension and masked hypertension in males with severe obstructive sleep apnea found that the use of CPAP promotes significant reductions in blood pressure.[10] Another randomized trial of male and female patients with resistant hypertension and obstructive sleep apnea found that the use of CPAP for greater than 5.8 hours at a time resulted in significant blood pressure reductions.[11] For patients with obstructive sleep apnea and heart failure, studies have demonstrated improved left ventricular ejection fraction and cardiac remodeling, and a trend toward decreased mortality when treatment consists of CPAP in addition to optimal medical therapy for heart failure.[12-14] A study of nocturnal CPAP in obese patients with obstructive sleep apnea found that the use of CPAP increased exercise tolerance and improved dyspnea in these patients.[15] With appropriate titration, positive airway pressure devices resolve most sleep-disordered breathing regardless of the disease severity level;[16] goals of CPAP titration include achieving a respiratory disturbance index less than 5, a pulse oximetry greater than 90%, and tolerable air leak at the mask.[17] Performance of a split-night study may be indicated if the diagnosis of moderate or severe obstructive sleep apnea can be made within the first 2 hours of recorded sleep, and at least 3 hours of CPAP titration is demonstrated, including the ability of CPAP to eliminate respiratory events

during both rapid eye movement sleep and non-rapid eye movement sleep.[18, 19] Specialty society practice parameters note that a repeat CPAP titration study may be appropriate when the initial CPAP titration fails to resolve obstructive sleep apnea findings sufficiently, when the response to therapy is inadequate despite good adherence and adequate interface fit, when symptoms return after a period of adequate response to CPAP therapy, or when greater than 10% body weight gain or loss necessitates adjustment of pressure settings.[20, 21]

For children, infants, or adolescents with obstructive sleep apnea, evidence demonstrates at least moderate certainty of at least moderate net benefit. The criteria for interpreting pediatric polysomnograms typically define mild obstructive sleep apnea as an apnea-hypopnea index of 1 to 5, moderate as 6 to 10, and severe as greater than 10.[22-24] A specialty society recommended using the pediatric scoring rules for children younger than 18 years of age; however, studies indicated that some of the adult scoring rules may be used in adolescents 13 to 18 years of age.[25-29] Specialty society clinical guidelines recommend that pediatric patients with symptoms of obstructive sleep apnea who are not candidates for adenotonsillectomy or who have persistent obstructive sleep apnea after adenotonsillectomy should be referred for CPAP management.[24, 30, 31] Although there is limited evidence for its use, a specialty society recommends using polysomnography when titrating CPAP in infants.[32] Performance of a split-night study may be indicated if the diagnosis of moderate or severe obstructive sleep apnea can be made within the first 2 hours of recorded sleep, and at least 3 hours of CPAP titration is demonstrated, including the ability of CPAP to eliminate respiratory events during both rapid eye movement sleep and non-rapid eye movement sleep.[18, 19] An evidence-based specialty society guideline is unable to recommend split-night CPAP titration for children younger than 12 years due to a lack of data.[20] A review article noted that obstructive sleep apnea in children may manifest as hyperactivity, emotional difficulties, decreased academic performance, and difficulty concentrating; in contrast, daytime sleepiness, morning headache, memory impairment, and daytime fatigue are more common symptoms in adults.[33] Specialty society guidelines note that repeat CPAP titration testing may be appropriate when the initial CPAP titration study fails to achieve optimal results, when symptoms return after an initial adequate CPAP therapy response, after 10% body weight gain or loss, and with growth in children using CPAP therapy for obstructive sleep apnea.[20, 24, 31”1]

The United States Preventive Services Task Force (USPSTF) issued updated recommendations on screening for obstructive sleep apnea in asymptomatic adults in November 2022.[34] The supporting evidence review examined the benefits, effectiveness, and harms of treatment with positive airway pressure in adults with obstructive sleep apnea and reports that, compared to inactive control, positive airway pressure was associated with a significant improvement in Epworth Sleepiness Scale score from baseline, sleep-related quality of life, and general health-related quality of life.[34] Additionally, the review summarizes evidence from other systematic reviews that show a small but statistically significant association of positive airway pressure with reduced blood pressure.[34] No included trials in this review found significant benefits of treatment with positive airway pressure on mortality, cardiovascular events, or motor vehicle crashes.[34]

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UR 67: Craniofacial Anomalies Policy and Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); James Rapson, DDS; Kelly Dezura, DMD	Number: UR 67 Effective: 01/2013 Last Reviewed/Approved: 1/23, 1/30/24

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

CRANIOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA

The purpose of these criteria is to define KFHPNW coverage of limited dental and orthodontic services associated with congenital craniofacial anomalies when medically necessary to restore facial configuration or function.

Oregon House Bill 4128 requires health benefit plans to provide coverage for dental and orthodontic services for the treatment of craniofacial anomalies if the services are medically necessary to restore function.

Note that separate policies/criteria exist for coverage of:
1. Maxillofacial prosthetic services for treatment of maxillofacial anomalies (UR 64),
2. general anesthesia for dental procedures performed in an inpatient or ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

DEFINITIONS

Congenital: present at birth

Craniofacial Anomaly (as defined by Oregon House Bill 4128): a physical disorder identifiable at birth that affects the bony structures of the face or head, including but not limited to: cleft palate, cleft lip, craniosynostosis, craniofacial microsomia and Treacher Collins syndrome. It does not include:

- Temporomandibular joint disorder (TMJ)
- Developmental maxillofacial conditions that result in overbite, crossbite, malocclusion or similar developmental irregularities of the teeth.

CRITERIA: Dental and Orthodontic Services as part of a treatment plan for CRANIOFACIAL ANOMALIES are covered when ALL of the following criteria are met.

NOTE: When the patient has one of the diagnoses listed in criterion 1 (including attachment), a referral to the Craniofacial Clinic (see Special Group Considerations for Added Choice members and members in Lane County) will be authorized for the member's condition to be assessed. The Kaiser Permanente (KP) multi-disciplinary Craniofacial Clinic team will make the clinical decision as to medical necessity and treatment plan that may include dental and orthodontic services necessary to restore facial configuration or function.

1) A congenital anomaly exists affecting the bony structures of the face or head which disrupts facial configuration and/or function and includes at least one of the following (see Attachment for more possible diagnoses):
- Cleft palate and/or cleft lip
- Craniosynostosis
- Craniofacial microsomia
- Mandibulofacial Dysostosis (Treacher Collins Syndrome)

2) The indication for dental and/or orthodontic services is directly related to the craniofacial anomaly.

The requested services are not related to treatment of a temporo-mandibular joint disorder or developmental maxillofacial condition resulting in an overbite, crossbite, malocclusion or similar developmental irregularity of the teeth.

3) Dental and/or orthodontic services for the treatment of craniofacial anomalies are medically necessary to restore facial configuration or function.

SPECIAL GROUP CONSIDERATIONS

OR/WA Commercial: Mandate applies to all commercial groups. For HMO members in Lane County, a referral to KP's Craniofacial Clinic in Portland is highly recommended but cannot be required due to the distance required to access services in Portland.

Oregon Medicaid: Mandate Not applicable to OR Medicaid; benefit coverage TBD

Added Choice/POS: A referral to KP's Craniofacial Clinic in Portland is highly recommended but not required. Members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Most procedures (e.g. advanced imaging and some DME) and levels of care other than office visits require prior-authorization (please refer to members' benefits but examples of exceptions to the above include outpatient labs, xrays, and preventive services).

Medicare: Mandate Not applicable to Medicare.

Washington Medicaid: Mandate Not applicable to WA Medicaid: If services are provided by a dentist or oral surgeon for dental diagnoses they are covered through DSHS FFS. The exception to this would be in the ED (the health plan is responsible for services provided in ED). See the Apple Health Benefit Index for more information:

REFERENCES:

COMMERCIAL Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment. The EOC also excludes "dental appliances and dentures" under DME section.

Relevant part of **Limited Dental Services Exclusions**
The following dental Services are not covered, except where specifically noted to the contrary in the EOC:

- Extraction of teeth, except as described in the "Covered Dental Services" section.
- Orthodontics, except as described in the "Covered Dental Services" section.

Relevant part of **Covered Dental Services**
We cover dental Services only as described below:

- Dental and orthodontic Services for the treatment of craniofacial anomalies if the Services are Medically Necessary to improve or restore function.

Oregon House Bill 4128: https://legiscan.com/OR/text/HB4128/id/586611

ATTACHMENT: ICD 10 diagnosis codes for skull, facial and jaw anomalies.**:**

Cleft palate, not otherwise specified: Q35.9

- Formerly ICD 9: 749.00 – 749.25

Congenital anomalies/malformations of skull and face bones, not otherwise specified: Q75.0

This code applies to:

- Absence of skull bones
- Acrocephaly
- Congenital deformity of skull or facial bones
- Craniosynostosis
- Crouzon's disease
- Delayed closure of anterior fontanel
- Goldenhar syndrome
- Hypertelorism
- Imperfect fusion of skull
- Mandibulofacial dysostosis
- Oculomandibular dysostosis
- Oxycephaly
- Platybasia
- Premature closure of cranial sutures
- Robin syndrome
- Tower skull
- Treacher Collins syndrome
- Trigonocephaly

Deformities and asymmetry of skull, face, and jaw: (These may or may not be congenital anomalies but will be evaluated further by the Craniofacial Clinic team.)

- Congenital facial asymmetry **Q67.0**
- Congenital compression facies **Q67.1**
- Depressions in skull
- Deviation of nasal septum, congenital
- Dolichocephaly **Q67.2**
- Plagiocephaly **Q67.3**
- Other congenital deformities of skull, face and jaw **Q67.4**
- Potter's facies
- Squashed or bent nose, congenital

KAISER PERMANENTE® **Northwest Region Utilization Review**

UR 56 Dental Anesthesia Policy and Medical Necessity Criteria: Commercial

Department: Northwest Permanente
Applies to: KPNW Region/NW UM Physician
Review Responsibility: PDA Dental Services Hospital Operating Room Committee; UROC
Subject Matter Expert: Michael Plunkett, DDS

Number: UR 56
Effective: 04/10
Last Reviewed: 4/18, 10/22, 9/23
Last Revised: 4/19, 6/20, 7/21, 9/21, 6/23

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

PURPOSE

Describe the policy and medical necessity criteria for the provision of general anesthesia (GA) in an operating room (OR) of a hospital or ambulatory surgery center (ASC) or a surgical suite of a dental clinic when GA is required to safely provide necessary dental treatment.

POLICY

It is an accepted community standard to provide necessary dental care under GA when the dental procedures cannot be safely performed in a traditional dental office setting because the member has special needs or because the member is 12 years of age or younger.

The eligibility criteria described herein are NOT intended to be used for patients who require GA in the OR for oral surgery services that are covered under medical benefit and provided by an Oral Surgeon.

DEFINITIONS

- General Anesthesia (GA): A reversible state of controlled unconsciousness produced by intravenous and/or inhaled anesthetic agents which results in the total loss or partial loss of reflexes and absence of pain over the entire body.
- Operating Room (OR): An Operating room or a surgery suite within a hospital or ambulatory surgery center or dental clinic within which surgical operations are carried out.
- General dentistry: The general practice of dentistry
- Pediatric dentistry: The practice of dentistry specializing in patients generally 12 years of age or younger
- Special Needs: Medical, developmental, or mental condition that may impair member's ability to receive dental care in a traditional dental office setting. These conditions may include:
  - Alzheimer's disease
  - Parkinson's disease
  - Autism spectrum disorder
  - Cerebral palsy
  - Down syndrome
  - Intellectual disability
  - Paralysis
  - Seizure disorder
  - Sensory disorder
  - Developmental delay

○ Allergy to all conventional local anesthetics (confirmed by documented evaluation by allergist)
NOTE: Dental Phobia in members older than 12 years is not considered to be a special need and does NOT meet the criteria for Medical Necessity of general anesthesia for dental procedures.

MEDICAL NECESSITY CRITERIA

Provision of general anesthesia in operating room of a hospital or ambulatory surgery center or a surgical suite of a dental clinic for dentally necessary dental services may be considered medically necessary when BOTH of the following criteria are met:

Criterion 1:

The pediatric dentist or general dentist or oral surgeon has documented that the member requires dentally necessary care AND clinically appropriate alternatives which can be provided in a traditional dental office setting are not available.

Criterion 2:

The member of any age has a special needs diagnosis which significantly impairs their ability to safely cooperate with dental care in a traditional dental office setting;

OR

The member is 12 years of age or younger and the pediatric dentist or general dentist or oral surgeon has documented that the member's dental care cannot be safely provided in a traditional dental office setting due to factors that include but are not limited to:

- age;
- physical, medical or mental status;
- extent of treatment planned / degree of difficulty of the procedure;
- member's inability to cooperate due to acute situational anxiety /dental phobia;
- exaggerated gag reflex;
- need for immediate comprehensive dental treatment prior to medical treatment;
- allergy to local anesthetic/ inability to achieve local anesthesia;
- protecting the developing psyche of patient and/ or reduce medical risk;
- failed attempt of dental treatment in dental office.

SPECIAL GROUP CONSIDERATIONS

Commercial: This policy applies to all commercial groups

Medicare: This policy does NOT apply to Medicare

Washington Medicaid: This policy does not apply, see references below

Oregon Medicaid: This policy does not apply, see references below (Unique criteria FOR OHP Members ONLY: Health Systems Division: Medical Assistance Programs - Chapter 410, Division 123 - https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=243030)

REFERENCES

American Academy of Pediatric Dentistry Oral Health Policy 2020, Policy on Hospitalization and Operating Room Access for Oral Care of Infants, Children, Adolescents, and Individuals with Special Health Care Needs

Policy Number: NW.DENTAL.BENEFITS.022.0 - Request for Extra Contractual Services in Operating Room

Oregon Medicaid:

Health Systems Division: Medical Assistance Programs - Chapter 410, Division 123 – Dental/Denturist Services, 410-123-1490 - Hospital Dentistry - Oregon Secretary of State Administrative Rules

(1) The purpose of hospital dentistry is to provide safe, efficient dental care when providing routine (non-emergency) dental services for Division of Medical Assistance Programs (Division) clients who present special challenges that require the use of general anesthesia or IV conscious sedation services in an Ambulatory Surgical Center (ASC), inpatient or outpatient setting.

(3) Hospital dentistry is intended for:

1. Children (18 or younger) who:
   a. Through age 3 and have extensive dental needs;
   b. 4 years of age or older and have unsuccessfully attempted treatment in the office setting with some type of sedation or nitrous oxide;
   c. Have acute situational anxiety, fearfulness, extreme uncooperative behavior, uncommunicative such as a client with developmental or mental disability, a client that is pre-verbal or extreme age where dental needs are deemed sufficiently important that dental care cannot be deferred;
   d. Need the use of general anesthesia (or IV sedation) to protect the developing psyche;
   e. Have sustained extensive orofacial or dental trauma;
   f. Have physical, mental or medically compromising conditions; or
   g. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
      i. Acute situational anxiety and extreme uncooperative behavior; and/or
      ii. A physically compromising condition.
2. Adults (19 or older) who:
   a. Have a developmental disability or other severe cognitive impairment and one or more of the following characteristics that prevent routine dental care in an office setting:
      i. Acute situational anxiety and extreme uncooperative behavior; and/or
      ii. A physically compromising condition
   b. Have sustained extensive orofacial or dental trauma; or
   c. Are medically fragile, have complex medical needs, contractures or other significant medical conditions potentially making the dental office setting unsafe for the client

Washington Medicaid:

RCW 48.43.185 - General anesthesia services for dental procedures.

RCW 48.43.185: General anesthesia services for dental procedures. (wa.gov)

(1) Each group health benefit plan that provides coverage for hospital, medical, or ambulatory surgery center services must cover general anesthesia services and related facility charges in conjunction with any dental procedure performed in a hospital or ambulatory surgical center if such anesthesia services and related facility charges are medically necessary because the covered person:

(a) Is under the age of seven, or physically or developmentally disabled, with a dental condition that cannot be safely and effectively treated in a dental office; or

(b) Has a medical condition that the person's physician determines would place the person at undue risk if the dental procedure were performed in a dental office. The procedure must be approved by the person's physician.

(2) Each group health benefit plan or group dental plan that provides coverage for dental services must cover medically necessary general anesthesia services in conjunction with any covered dental procedure performed in a dental office if the general anesthesia services are medically necessary because the covered person is under the age of seven or physically or developmentally disabled.

(3) This section does not prohibit a group health benefit plan or group dental plan from:

(a) Applying cost-sharing requirements, maximum annual benefit limitations, and prior authorization requirements to the services required under this section; or

(b) Covering only those services performed by a health care provider, or in a health care facility, that is part of its provider network; nor does it limit the health carrier in negotiating rates and contracts with specific providers.

(4) This section does not apply to Medicare supplement policies, or supplemental contracts covering a specified disease or other limited benefits.

(5) For the purpose of this section, "general anesthesia services" means services to induce a state of unconsciousness accompanied by a loss of protective reflexes, including the ability to maintain an airway independently and respond purposefully to physical stimulation or verbal command.

(6) This section applies to group health benefit plans and group dental plans issued or renewed on or after January 1, 2002.

WAC 182-531-0300 - Anesthesia providers and covered physician-related services. The Medicaid agency bases coverage of anesthesia services on Medicare policies and the following rules:

(1) The agency reimburses providers for covered anesthesia serv-ices performed by:

(a) Anesthesiologists;

(b) Certified registered nurse anesthetists (CRNAs);

(c) Oral surgeons with a special agreement with the agency to provide anesthesia services; and

(d) Other providers who have a special agreement with the agency to provide anesthesia services.

(2) The agency covers and reimburses anesthesia services for children and noncooperative clients in those situations where the medically necessary procedure cannot be performed if the client is not anesthetized. A statement of the client-specific reasons why the procedure could not be performed without specific anesthesia services must be kept in the client's medical record. Examples of such procedures include:

(a) Computerized tomography (CT);

(b) Dental procedures;

(c) Electroconvulsive therapy; and

(d) Magnetic resonance imaging (MRI).

(3) The agency covers anesthesia services provided for any of the following:

(a) Dental restorations and/or extractions:

(b) Maternity per subsection (9) of this section. See WAC 182-531-1550 for information about sterilization/hysterectomy anesthesia;

(c) Pain management per subsection (5) of this section;

(d) Radiological services as listed in WAC 182-531-1450; and

(e) Surgical procedures.

(4) For each client, the anesthesiologist provider must do all of the following:

(a) Perform a preanesthetic examination and evaluation;

(b) Prescribe the anesthesia plan;

(c) Personally participate in the most demanding aspects of the anesthesia plan, including, if applicable, induction and emergence;

(d) Ensure that any procedures in the anesthesia plan that the provider does not perform, are performed by a qualified individual as defined in the program operating instructions;
(e) At frequent intervals, monitor the course of anesthesia during administration;
(f) Remain physically present and available for immediate diagnosis and treatment of emergencies; and
(g) Provide indicated post anesthesia care.

(5) The agency does not allow the anesthesiologist provider to:
(a) Direct more than four anesthesia services concurrently; and
(b) Perform any other services while directing the single or con-current services, other than attending to medical emergencies and other limited services as allowed by Medicare instructions.

(6) The agency requires the anesthesiologist provider to document in the client's medical record that the medical direction requirements were met.

(7) General anesthesia:

(a) When a provider performs multiple operative procedures for the same client at the same time, the agency reimburses the base anesthesia units (BAU) for the major procedure only.

WAC 182-500-0070 - Definitions:

"Medically necessary" is a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative or substantially less costly course of treatment available or suitable for the client requesting the service. For the purposes of this section, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all.

Molina: 2021Redline_Medicaid_MHWFinalDraft2_forRRD_R (molinahealthcare.com)
"Medically Necessary" ***or*** **"Medical Necessity"** ***means a requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent worsening of conditions in the Enrollee that endanger life, or cause suffering of pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity, or malfunction. There is no other equally effective, more conservative, or substantially less costly course of treatment available or suitable for the Enrollee requesting the service. For the purpose of this Contract, "course of treatment" may include mere observation or, where appropriate, no medical treatment at all (WAC 182-500-0070).***

This is for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms. Those services must be deemed by Molina to be:
1. In accordance with generally accepted standards of medical practice:
2. Clinically appropriate and clinically significant, in terms of type, frequency, extent, site and duration. They are considered effective for the patient's illness, injury or disease; and, 3. Not primarily for the convenience of the patient, physician, or other health care Provider. The services must not be more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease. For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature. This literature is generally recognized by the relevant medical community, physician specialty society recommendations, the views of physicians practicing in relevant clinical areas and any other relevant factors. The fact that a Provider has prescribed, recommended or approved medical or allied goods or services does not, in itself, make such care, goods or services medically necessary, a medical necessity or a covered service/benefit.

KAISER PERMANENTE®

Northwest Region Utilization Review

UR 53: Repatriation/Transfer Guidelines

Department: Regional Telephonic Medicine Ctr
Section: KPNW Region
Applies to: KPNW Region
Review Responsibility: Cynthia Horak, MD (RTMC);
Kathryn Kelly, MD (Pediatrics)

Number: UR 53
Effective: 08/09
Last Reviewed/Approved: 2/22, 2/23, 2/24

REPATRIATION/TRANSFER GUIDELINES
PURPOSE

These guidelines are utilized when determining whether a patient is stable for repatriation/transfer from a non-KP facility (inpatient or ED) to a KP-contracted or Kaiser Foundation Hospital (inpatient or ED).

In addition to these guidelines, the capability of both the sending facility and the receiving facility will be considered in addition to the appropriate provider availability.

PLEASE NOTE: "Higher Level of Care" transfers are those are done to obtain a higher level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by the Regional Telephonic Medicine Center (RTMC) for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

SUBJECT TO CHANGE: Confirm prior to a transfer to Kaiser Sunnyside OR Kaiser Westside Medical Center that a patient weighing ≥550 lbs can be accommodated.

BURNS

MILD BURNS OR BURNS OF QUESTIONABLE SEVERITY

Stable for transfer:

a) Patients with vital signs reflecting hemodynamic stability; and
b) Patients that received adequate initial treatment; and
c) They will advise as to the need for transfer to a burn center rather than to a Kaiser Permanente facility.

Unstable for transfer (Unless higher level of care requested):

a) Patients exhibiting hemodynamic instability; or
b) Patients requiring tertiary services due to other injuries or illnesses who are at a facility capable of providing appropriate care. (e.g. Smoke inhalation at a facility offering hyperbaric treatment.)

MODERATE / SEVERE BURNS (calls from KP ED's and NKP ED's)

These are primarily higher level of care transfers to the burn unit at Legacy Randall Children's Hospital. Generally, >20% total body surface area burn will be considered for transfer.

Candidates for Burn center: (meet any of the following):

- 2nd & 3rd degree burns of more than 10% BSA in patients under 10 and over 50 y/o;
- 2nd & 3rd degree burns of more than 15% BSA in other age groups;
- 2nd & 3rd degree burns with serious threat of functional or cosmetic impairment that involve - face, hands, feet, genitalia, perineum and major joints;
- 3rd degree burns greater than 2% BSA any age group;
- Significant electric burn injuries including lightening injury;
- Chemical injuries with serious threat of functional or cosmetic impairment;
- Inhalation injury with burn injury;
- Circumferential burns of an extremity or chest;
- Burn injury in patients with preexisting medical disorders which could complicate management, prolong recovery, or affect mortality;
- Major trauma with burns

CARDIAC

GENERAL

Diagnoses to be considered in this category include but are not limited to unstable angina, acute coronary syndrome, or "rule out" MI.

Stable for transfer:

Patients may be appropriate for transfer consideration (Advanced Life Support (ALS) or Critical Care Transport (CCT)) as long as the following conditions are met:

1. No persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. A patient who has received fibrinolytics or has unstable angina with dynamic EKG changes but otherwise stable (as defined here) is appropriate for transfer;
3. Patient has stable vital signs, and appears hemodynamically stable;
4. Patient is free of active ischemic chest pain (Pharmaceutical intervention up to and including IV nitroglycerin is acceptable), titrate dose/amount acceptable.
5. Patient has a Swan-Ganz catheter inserted but otherwise stable (as defined here) is appropriate for transfer.

Unstable for transfer: **(UNLESS HIGHER LEVEL OF CARE REQUIRED/REQUESTED)**

1. Persistent acute EKG changes (acute injury current ST elevation or ST depression);
2. Active ectopy (greater than 6 PVC's/min. or short runs of V-Tach), acute MI.

CARDIAC CATH / PTCA/PCI

Patients requiring cardiac catheterization/PTCA/PCI (per the community MD)
Transfer for primary PTCA can be considered if:

a) There is evidence of an acute MI;
b) There is an absolute contraindication to thrombolysis; and the facility in which the patient is being treated does not have the capability to perform the procedure.

AORTIC DISEASE / AORTIC ANEURYSM

Criteria for management of Aortic Dissections and Aortic Aneurysms

a) Ascending Dissection - surgical emergency - requires immediate transfer to Kaiser Sunnyside MC or OHSU depending on stability and location; contact on-call cardiac surgeon to determine best disposition.
b) Type B Dissection – Call Cardiology first for advice. Cardiac Surgery needs to evaluate the case, but often medically managed in ICU;
c) Patients > 80 years of age - Cardiac Surgery needs to evaluate the case, but often medically managed;
d) Abdominal Aneurysm – Consult Vascular Surgeon on-call. This can generally be handled at any plan facility, unless higher level of care is required.

NOTE: if transferring for higher level of care and on IABP (intra-aortic balloon pump), ensure IABP compatibility with pump at SMC.

Patients who may be considered **stable for transfer:**

a) Have responded to appropriate therapies;
b) Are not significantly hypoxic or dyspneic;
c) Remain alert without evidence of hypercapnea;
d) Maintain stable vital signs;
e) Have no persistent acute EKG changes (acute injury current ST elevation or ST depression);
f) Meet general cardiac criteria.

Exclusion Criteria: Cardiac-<u>EXCEPT FOR HIGHER LEVEL OF CARE REQUESTS</u>

Cardiovascular/Hemodynamic

- Hypotension or hypertension not controlled
  - SBP < 90 or >180. Check for baseline BP.
- On moderate-to-high-dose vasopressors
  - Norepinephrine >10 mcg/min >0.1 mcg/kg/min
  - Epinephrine >10 mcg/min >0.1 mcg/kg/min
  - Phenylephrine >100 mcg/min >1 mcg/kg/min
  - Dopamine >10 mcg/kg/min
  - Dobutamine >10mcg/kg/min
- On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access preferred)
- Brisk ongoing hemorrhage or high risk of recurrent hemorrhage

Other exclusion criteria:

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed

CRITICAL ILLNESS

GENERAL

Patients with critical illness are those requiring ICU-level care.

The criteria for transfer of critically ill patients are the same regardless of whether the accepting service is Critical Care Medicine or another specialty. In all cases, there should be multisystem review of the case to determine stability for transfer.

"Lateral" transfers are those done between facilities which can provide the same level of care. This includes patients who are in an ICU at a non-plan hospital and those who are in an ED at a non-plan hospital that has an ICU bed available and that hospital can provide the services needed by the patient. For lateral transfers, the RTMC should use the Screening Exclusion Criteria below to determine which patients should be immediately excluded for transport. If there are no exclusion criteria present, then a potential accepting physician can be identified. The potential accepting physician will then review the case and integrate all the available information to determine if the patient is sufficiently stable for transport.

"Higher Level of Care" transfers are those which are done to obtain a level of care or service for the patient than is available at the Sending Facility. The Screening Exclusion Criteria are not used by RTMC for transfers being considered for a higher level of care. In these cases, the sending and accepting physicians will consider both the advantages to obtaining the higher level of care and the risks of transport in order to make a decision about transfer.

SCREENING EXCLUSION CRITERIA FOR LATERAL TRANSFERS

The below Screening Exclusion Criteria are in place for lateral transfers, and do not apply to 1) patients with the need for a level of care available at Sunnyside or Westside, and that are not available at the originating facility (e.g. coronary intervention); and 2) patients being transported due to the need for a higher level of care (SEE ABOVE).

If exclusion criteria are present, then do not pursue transfer. Even if no exclusion criteria are present, the patient still needs to be considered stable for transport by Sending and Accepting Physicians.

Exclusion Criteria

- Patients under 18 years of age for transfer to a Kaiser ICU

Cardiovascular/Hemodynamic

- Symptomatic hypertension
- SBP < 90 or MAP < 60
    - Exception: Baseline blood pressure is similarly low, and hypotension not related to primary diagnosis.
- On moderate-to-high-dose vasopressors
    - Norepinephrine >10 mcg/min >0.1 mcg/kg/min
    - Epinephrine >10 mcg/min >0.1 mcg/kg/min
    - Phenylephrine >100 mcg/min >1 mcg/kg/min
    - Dopamine >10 mcg/kg/min
    - Dobutamine 10mcg/kg/min

- On any dose of vasopressor/inotrope without central venous access or without multiple secure peripheral catheters (central access is preferred)
- Brisk ongoing hemorrhage or high risk of recurrent hemorrhage
- Other exclusion criteria as described in the Cardiac section*

Respiratory

- On ventilator with high levels of support required
    - FiO2 > 0.7
    - PEEP >14
    - Minute ventilation > 13
    - Peak pressures > 45
- < 1 hour since intubation unless intubated for airway protection
- < 6 hours since extubation
- No ABG on current ventilator settings
- Not intubated, and requiring high-flow oxygen (> 15 L/min)
- Not intubated, questionable ability to protect airway, and vomiting
- Sat < 92% or PaO_2 < 70 on settings achievable during transport, intubated or not intubated
    - BiPAP or CPAP-dependent (reference BiPAP Guidelines under Respiratory section)
    - Unable to be off BiPAP or CPAP for at least 2 hours (must demonstrate)
    - Exceptions:
        - Patient is DNI
        - Patient is on chronic home or SNF non-invasive ventilation and the primary acute problem is not cardio-respiratory

Neurological

- Elevated intracranial pressure (suspected or proven)
- Expanding intracranial hemorrhage or midline shift present (See NS section)
- Actively deteriorating level of consciousness or otherwise evolving neurological exam
- Received alteplase for stroke within past 24 hours and are in a Certified Stroke Center (if patient is not in a Stroke Center, transfer patient)
- Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
- Severe agitated delirium not safely controlled

Metabolic abnormalities

- Temp < 36 (induced or spontaneous)
- Hyperkalemia with EKG changes or K > 7 even without EKG changes
- Hyper/hyponatremia:
    Acute seizures in setting of hyponatremia
    Acute (or presumed acute) severe hyponatremia, Na<115
    Acute severe hypernatremia, Na>165
- pH < 7.25 unless part of controlled hypoventilation strategy

*Cardiac Exclusion Criteria **<u>(unless higher level of care request)</u>**

1. ST Elevation Myocardial Infarction (STEMI) who are within 12 hours of onset of symptoms or are having ongoing symptoms and ST elevation consistent with active ischemia.
2. Non-STEMIs whose pain/symptoms cannot be stabilized acutely with medicinal therapy and are having symptoms consistent with ongoing cardiac ischemia.
3. Ischemic syndromes with evidence of cardiogenic shock.
4. Patients with recurring sustained ventricular tachycardia or life-threatening bradycardias.
5. Ischemic syndromes requiring an intra-aortic balloon pump to maintain adequate blood pressure.
6. Sustained bradycardia or tachycardia with cardiogenic shock or hemodynamic instability.
7. Valvular heart disease with cardiogenic shock and/or active ischemic symptoms.
8. Pericardial effusion with hemodynamic compromise from tamponade.
9. Patients with resuscitated sudden cardiac death on mechanical ventilation in the 24 hours post event or who are receiving therapeutic hypothermia and have not yet been re-warmed.

USE OF CRITICAL CARE TRANSPORT (CCT)

Critical Care Transport service is provided by MetroWest Ambulance.

GASTROINTESTINAL BLEEDING

GENERAL

Due to the nature of GI bleeds and the lack of specific markers, the RTMC MD should always overlay their medical knowledge and judgment when determining the stability for transfer of these cases.

Stable for transfer:

a) Patient has stable vital signs including orthostatics where indicated;
b) GI hemorrhage inactive without evidence of current brisk bleed;
c) Stable CBC or H/H as compared to baseline;
    1) Patients may require transfusion at the community ED prior to transfer;
    2) Transfusion may also be continued during transfer if indicated. (Note: RN transport may be needed when patient is receiving blood transfusion).

Unstable for transfer (unless higher level of care required):

a) Patient has unstable vital signs (hemodynamically unstable- see Critical Care Exclusion Criteria, pg 6-8) after resuscitation is completed;
b) Patient has an active brisk bleed from rectum or NG tube (if used), i.e. maroon-colored stool with decreasing H&H (decrease in Hgb >1 g/dl);
c) Evidence of esophageal obstruction with airway compromise or inability to manage secretions;
d) Patient requires urgent transfusion not available in the ED.

GENERAL SURGERY

Includes patients with diagnoses such as appendicitis, cholecystitis, diverticulitis, and SBO.

Stable for transfer:

a) Patient has stable vital signs; and
b) Normal neurologic exam without airway compromise; and
c) Stable HCT without significant active bleeding; and
d) GS guidelines
e) If transporting to KP facility, patient is ≥16 years of age

Unstable for transfer (unless higher level of care required):

a) Patient has unstable vital signs (see Critical Care Exclusion Criteria, pg 6-8); or
b) Patient has active or significant potential for airway compromise or deterioration; or
c) Patients with evidence of ongoing significant bleeding.

General Surgery Transfer Guidelines (Non-Trauma)

Stable for Transfer, assuming facility and provider availability at Plan facility:

a. Patient has stable vital signs, good general appearance
b. No signs of a surgical abdomen
c. Antibiotics if applicable have been started
d. Acute abdominal series +/or abdominal/pelvic CT scan if performed does not demonstrate;
    1) Free air
    2) Acute Dissecting AAA (discussion with vascular surgeon will occur as needed)
    3) Ischemic Small Bowel
    4) Air in the Biliary Tree (not post procedural)
    5) Ruptured Appendix

    NOTE: 1), 3), 4) and 5) will be discussed with surgeon prior to transfer
e. Early Appendicitis
    1) Onset of symptoms and physical exam consistent with early presentation
    2) Reading of abdominal CT by radiologist indicates "Early Appendicitis"
f. Sending facility has no plans or opportunity to operate for >6 hours
g. If transporting to KP facility, patient is ≥15 years of age. If age <15, transport to DCH.

NEUROLOGY including STROKE

CVA - Ischemic Stroke

Stable for transfer:

Patient has:
1) stable vital signs;
2) stable neurologic exam; determined optimally by a neurologist at non-plan facility, if available;
3) symptoms/deficit stable;
4) head CT scan (CTA, if facility has the capability) should be done prior to making decision to transfer patient to a non-neurosurgical facility (always request that a copy of CT/CTA accompany the patient in transfer).

Unstable for transfer (unless higher level of care request for transfer):

Patient has:
1) unstable vital signs (see Critical Care);
2) unstable neurologic exam;
3) ≥1/4 hemisphere infarct
4) cerebellar or cortical hematomas with midline shift;
5) brainstem involvement
6) intracerebral hemorrhage/cerebral hematoma;
7) acute surgical intervention indicated and available at treating facility;
8) symptoms consistent with evolving stroke;
9) patient not surgical candidate but with impending demise, unless patient's family requests transfer to Kaiser.

Other Considerations:

1) Receiving facility must be within 2 hours transit time.
2) The decision to administer thrombolytics for acute CVA rests with the treating physician.
3) For an anterior circulation infarct that is outside the window for appropriate thrombolytics (<3 hours) but <6 hours of onset, patient must be considered for intravascular intervention at appropriate facility for transfer.
4) For a posterior circulation infarct that is within 24 hours of onset, discuss case with KP neurologist to determine if patient is appropriate for intravascular intervention and the most appropriate facility to receive the patient.

Exclusion Criteria: (unless higher level of care, not in a stroke center)

Neurological

- Elevated intracranial pressure
- Expanding intracranial hemorrhage or midline shift present
- Actively deteriorating level of consciousness or otherwise evolving neurological exam
- Seizures: if has had 2 seizures within less than 30 min of each other, patient is excluded from transfer until 4 hours have passed without seizures and patient has returned to baseline mental status or EEG demonstrates that status epilepticus is not present
- Severe agitated delirium not safely controlled

NEUROSURGERY, ADULT

Patients in Non-KP EDs

Normal CT

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale ≥13 will be transferred to a KP facility (or other facility, as deemed appropriate) when observation is indicated.

Patients presenting with traumatic closed head injuries with a normal CT and Glasgow Coma Scale <13 will be transferred to KSMC and evaluated by the Neurosurgeon to determine why GCS is so low, complete any indicated toxicology screen, and conduct other tests as indicated. If admission to another service is deemed more appropriate, the RTMC will arrange the admission and the Neurosurgeon will communicate with the accepting Physician and/or family if requested.

Abnormal CTs

All acute intracranial bleeds and cervical spinal cord injuries in non-KP neurosurgical EDs should have an onsite neurosurgical consult to ensure their safe transfer if available and indicated. If it is determined that the patient is not a candidate for neurosurgical intervention, the neurosurgeon will notify the hospitalist or intensivist and the patient will be admitted to that service with neurosurgery as consult. Neurosurgeon will communicate with the family if requested.

Spine:
Patients with spinal injury and subjective or objective neurologic deficit should be transferred to KSMC. Consult spine on call. Patients less than 18 years of age should be referred to DCH.

- Reference Trauma section
- Reference Critical Care Exclusion Criteria
- Reference Higher Level of Care

NEUROSURGERY, PEDIATRIC

General issues: Need to communicate with the Pediatric Neurosurgeon on call regarding each case. All cases should be referred to OHSU/Doernbecher.

a) The patient should receive care in a setting capable of providing all services required by a child, including care for potential complications;
b) Neonatal neurosurgical cases must be in a facility with Neonatal ICU level 3-4 capability (depending on severity);
c) Patients who will likely require Pediatric ICU (PICU) services may only be transferred to Doernbecher PICU (unless also suffering severe burns which would require Legacy Randall Children's Hospital PICU);
d) Patients with coma or depressed Glasgow Coma Score require pediatric intensive care services.
    --All pediatric patients <18 should be cared for at Doernbecher/ OHSU by the trauma service;
    --Glasgow coma score (GCS) < 10;

ORTHOPEDIC

GENERAL

Stable for transfer:

a) Patients with stable vital signs;
b) Patients with closed fracture without neurovascular compromise
   Note: Displaced **acetabular** fractures are not usually repatriated.
   Note: closed tibial fractures sustained with high energy mechanisms of injury will require some objective evidence indicating normal (or near normal) compartment pressures even in the setting of normal neurovascular status.
c) Patients with open fractures without neurovascular compromise.
   i. Grade 1, <1 cm laceration- can potentially go to OR more than 6 hours from the time of injury, check with on call KP orthopedist.
   ii. Grade 2, >1 cm laceration- ideal to get to OR within 6 hours from the time of injury, but decision of time to surgery is left to the discretion of the KP orthopedist.
      - Do not transfer if it has been >4 hours since the time of injury, unless the sending facility is unable to deliver care or get the patient to the OR in a timely fashion.
   iii. Grade 3 would be handled at a trauma center.
   iv. Distal phalanx can be managed with ER/urgent care washout and antibiotics only, does not need urgent OR.
d) Pediatric closed fractures can be handled at KSMC. Check with on-call KP orthopedist.

NOTE: For each case the RTMC MD is expected to provide complete information to the orthopedist including:

- Patient's age and gender;
- Time of the injury;
- Mechanism of the injury;
- Extent of injury including all systems;
- Current location of the patient;
- Name and phone number of the current treating physician, if requested;
- Estimated transportation time.

Unstable for transfer (Unless higher level of care is requested):

a) Patients with unstable vital signs (see Critical Care Exclusion Criteria);
b) Patients with evidence of vascular compromise;
c) Patients with evidence of compartment syndrome;
d) Patients with multiple trauma/multiple system injuries that cannot be managed within the Kaiser Permanente system;
e) Patients with amputation injury requiring reimplantation.
f) Gustillo Fracture Classification, Grades II-III (see description of Grade I above)

O.M.F.S./H.N.S./Plastic Surgery

GENERAL

Mandibular fractures, facial fractures, laceration repairs, epistaxis, etc.

Stable for transfer:

a) Patient has stable vital signs;
b) Normal neurologic exam without airway compromise;
c) Stable HCT without significant active bleeding;
d) Significant oral edema should be evaluated by non-Plan ENT when available prior to transfer.

Unstable for transfer (unless higher level of care required):

a) Patient has unstable vital signs (see Critical Care Exclusion Criteria);
b) Patient has active or significant potential for airway compromise;
c) Patients with evidence of ongoing significant bleeding or epistaxis.

PEDIATRICS

GENERAL

Pediatric cases are managed by the Kaiser Pediatrician on call at Doernbecher, who can be reached by calling the OHSU transfer center at 503-494-7000 or by paging the pediatrician directly (contact number on staff availability). If the child is felt to be critically ill or injured, then the Pediatric ICU attending physician at Doernbecher would manage the case/transfer. Also of note, the Doernbecher PANDA (Pediatric and Neonatal Doernbecher Ambulance) transport team may use air transport, typically at the discretion of the pediatric ICU attending physician at DCH. Closed fractures requiring closed reduction can typically be handled at KSMC or KWMC, therefore transfer to Doernbecher may not be indicated.

Common pediatric diagnoses encountered include, but are not limited to, asthma, croup, dehydration, head injuries, infections and poisonings.

Stable for transfer:

1) Patients with vital signs reflecting hemodynamic stability;
2) Patients who received adequate initial treatment;
3) Patients accepted by Kaiser Permanente pediatric Doernbecher hospitalist MD or PICU attending on call. Appropriate mode of transfer is arranged (ACLS or PANDA).

Unstable for transfer (Unless higher level of care requested):

1) Patients exhibiting hemodynamic instability;
   NOTE: We may opt to transfer (in particular PANDA) if the sending facility is not able to stabilize as the transport team often is better skilled in getting the patient stabilized than some of our local ER's.
2) KP pediatric MD unwilling to accept due to clinical concerns.

Decisions will be made by Doernbecher KP hospitalist and PICU attending.

PSYCHIATRY

GENERAL

Medical Clearance – The patient is determined to be medically cleared when all medical conditions have been evaluated and treated so that the patient could return home if there was no underlying psychiatric condition. The extent of the evaluation to determine medical clearance is at the discretion of the treating physician in consultation with the Brookside on-call MD. Specific drug or alcohol levels are not required unless clinically pertinent to the medical clearance. However, most cases require toxicology screening.

Stable for transfer:

a) Patients with vital signs reflecting hemodynamic stability;
b) Patients that received adequate initial evaluation and treatment;
c) Patients meeting medical clearance criteria for transfers directly to psych facilities.

Unstable for transfer (Unless higher level of care requested):

a) Patients exhibiting hemodynamic instability;
b) Patients with significant overdoses and evidence of pending cardiovascular complications (i.e.: TCA's).

NOTE: Doernbecher Children's Hospital Inpatient Pediatric Ward does not accept medically stable/cleared psychiatric patients who are awaiting inpatient or residential psychiatric treatment.

Hemodialysis patients exhibiting volume overload or electrolyte imbalance and are often in need of urgent or emergent dialysis.

Patients on sustained low-efficiency dialysis (SLED) can be repatriated at Sunnyside Medical Center whereas patients on continuous renal replacement therapy (CRRT) cannot be repatriated. Patients need to be able to be on intermittent not continuous dialysis. They can only move when able to be off CRRT for 15 hours and then transferred to SLED.

Stable for transfer:

a) Patients with vital signs reflecting hemodynamic stability;
b) Renal failure patients presenting with serum potassium below 7.0 without EKG changes (second potassium may need to be obtained after medical therapy at the community ED);
c) Patients with appropriate mental status;
d) Patients with adequate oxygenation with low or moderate O2 supplementation.

- Before repatriating dialysis patients, make sure the nephrologist on call is notified and that dialysis capacity has not been exceeded
- Notify the hospitalist so they can admit the patient

Unstable for transfer (Unless higher level of care requested):

a) Patients exhibiting hemodynamic instability;
b) Renal failure patients with serum potassium above 7.0.
c) Patients with pulmonary edema not responsive to initial medical therapy and in need of emergent dialysis to avoid respiratory failure

RENALTRANSPLANT PATIENTS:

The patient can receive related care at the transplant facility for a maximum of 3 months post-transplant. After 3 months the patient is usually transferred for care to their home Kaiser Permanente facility. The appropriate nephrologist on call should be consulted after hours to aid in the disposition of these cases.

Other Organ transplants: Refer to NTN Database for information on: Centers of Excellence (COE), transplant Coordinator's name, Transplant MD's name and case rate ending date.

RESPIRATORY

GENERAL

Note that the Pulmonary Service is not an admitting service at KSMC. The following sections address certain respiratory therapies that may be encountered when considering transport of patients to any accepting service.

Oxygen Therapy

Patients cannot be transported on high flow nasal cannula oxygen. Adequate oxygenation on flows up to 15 L/min by mask must be demonstrated prior to transport. Reference Critical Care Exclusion Criteria.

NIV, BiPAP, CPAP

Ventilatory support with noninvasive ventilation (NIV), BiPAP, or CPAP is not considered to be as reliable as invasive ventilation and has only been proven to be effective for a limited number of indications.

Lateral Level of Care Transfers or Transfers to a Lower Level of Care

Lateral transfers should not be initiated for patients who are dependent on NIV, Bi-pap, or CPAP. "Dependency" is defined as being unable to be off the device at least 2 hours. However, after demonstrating NIV/BiPAP/CPAP independency at the Sending Facility, NIV/BiPAP/CPAP can and should be utilized during transport if it has been a part of the treatment regimen up until that point.

Exceptions—lateral transfers may be considered in these situations:

1. NIV/BiPAP/CPAP is being used for palliative purposes
2. DNI and DNR status
3. Patient is on chronic home NIV/BiPAP/CPAP and the acute medical problem is not cardio-pulmonary
4. NIV/BiPAP/CPAP is being used for COPD or CHF, and a physician privileged in advanced airway management is part of the transport team.

In all cases of lateral transfer, an RT or nurse with competency in administering non-invasive ventilation must be part of the transport team. This implies that Critical Care transport will typically be required.

Transfers to Achieve a Higher Level of Care

Alternatives to transporting a patient on NIV, BiPAP or CPAP should be thoroughly explored before deciding on transport for a higher level of care. Consideration should be given to intubation prior to transport. Keeping the patient at the sending facility long enough to demonstrate improvement in the clinical respiratory status and in blood gas results on noninvasive therapy is strongly encouraged prior to transport.

If transport must take place using NIV, the transport team should be assembled with the best available skills in NIV and advanced airway management available in a time frame consistent with patient safety. Efforts should be made to enlist both an RT or RN with NIV competency and a physician with advanced airway management skills for the transport team.

Higher Level of Care Transports

Critical Care Transport should be used whenever possible. However, if the use of CCT would result in a delay which would put the patient at risk, then transport without the CCT can be considered as part of the decision-making process which weighs the overall risks and benefits of transfer.

TRAUMA

GENERAL

Major, multi-system trauma would never be appropriate for repatriation to a KP hospital in the acute setting.

PENETRATING: (GUN SHOT WOUND / STAB WOUND) –DO NOT TRANSFER

Blunt Trauma-

For patient in a non-KP facility

a) Chest: Stable for transfer if:
   1) Hemodynamically stable during 2-hour observation; and
   2) Chest x-ray, EKG without change; and
   3) ABG pH > 7.3, pO2 > 65, pCO2 < 50; and
   4) No signs of aortic disruption - CT scan or aortogram.

b) Abdomen: Stable for transfer if:
   1) Hemodynamically stable during 2-hour observation; and
   2) CT scan performed prior to transfer shows no signs of acute injury to spleen, liver, or pancreas; no free fluid, free air, or pelvic fracture.

Trauma Criteria

For KP patients presenting at a non-KP facility. Transfer to Trauma Center if:

a) Critical Trauma Victim (CTV): an **adult** victim of blunt or penetrating trauma, which results in any of the following alterations in vital signs.

Respirations	< 12 or > 30
Pulse	< 50 or > 130
Systolic BP	< 80

b) Moderate Trauma Victim (MTV): a victim of blunt or penetrating trauma with parameters to consider for trauma center designation including:
   1) Mechanism of injury - pedestrians struck by auto, ejection from vehicle;
   2) Unable to follow commands;
   3) Abnormal capillary refill;
   4) Age <5 or > 65 years old and with precarious previous medical histories;
   5) Prolonged extrication;
   6) Fatalities involved in the event;
   7) Adults with systolic BP < 90 or children with systolic BP <60;
   8) No spontaneous eye opening;
   9) Penetrating cranial injury;
   10) Penetrating thoracic injury between the midclavicular lines;
   11) Gunshot wound (GSW) to trunk
   12) Blunt injury to chest with unstable chest wall (flail chest);
   13) Penetrating injury to neck;
   14) Diffuse abdominal tenderness following blunt trauma;
   15) Fall from height >15 feet;
   16) Intrusion of motor vehicle into passenger space

Patients with an acute isolated **head trauma** and persistent Glasgow Coma scale of 14 or less should be referred to KSMC.

Patients with an isolated **spinal injury** and subjective or objective neurologic deficit should be transferred to KSMC. Consult Spine on call.

Stable for transfer:

a) Patient has stable vital signs;
b) Stable neurologic exam without evolving deficit;
c) Determination of stability by neurosurgeon at non-Plan facility, if available;
d) Spinal fracture immobilized appropriately prior to transfer if determined to be stable by treating physician.

Unstable for transfer (unless higher level of care):

a) Patient has unstable vital signs;
b) Patient has unstable neurologic exam;
c) Patients with acute epidural, subdural, or subarachnoid hemorrhage, especially with midline shift (at facilities where neurosurgical service are available);
d) Patients with unstable spine fractures or spine fractures with deficit at facilities with appropriate surgical services available.

SPECIAL GROUP CONSIDERATIONS

Added Choice/POS: members may access non-KP facilities for routine and post-emergency care under their Tier 2 and Tier 3 benefits, however prior-authorization is required.

EPIDURAL STEROID INJECTIONS

Policy Number: 0001
Effective Date: Jan 20, 2015
Reviewed Date: March 2024
Next Review: March 2025
Clinical Reviewer: John Borgoy, MD, Anesthesiology and Pain Management

BACKGROUND

CLINICAL BACKGROUND *(excerpted directly from Hayes 2017)*

"Approximately 25% of the adults in the United States reported low back pain in the past 3 months (Deyo et al., 2006), and low back pain is a global health issue that is likely to increase over future decades (Hoy et al., 2012). According to some estimates, the total annual economic cost for patients with low back pain in the United States approaches $100 billion (Crow and Willis, 2009).

Despite the increased sensitivity of diagnostic tools in detecting abnormalities in the structures of the lumbar spine, the cause of back pain may remain unknown in many patients. However, if back pain is not due to malignancy or underlying infection, 90% of patients will experience symptom resolution in ≤ 2 months. Causes that are identified include herniation of a lumbar intervertebral disc and spinal stenosis, or narrowing of the spinal canal (Valat et al. 2010; Jacobs et al., 2011). Conservative treatments for low back pain and sciatica include rest, analgesics, and anti-inflammatory medications; physical therapy; and advice regarding posture and exercise (Manchikanti et al., 2012a).

If symptoms persist, injections of local anesthetics and/or steroids along the nerve root or into the epidural space can provide a nonsurgical treatment option for some patients. Since low back pain and sciatica may also be due to other potentially serious spinal conditions, such as spinal tumor, infection, fracture, or cauda equina syndrome, these conditions must be ruled out based on medical history, physical examination, and laboratory and imaging studies before epidural steroid injections (ESIs) are considered (WebMD Medical Reference, 2012).

The rationale for the use of ESIs to treat low back pain and sciatica rests on the idea that steroids reduce inflammation and decrease pain by inhibition of inflammatory mediators such as phospholipase A2, stabilization of hyperexcitable nerve membranes, and reduction of capillary permeability.

Delivery of steroids directly into the epidural space exposes the spinal nerve roots to higher concentrations of medications for a longer period of time than systemic administration. Although positive reports of pain reduction by ESIs have led to widespread acceptance and prescription of this treatment, some studies have suggested that steroids do not provide additional pain relief beyond the anesthetic that is typically included in ESIs, and safety concerns have been raised (Price et al., 2005; Abdi et al., 2007)."

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	L39242
Local Coverage Article	A58995
Kaiser Permanente Medical Policy	For Medicare lines of business, apply the criteria in the LCD to determine medical necessity.

For non-Medicare Members

For patients initiating epidural steroid treatment
The patient may receive up to 2 epidural steroid injections at least 2 weeks apart to determine adequacy of response if the following criteria are met:

A) The patient has neck or back pain with a radicular component, AND

B) Pain has been present for at least 1 month duration without improvement despite medical treatment OR has severe radicular pain with concordant structural abnormality, AND

C) The patient has none of the following contraindications for epidural steroid injection:
   a. Use of Coumadin or platelet inhibitors, or other signs of compromised blood clotting status*
   b. Local site infection
   c. Ongoing infection (acute viral or bacterial illness)
   d. Patient refusal
   e. Allergy to steroid or anesthetics

   *NOTE: this contraindication does not apply if there is documentation that antiplatelet/anticoagulant medications can be stopped prior to the injection, or if compromised clotting status due to other causes (if present) will be corrected.

Additional injections for patients not experiencing at least 50% reduction in pain during the 6 weeks following the first one or two injections are not medically necessary.

Subsequent injections

D) The patient has experienced a documented reduction in pain of at least 50% for at least three months following the first injection; AND

E) The patient has NOT received an epidural steroid injection within the previous 6 weeks for the same pain; AND

F) The patient has NOT received 4 epidural steroid injections within the past twelve months in the same spinal region.

Repeat injections extending beyond 12 months will be reviewed for continued medical necessity.

NOTE: A particular patient will often exhibit a fair amount of variability in terms of response from one injection to another. If a patient has an established pattern of responsiveness to ESI prior to an ineffective ESI, subsequent injections may still be beneficial.

1. There are different techniques for ESI.
   a. No individual technique has been proven consistently superior across patients.
   b. Individual patients may respond better to a particular technique.
2. At different points in time, the same patient may have different generator(s) of similar symptoms, that could benefit from injection(s) at different location and/ or with different technique.
3. ESI often has significant advantage over other interventions in terms of cost, access, and potential risk.

RATIONALE

EVIDENCE BASIS

"For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. For non-radicular low back pain, there is likewise no convincing evidence that injections and other interventional therapies are effective, while there is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies." (HERC 2017)

"For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others found no differences versus placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials that compared epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, there are case reports of paralysis and infections. There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection, or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though one higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes." (HERC 2017)

"There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms. Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects. Although chymopapain chemonucleolysis is effective for radiculopathy due to herniated lumbar disc, it is less effective than discectomy and is no longer widely available in the United States, in part due to risk of severe allergic reactions. Three trials suggest that intradiscal steroid injection has similar efficacy to chemonucleolysis, although none were placebo controlled." (HERC 2017)

"For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions. Trials of IDET and radiofrequency denervation reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings, making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to one to two small placebo-controlled randomized trials (botulinum toxin injection, epidural steroid injection for nonradicular low back pain, PIRFT and sacroiliac joint steroid injection), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty….or other medications)." (HERC 2017)

A 2019 Health Technology Assessment of epidural steroid injections for cervical radiculopathy identified 6 RCTs evaluating ESI for treatment of cervical radiculopathy and determined that the overall quality of the evidence was low due to individual study limitations and a small quantity of evidence for each comparison of ESI to alternate treatment options. This report concluded that the evidence on ESI for cervical radiculopathy failed to demonstrate beneficial effects of ESI on pain or disability associated with cervical radiculopathy compared with an epidural injection of anesthetic alone. No available studies included a placebo group, thus it is unclear whether and to what extent any observed improvements after ESI are attributable to the anesthetic, the injection itself, placebo effects, or other factors. Based on the available evidence reviewed in the report, ESI appeared safe and well-tolerated, with reported AEs generally mild and transient. ESI does have potential for serious AEs, including paralysis. The report notes a need for

additional information to determine whether effectiveness of ESI varies by patient characteristics, type of ESI, and how ESI compares to well-defined controls as well as evidence for long-term outcomes in those treated with ESI. (Hayes 2019)

RELEVANT GUIDELINES

In guidelines issued by the American Society of Interventional Pain Physicians (ASIPP), patients may receive diagnostic injections (no more than two) at least one week apart (preferably two). If patients experience at least a 50% reduction in pain, they are eligible for therapeutic injections, to be provided every two to three months if there is evidence of at least 8 weeks of at least 50% pain relief. (ASIPP 2009).

CODES

CPT Code	Description
62310	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic sybstance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; cervical or thoracic
62311	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic sybstance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; lumar, sacral (caudal)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural, cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484	Injection(s), anesthetic agent and/or steroid, transoframinal 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, subarachnoid, or sacroiliac joint), including neurolytic agent destruction
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
J1020	Injection, methylprednisone acetate, 20mg
J1030	Injection, methylprednisone acetate, 40mg
J1040	Injection, methylprednisone acetate, 80mg

ICD-10 Code	Description
M47.20 – M47.28	Other spondylosis with radiculopathy
M50.10 – M50.13	Cervical disc disorder with radiculopathy
M51.14 – M51.17	Intervertebral disc disorders with radiculopathy
M53.0 – M53.1	Cervicocranial – cervicobrachial syndrome
M53.81 – M53.83	Other specified dorsopathies [cervical region]
M54.10 – M54.18	Radiculopathy
M54.2	Cervicalgia
M54.30 – M54.5	Sciatica and lumbago
M54.6	Pain in thoracic spine
M54.9	Dorsalgia, unspecified

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Extracorporeal Shockwave Therapy

Policy Number: 0020
Effective Date: February 2020
Reviewed Date: June 2023
Next Review: June 2024
Specialist Reviewer: Ryan Downey, DPM

BACKGROUND

CLINICAL BACKGROUND *(excerpted from INTC 2017)*

Extracorporeal shockwave therapy (ESWT) is based on the same mechanism of action as conventional shock wave treatment used to break kidney stones. Although the exact physiologic mechanism of effect for ESWT is unclear, it is thought that the shock waves work through direct and/or indirect effects that help to reduce pain transmission, break down calcium deposits and scarring, cause a temporary inflammatory response, and/or simulate healing of tissues. Therapy with ESWT usually consists of 1 to 3 sessions, during which 1000 to 3000 pulses of low- or high-energy shock waves are administered to the pain site. It is theorized that once the deposits are ablated, the associated pain subsides, and new blood vessel formation and tissue development follows.

POLICY AND CRITERIA

Extracorporeal shockwave therapy (ESWT) is considered experimental and investigational for all indications including (but not limited to) musculoskeletal conditions such as Achilles' tendonitis, plantar fasciitis, epicondylitis, as well as soft tissue indications, such as wounds and burns. There is insufficient evidence to determine whether ESWT is medically appropriate for any indication.

NOTE: This policy does not pertain to extracorporeal shock wave lithotripsy for treatment of kidney stones.

RATIONALE

EVIDENCE BASIS

The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence for extracorporeal shockwave therapy in 2017. Their findings include the following:

"Findings from existing systematic reviews and HTAs were mixed, with some authors concluding that the evidence base is conflicting, insufficient, limited, and/or weak, and others concluding that ESWT is an effective treatment for plantar fasciitis and is based on moderate- or high-quality evidence. Reviews with more positive results tended to focus on relatively high-energy ESWT and/or avoidance of anesthesia during ESWT treatment. ESWT for treatment of plantar fasciitis appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

In addition to existing systematic reviews and HTAs, evidence from randomized trials of patients with chronic plantar fasciitis that enrolled at least 100 patients were included. Based on these criteria, the body of evidence on ESWT for treatment of chronic plantar fasciitis includes 10 RCTs that evaluated ~2000 patients. In these RCTs, treatment with ESWT resulted in significantly improved overall pain, pain with daily activity, and pain with applied pressure compared to sham ESWT. However, findings were less consistent for other outcomes, including measures of function and pain with the first steps of the day. Although 10 randomized trials with more than 2000 patients were identified, the overall quality of evidence is low-to-moderate given the relatively small sample size, variations in treatment protocols, and inconsistencies in findings across outcomes.

Most of the studies used a double-blind, sham-controlled study design. Most studies used focused ESWT (as opposed to radial ESWT), although specific treatment parameters varied considerably across studies (e.g., energy flux density [EFD], number of pulses, number of ESWT sessions). Despite limiting enrollment to patients with treatment-refractory, chronic plantar fasciitis, several studies noted than sham patients had substantial improvements compared to baseline. Seven of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

The overall body of evidence on ESWT for treatment of wounds, ulcers, or burns includes 10 comparative studies of 473 wounds, ulcers, or burns. In these controlled studies, treatment with ESWT plus standard wound care resulted in significantly improved wound healing compared to either standard wound care alone or hyperbaric oxygen therapy (HBOT) plus standard wound care. Despite clinically heterogeneous study populations and treatment protocols, results were consistent across studies. ESWT for ulcers, wounds, and burns appears to be reasonably safe, although few studies evaluated adverse events as outcomes.

Although many of the studies found statistically significant differences in wound healing outcomes for ESWT versus standard wound care, the overall precision is poor due to the small total sample size (473 wounds, ulcers, or burns). There was notable clinical heterogeneity across studies and the findings for any single indication and treatment protocol are even more limited. Two studies had poor results reporting in which results were not clearly presented and/or data discrepancies were observed for text, tables, and figures. Two studies had inadequate randomization (e.g., based on odd vs. even days of week). Three studies excluded randomized patients with poor compliance or incomplete follow-up data. One study was terminated early due to apparent benefit of ESWT and the published results were from an unscheduled interim analysis. Nine of the 10 studies had some industry affiliation, including 1 or more co-authors currently or formerly employed by a device manufacturer and/or manufacturer-supposed equipment or funding.

Overall, these promising but preliminary findings suggest that ESWT plus standard wound care may result in improved wound healing compared to either standard wound care alone or HBOT plus standard wound care. Although 9 randomized trials were identified, the overall quality of evidence is low given the limitations of the included studies. Additional randomized, double-blind trials are needed to confirm these findings. Clinical input gathered on this topic was consistent with this review. SCPMG is considering an IRB-approved study as some clinicians have some experience with the technology and consider ESWT as a potential alternative to surgery in some patients with chronic plantar fasciitis."

CODES

CPT Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving humeral epicondyle
0299T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound
0300T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care, each additional wound
0512T-0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

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Northwest Region Utilization Review

UR 57: Facial Dermal Fillers Policy and Medical Necessity Criteria

Departments: Plastic Surgery	Number: UR 57
Section: KPNW Region	Effective: 08/10
Applies to: KPNW Region	Last Reviewed: 2/19, 2/20, 6/23
SME: Jennifer Murphy, MD - Plastic Surgery	Last Revised: 2/21, 2/22, 6/22
Medicare Criteria	

Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

The purpose of these criteria is to provide coverage of limited facial enhancement to patients with HIV-associated lipodystrophy to alleviate the stigma associated with this condition. Due to their appearance, patients with facial lipodystrophy syndrome (LDS) may become depressed, socially isolated, and in some cases, may stop their HIV treatments to halt or reverse this complication.

Many systemic illnesses cause bodily shape changes. Any weight loss from illness, chemotherapy, or voluntary weight loss will lead to some facial skin sagging. Kaiser Permanente does not cover the correction of these conditions. The specialist administering the injections will use his/her best judgment in determining the difference between HIV lipodystrophy and natural, age-appropriate atrophy and aging. Kaiser Permanente coverage extends to improving the gaunt look of lipodystrophy. Coverage is not meant to be a yearly touch up. Frequency of treatment will be determined by the specialist administering the injections.

DEFINITIONS

Facial Lipodystrophy/lipoatrophy: a progressive, symmetrical loss of subcutaneous fat that results in a facial abnormality such as severely sunken cheeks. This fat loss can be a result of aging or weight loss or can arise as a complication of HIV and/or antiretroviral therapy (ART).

Filler: an injectable substance that fills in hollowed areas created by lipoatrophy.

CRITERIA

Filler injections are covered when the following criteria are met:

1) The member has the following conditions:

a) diagnosis of human immunodeficiency virus (HIV),

AND

b) diagnosis of facial lipodystrophy/lipoatrophy, grades 3-4, related to HIV or antiretroviral therapy (ART).

AND

2) The filler is FDA approved for the treatment of facial lipodystrophy/lipoatrophy or otherwise approved by the KPNW Plastic Surgery Department (e.g., autologous fat transplantation).

CONTRAINDICATIONS

Coagulopathy, active infection (whether or not related to HIV disease), inadequate immune function.

OTHER CONSIDERATIONS

Multiple sessions may be necessary to complete the therapy depending upon the severity of the lipodystrophy. Grade 3 may take up to 4 sessions; and Grade 4 may take up to 8 sessions. The following link provides photographic examples of the Carruthers grading system (scale of 1- 4): www.facialwasting.org. If additional treatments are desired, the treating specialist will need to reevaluate the patient or repeat photos of the patient's face will be required to determine if further treatments are warranted. Re-treatment may be needed long term.

SPECIAL GROUP CONSIDERATIONS

These criteria apply to Medicare and Commercial group/individual members. They do not apply to Medicaid members.

CLINICAL

Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations Manual, Chapter 1, part 250.5- Dermal Injections for the Treatment of Facial Lipodystrophy Syndrome (LDS)- *Rev. 122, Issued: 06-04-10, Effective: 03-23-10, Implementation: 07-06-10)*

RATIONALE

BACKGROUND

UpToDate – "Injectable soft tissue fillers: Permanent agents":

- **Surgical approaches:** Plastic surgery is the main therapy for severe facial lipoatrophy; autologous fat transplantation or, more commonly, injections of biodegradable or nonbiodegradable gel fillers can be performed.
- **Fillers:** Plastic surgeons, dermatologists, and others with specific training have treated facial lipoatrophy with various injectable fillers (19,20). Fillers can be temporary or permanent. Overall, temporary fillers are preferred.
- **Autologous fat transplantation:** Autologous fat transplantation involves harvesting of a small intact lump of fatty tissue from the abdomen, cervicodorsal area, or elsewhere that can be processed into small fat "parcels" that are injected by syringe with local anesthesia (47). Use of autologous fat implantation may be less costly than gel fillers but is often limited by the lack of suitable donor sites in patients with extensive lipoatrophy (48).

EVIDENCE BASIS

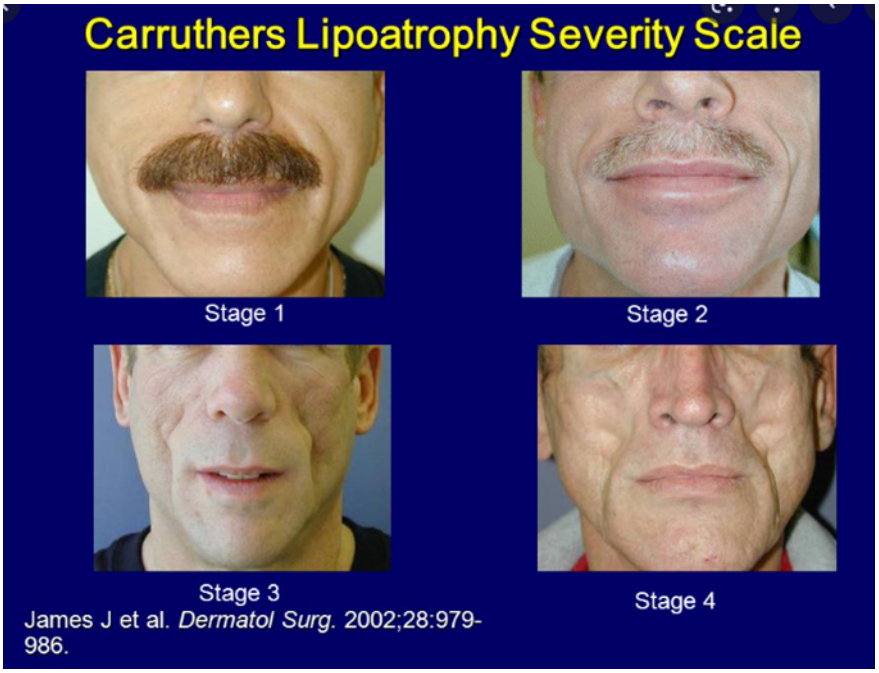
The Kaiser Permanente Interregional New Technologies Committee (INTC) reviewed the evidence on dermal injections for the treatment of facial lipodystrophy syndrome in 2010. A summary of their findings is provided below:

"There is sufficient evidence to determine that polylactic acid dermal filler injections are a medically appropriate treatment for select patients with HIV-associated facial lipoatrophy. The current evidence base consists of one RCT, several comparative studies and additional case series studies indicating improvements in skin thickness measurements and subjective ratings of lipoatrophy, including improved quality of life and patient satisfaction."[1]

The focus of the INTC assessment was on FDA approved dermal fillers (i.e., Sculptra, Radiesse and New-Fill) and did not describe evidence on autologous fat transplantation.

A 2013 systematic review of the durability, safety, and clinical outcomes from autologous fat grafting compared to hyaluronic acid and poly-L-lactic acid injectable fillers included 19 primary studies (12 on hyaluronic/PLLA filler, 7 on autologous fat), none of which made direct comparisons between treatment approaches. All included studies were relatively small in sample size (including fewer than 100 participants) and report a range of outcomes, thus, meta-analysis was not possible. Across studies, there were similar improvements in facial volume and durability of treatment between dermal fillers and fat transfer. However, patients treated with poly-L-lactic acid received more sets of injections than those treated with hyaluronic acid or fat transfer (3 or more sets of injections vs. up to 2 sets of injections, respectively). Studies of autologous fat transfer reported no serious adverse events or papule formation, whereas all reports of papule formation occurred in patients treated with poly-L-lactic acid.[2]

A 2018 prospective study (n=147) comparing Sculptra, Radiesse, Aquamid and autologous fat for treatment of HIV-induced lipoatrophy reports an improvement in self-perceived appearance and impact of lipodystrophy on quality of life in all treatment groups except the Radiesse group.[3]



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KAISER PERMANENTE®

UR 65 Gender-Affirming Procedures Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Stephanie Detlefsen, MD	Number: UR 65 Effective: 12/2023 Last Reviewed/Approved: 11/1/22, 1/2/24, 1/30/24

BACKGROUND

Goals of surgery: to bring appearance into the cisgendered range for the patient's expressed gender identity, with the goal of alleviating gender dysphoria/gender incongruence.

Internal & Outside Referral Guidelines:

Kaiser Foundation Health Plan (KFHP) provides Gender-Affirming Procedures for the treatment of gender dysphoria/ gender incongruence when the below medical criteria are met.
Members whose employer groups do not cover Gender-Affirming Procedures but who wish to access these services out of pocket, will be evaluated according to the same medical criteria.

POLICY AND CRITERIA

Members are eligible for coverage of gender-affirming procedures if they meet all of the following criteria and any related procedure-specific criteria (if they exist - see below):

1. Referral must be generated by a Gender Pathways Clinic (GPC) physician; AND
2. Age 18 years and older unless otherwise indicated in the below procedure-specific criteria; AND
3. Persistent, well-documented gender incongruence; and
4. Capacity to make a fully informed decision and to consent for treatment; and
5. Documented mental health assessment(s) and 1 WPATH letter from an experienced gender therapist in accordance with WPATH guidelines dated within the past 12 months; and
6. If significant medical or mental health concerns are present, they are reasonably well-controlled. Prior to placing a surgery referral the GPC physician should assess that there has been no significant change to mental health since the date of the WPATH letter. Prior to surgery, the surgeon should assess that there has been no significant change to mental health from the time of the referral to surgery. If there has been a significant change in mental health (e.g., ED or hospital admission related to mental health instability), patient should be referred back to the writer of the WPATH letter or to Mental Health for reassessment and care; and
7. Must be nicotine-free in order for surgery; AND
8. Patient is paneled with a Primary Care provider; AND
9. Meets BMI requirements if the specific procedure requires them (see below)

A. Chest Surgery

- **a. Masculinizing chest surgery** (chest contouring surgery, chest reduction)
  - **i.** Age 18 years or older OR age less than 18 years with parent/guardian consent or are legally emancipated.
- **b. Feminizing chest surgery** (Breast Augmentation)
  - **i.** 12 months of estradiol treatment unless contraindicated. Hormone therapy for at least 12 months is recommended to maximize breast development.

B. Genital Surgery (Vaginoplasty, vulvoplasty, labiaplasty, penectomy, orchiectomy, scrotectomy, hysterectomy, oophorectomy, metoidioplasty, phalloplasty, scrotoplasty, testicular implants, penile implants, monsplasty, vaginectomy, etc.)

a. 12 months of hormone therapy to allow maturation of some tissues, unless contraindicated.

C. Hair Removal

a. Genital Hair Removal in preparation for genital gender-affirming surgery

i. Surgical site hair removal can begin at the time of referral for vaginoplasty.

ii. Surgical site hair removal for phalloplasty can begin after consultation with a surgeon to determine graft site for surgery.

b. Body Hair Removal (Face, neck, back, chest, abdomen for members assigned male at birth)

i. Age 18 years or older OR age 16 years or older with parent/guardian consent or for those legally emancipated; AND

ii. Testosterone levels <100 ng/dL; AND

iii. On anti-androgen and/or hormone therapy for at least 2 years, unless contraindicated.

D. Hair Transplants

a. Patient with androgenic alopecia due to male assignment at birth; AND

b. Androgenic alopecia is not due to a side effect of medication (e.g., gender-affirming testosterone therapy); AND

c. 12 months of hormone therapy, unless contraindicated; AND

d. Documented failure or contraindication to standard conservative management (e.g., Finasteride, spironolactone, oral dutasteride, minoxidil)

E. Gender-affirming Facial Procedures

(To qualify for a referral to Plastic Surgery for consultation, must meet criteria "a" and "c"; to qualify for gender-affirming facial procedures, must meet criteria "a", "b" and "c".)

a. On hormone therapy for at least 12 months unless medically contraindicated; AND

b. Documentation by Plastic Surgery about which facial feature(s) causes member's gender incongruence and which facial features can be reasonably surgically altered; AND

c. Surgery is not for the purpose of reversing the appearance of aging

F. Body Contouring

a. Member has completed at least 12 months of hormone therapy to allow stable body fat redistribution to occur, unless contraindicated; AND

b. As BMI impacts body fat distribution, surgery will not be offered until a *stable* BMI < 30 is achieved *(stable is defined as 6 months or longer)*

G. Voice Modification Surgery

a. Gender-affirming voice modification surgery is considered medically necessary when:

i. Masculinizing surgery (pitch lowering surgery, e.g., Type III thyroplasty)

1. Member has completed 18+ months of consistent masculinization hormone therapy; AND

2. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 below 150 Hz as determined by a Speech Therapist

ii. Feminizing surgery (pitch elevation surgery, e.g., anterior glottal web formation, cricothyroid approximation (CTA))

1. Voice/speech therapy has been ineffective – member has ongoing voice complaints including inability to reliably maintain speaking F0 above 150 Hz as determined by a Speech Therapist

H. **Surgical Detransition Procedures**

Surgery to reverse partially or fully completed gender-affirming procedures when medically necessary as indicated by:

i. 2 WPATH letters within past 12 months; AND

ii. Documentation from GPC physician, surgeon, and mental health provider that surgical detransition procedures are necessary

I. Surgical Revisions

a. Surgical revisions following gender-affirming surgery may be considered medically necessary if at least one of the following is true, as determined by a physician board-certified in Plastic Surgery (or other specialty physician, as appropriate):
   i. Revision would result in improved function; OR
   ii. Revision is likely to result in relief of pain associated with the gender-affirming surgery; OR
   iii. Revision is intended to change physical appearance that is NOT within cisgender anatomic variation consistent with the member's gender identity. Revisions of prior gender-affirming procedures will not be covered when intended only to correct changes in form or symmetry that are due to natural processes, such as aging or changes in weight.

Special Group Considerations

These criteria apply to OR/WA Commercial members.

These criteria apply to Federal Employees Health Benefits (FEHB) members

These criteria apply to Medicare.

These criteria do NOT apply to WA Medicaid/Molina. Surgical procedures related to gender affirmation/reassignment are covered on a fee-for-service basis (HCA Physician-Related Services/Healthcare Professional Services Medicaid Provider Guide, Transgender Health Services; and WAC 182-531-1675)

OHP (Oregon Medicaid) see OHP Prioritized List, Guideline Note 127 for treatment of Gender Dysphoria.

Self-Funded (SF) groups must be verified to see if they have a transgender benefit (GRS in CM). If so, the above criteria applies.

Visiting Members: refer to National Visiting Member policy.

RATIONALE

EVIDENCE BASIS

The World Professional Association for Transgender Health (WPATH) *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8,* published in 2022, includes a summary of the evidence for gender-affirming procedures. Their findings include the following:

Gender-Affirming Procedures

"In appropriately selected TGD individuals, the current literature supports the benefits of gender-affirming surgery (GAS). While complications following GAS occur, many are either minor or can be treated with local care on an outpatient basis. In addition, complication rates are consistent with those of similar procedures performed for different diagnoses (i.e., non-gender-affirming procedures).

In individuals AFAB, gender-affirming chest surgery or "top surgery" (i.e. "subcutaneous mastectomy") has been studied in prospective, retrospective, and cross-sectional cohort. The efficacy of top surgery has been demonstrated in multiple domains, including a consistent and direct increase in health-related quality of life, a significant decrease in gender dysphoria, and a consistent increase in satisfaction with body and appearance. Additionally, rates of regret remain very low, varying from 0 to 4%. While the effect of top surgery on additional outcome measures such as depression, anxiety, and sexual function also demonstrated a benefit, the studies were of insufficient strength to draw definitive conclusions. Although further investigation is needed to draw more robust conclusions, the evidence demonstrates top surgery to be a safe and effective intervention.

In individuals AMAB, fewer studies have been published regarding gender-affirming breast surgery ("breast augmentation") and include 2 prospective, 1 retrospective cohort, and 3 cross-sectional cohort studies. All the studies reported a consistent and direct improvement in patient satisfaction, including general satisfaction, body image satisfaction, and body image following surgery. Owen-Smith et al. (2018) demonstrated a positive trend toward improvement in both depression and

anxiety scores with increasing levels of gender-affirming interventions. However, there was no statistical comparison between individuals who underwent top surgery and any other group.

Gender-affirming vaginoplasty is one of the most frequently reported gender-affirming surgical interventions; 8 prospective, 15 retrospective cohort, and 3 cross-sectional cohort studies have recently been reported.

Although different assessment measurements were used, the results from all studies consistently reported both a high level of patient satisfaction (78–100%) as well as satisfaction with sexual function (75–100%). This was especially evident when using more recent surgical techniques. Gender-affirming vaginoplasty was also associated with a low rate of complications and a low incidence of regret (0–8%).

Recent literature reflects the increased clinical interest in metoidioplasty and phalloplasty as reflected by 3 prospective cohort, 6 retrospective cohort, and 4 cross-sectional studies, which reviewed the risks and benefits of these procedures. In terms of urinary function, between 75 and 100% of study participants were able to void while standing. In terms of sexual function, between 77 and 95% of study participants reported satisfaction with their sexual function. Most of these studies report high overall levels of postoperative satisfaction (range 83–100%), with higher rates of satisfaction in studies involving newer surgical techniques. Two prospective and two retrospective cohort studies specifically assessed regret following surgery and found no transgender men experienced regret. While study limitations were identified, the reported results were consistent and direct.

Gender-Affirming Facial Procedures

"In recent years, facial GAS (FGAS) has received increased attention, and current literature supports its benefits. Eight recent publications include 1 prospective cohort, 5 retrospective cohort, and 2 cross-sectional studies. All 8 studies clearly demonstrated individuals were very satisfied with their surgical results (between 72% and 100% of individuals). Additionally, individuals were significantly more satisfied with the appearance of their face compared with individuals who had not undergone surgery. One prospective, international, multicenter, cohort study found facial GAS significantly improves both mid- and long-term quality of life. The results were direct and consistent, but somewhat imprecise because of certain study limitations. While gender-affirming facial surgery for AFAB individuals is an emerging field, current limited data points toward equal benefits in select patients. Future studies are recommended."

Voice Modification Procedures

"Reported acoustic benefits of pitch-raising surgery include increased voice pitch (average frequency (f_o)) and increased Min f_o (the lowest frequency in physiological voice range). TGD people's self-rating ratings show general satisfaction with voice postsurgery, although individuals who are interested in more comprehensive changes to vocal self-presentation may need to engage in behavioral interventions with a voice and communication specialist in addition to laryngeal surgery. Potential harms of pitch-raising surgery can be assessed and addressed in voice training by a voice and communication specialist. Reported harms of pitch-raising surgery include voice problems such as dysphonia, weak voice, restricted speaking voice range especially upper range (lowered Max f_o, in the physiological voice range), hoarseness, vocal instability, and lowering of frequency values over time, although the rate of these outcomes is inconsistent.

Research on pitch-lowering surgeries is limited. However, studies including eight TGD people who elected to undergo thyroplasty type III after continued dissatisfaction with hormonal treatment and one person who received injection augmentation after testosterone therapy and voice training, reported statistically significant lowering of fundamental frequency, perceived as pitch."

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KAISER PERMANENTE®

Northwest Region Utilization Review

UR 20.4 Gynecomastia Surgery Medical Necessity Criteria (Commercial members)

Department: Surgery
Section: Plastic Surgery
Applies to: KPNW Region
Review Responsibility: UROC
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; H. Jonathan Chong, MD (Plastic Surgery)
Catherine Lum, MD (Peds Endocrinology)

Number: UR 20.4
Effective: 7/09
Last Reviewed: 2/19, 2/20/24
Last Revised: 2/20, 7/20, 2/21, 6/21, 3/22, 2/23

MEDICAL NECESSITY CRITERIA FOR GYNECOMASTIA SURGERY

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* may vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

To be considered for consultation and/or surgical intervention for treatment of gynecomastia, all of the following must be met:

1. Presence of moderate or marked true gynecomastia*, diagnosed by clinical examination:
    a. In adolescent patients (15-18 y/o), moderate palpable glandular breast tissue exceeding areolar boundaries, with or without skin redundancy, present for >12 months. [1]
    b. In adult patients (>18 y/o), moderate palpable glandular breast tissue exceeding areolar boundaries, with or without skin redundancy, present for >6 months. [1]

    * In true gynecomastia, breast enlargement is due to proliferation of glandular breast tissue; on physical examination, there is a discrete palpable glandular mass. In pseudogynecomastia (i.e., lipomastia), breast enlargement is secondary to fat accumulation; on physical examination, there is no palpable glandular mass and the fingers will not meet any resistance. [1]
2. Endocrine assessment completed by primary care, with consultation by endocrinology or pediatric endocrinology if appropriate.
3. Physical exam completed including breast and testicular exam within the last 12 months.

4. Documentation indicating no offending medications, including anabolic steroids and/or illicit substances such as marijuana are contributing to the gynecomastia within the last 12 months. [14, 19]
5. Documentation indicating no other medical conditions such as renal failure, cirrhosis, endocrine problems, testicular or other HCG (human chorionic gonadotropin) secreting cancer, or malnutrition and refeeding are contributing to the gynecomastia. [3, 19]
6. Failed conventional medical treatments including stopping offending medications/substances, treating reversible medical conditions, using pain medications or consideration of 6 to 12-week trial of tamoxifen in appropriate candidates. [3, 16]
7. Minimum age 15 or completed or nearly completed puberty. [3, 14]
8. BMI less than or equal to 34. [7, 17, 20]
9. Members with a history of tobacco products* use must have:
    a. a documented "quit" date ≥6 months prior to referral for consultation, **or**
    b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).
**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher.
3. Obesity (BMI >34).
4. Any other surgical contraindications will be determined by the surgeon.

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial members
Policy does not apply to Medicare (see Medicare Plastic Surgery LCD 37020)
Policy does not apply to Washington Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder

RATIONALE

GENERAL CLINICAL INFORMATION AND EVIDENCE BASIS

1. Gynecomastia (enlargement of the male breast) is usually benign. [3]
2. Most cases of gynecomastia result from an imbalance between estrogenic (stimulatory) and androgenic (inhibitory) effects on the breast. [3]
3. Gynecomastia frequently occurs in a bimodal pattern during puberty (pubertal gynecomastia) and in men 50-80 years old (senescent gynecomastia). [3]

4. Pseudogynecomastia (adipose tissue without glandular proliferation) is common in obese men and needs to be differentiated from true gynecomastia. In true gynecomastia there may be a button of firm subareolar glandular tissue, or there may be a more diffuse collection of fibroglandular tissue. [3]
5. Absolute estrogen excess which contributes to gynecomastia: Leydig cell tumors, estrogen-producing adrenal tumors, tumors producing chorionic gonadotropin. [3]
6. Relative estrogen excess which contributes to gynecomastia: primary hypogonadism, Klinefelter syndrome, secondary hypogonadism, puberty, refeeding syndrome, renal failure and dialysis, cirrhosis of the liver, hyperthyroidism [3]
7. Drugs which contribute to gynecomastia include, but are not limited to: histamine H_2-receptor blockers, phenytoin, digoxin, spironolactone, nifedipine, reserpine and other cardiovascular drugs, diethylstilbestrol, testosterone antagonists, flutamide, leuprolide, finasteride, diazepam, tricyclic anti-depressants, phenothiazine, risperidone, haloperidol, alcohol, amphetamines, marijuana, heroin, methadone, anti-tuberculosis drugs, cytotoxic agents. [4, 14, 19]
8. Herbal products that can cause gynecomastia include lavender oil or tea tree oil. [4]
9. Lab screening should include: thyroid function, liver enzymes, serum creatinine and serum total testosterone, and *may* also include serum beta-hCG, estradiol, LH, FSH and prolactin, and serum DHEA-S or urine 17-keto-steroids as directed by endocrinology or per practice resource algorithm. [3]
10. Glandular tissue of more than 4 cm in diameter is unlikely to regress spontaneously. [19]
11. Gynecomastia may cause considerable psychological distress, especially in adolescents who are struggling with issues relative to sexual identity and self-image. If neither reassurance *nor* medical treatment is successful, surgery should be considered. [19]
12. Tamoxifen at 10 mg bid for 6 to 12 weeks has been shown to be helpful in several small studies in adolescents and adults. It is usually more effective early in the course of gynecomastia and is less likely to be helpful in long established gynecomastia. Although this is not an FDA approved indication, it is suggested as an option for adolescents and adults in UpToDate and other references if symptoms are significant and persistent. Testosterone is the appropriate treatment in hypogonadal men with gynecomastia. Tamoxifen should not be used in these patients. [4, 8, 14,16, 18, 21]

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KAISER PERMANENTE®

Northwest Utilization Review

UR 8 Home Health Admission Medical Necessity Criteria

Department: Continuing Care
Section: Home Health
Applies to: KPNW Region
Review Responsibility: UROC
SME: Preston Peterson, MD & HH Medical Director; Joclyn Tosch, RN

Number: UR 8
Effective: 8/97
Last Reviewed: 9/16, 8/19, 10/20, 9/22, 8/23
Last Revised: 9/17, 9/18, 9/21

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR HOME HEALTH ADMISSION

CRITERIA-See Special Group Considerations for Medicare-specific information

A. Patients must require skilled and intermittent care which can be safely provided in the home setting with reasonable expectation of clinical improvement or the need for these services are required to maintain the maximum practicable level of function.

Skilled care includes care services such as physical and occupational therapy, speech language therapy, medical and social services. "Skilled care" is care that must be provided by a Registered Nurse (RN), licensed physical or occupational therapist or speech and language pathologist, which is primarily rehabilitative in nature.

"Intermittent care" in general is not performed on a daily basis. In some cases, where daily care is required, it may be provided only for a period of short duration (weeks versus months).

B. Patient is homebound.

For purposes of the statute, an individual shall be considered "confined to the home" (homebound) if the following two criteria are met:

1. Criteria One: The patient must either:

    a. Because of illness or injury - need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence.

    OR

    b. Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets Criteria-One conditions, then the patient must ALSO meet two additional requirements defined below:

2. Criteria Two:

    a. There must exist a normal inability to leave home;

    AND

    b. Leaving home must require a considerable and taxing effort.

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited to furnish adult day-care services in a State, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration.

For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

OTHER REQUIREMENTS

Decisions for accepting patients for care by the Home Health Department are based on medical, nursing, therapy, and social information provided by the physician responsible for the patient's care and is determined after assessing the member's unique medical condition. Decisions are made by institutional personnel and staff of the Home Health Program.

Considerations Prior to Acceptance of patient for Home Health Services

- There are adequate and suitable department personnel and resources to provide the services required by the patient.
- Attitudes of patient and his family toward his care at home.
- There is a benefit to the patient's health to receive care at home as distinguished from care in a hospital, long-term care facility, or medical office setting.
- There is a reasonable expectation that patient's medical, nursing, therapy and social needs can be met adequately and safely in his residence, including the availability of a plan to meet medical emergencies.
- There are adequate physical facilities and equipment in the patient's residence for safe care.
- There is an assessment whether there is the availability of family or other caregiver in the home, with the ability and willingness to participate in the care and if it is required to assure the patient's safety and adequacy of care.

- There is an assessment of the degree of patient and family awareness of their rights and responsibilities.
- How recently the patient has had contact with the ordering physician.
- Assurance that services can be effectively coordinated through liaison with other organizations and individuals also providing care to the patient.
- Acceptance of any patient by Home Health is at the discretion of Continuing Care Services (CCS), which exists to provide home health services to members of the Kaiser Foundation Health Plan. Medical necessity denials are made by a MD or DO.

NOTE: In addition to the list of excluded services provided within a member's evidence of coverage (EOC), the following will be applied to all lines of business, except for Medicaid under some circumstances:

- **Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act** specifically exclude venipuncture (blood draws) as a basis for qualifying for home health services if this is the sole skilled service the beneficiary requires. However, the home health benefit will continue to pay for a blood draw if the beneficiary has a need for another qualified skilled service and meets all home health eligibility criteria.

CONTRAINDICATIONS

None

SPECIAL GROUP CONSIDERATIONS

See individual member's summary of benefits for specific coverage information. Procedures and/or services may be excluded under certain service agreements and/or employer group and individual contracts. In all instances, medical necessity must be established for the procedure to be a covered health benefit.

Commercial: None

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

Washington Medicaid: not applicable

Oregon Medicaid: not applicable

REFERENCES

Criteria Based: Medicare Regulations. CMS Publication 11 – Home Health Manual, Chapter 2. Coverage of Services.

Medicare Benefit Policy Manual, chapter 7, Home Health Services, section 30.1.1 (Patient Confined to the Home), effective 2/24/17.

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Northwest Region Utilization Review

UR 76: Home-Based Palliative Care Medical Necessity Criteria

Department: Continuing Care Services	Number: UR 76
Applies to: KPNW Region	Effective: 03/2021
Review Responsibility: Christina Kemper, MD; Allyson Snider, RN/Operations Manager	Reviewed: 03/21, 5/22
	Revised: 7/23

HOME-BASED PALLIATIVE CARE MEDICAL NECESSITY CRITERIA

DEFINITIONS

Home-based palliative care approach in the home aimed at optimizing quality of life, diminishing symptoms and mitigating suffering among people with a serious, complex illness. Services include palliative physician, nursing and social work services in the home. Home-based palliative care is supplemental medical care in addition to the patient's primary and specialty care teams.

CRITERIA

To qualify for Home-Based Palliative Care, patients must meet **ALL** of the following criteria:

1) Have a serious, progressive, terminal illness with a life expectancy of likely less than 1- 2 years;

2) Need specialty level assistance with symptom management;

3) Be functionally homebound;

4) Patients with dementia or pain unrelated to an advanced, progressive, terminal illness that causes symptoms, are *not* eligible.

SPECIAL GROUP CONSIDERATIONS

Commercial: None
Washington Medicaid: None
Oregon Medicaid: None
Medicare: HBPC services are not specifically covered by Medicare and are not addressed in an LCD/NCD but are covered by KPNW in the home to diminish symptoms of terminally ill members with a limited life expectancy. Although the current Senior Advantage EOC limits HBPC eligibility to members with a life expectancy of 7–12 months, the less restrictive criteria above will be applied to all requests.

INTRAOPERATIVE NEUROMONITORING

Policy Number: 0013
Effective Date: March 2019
Reviewed Date: June 2023
Next Review: June 2024
Clinician Reviewer: Kristophe Karami, DO, Neurosurgery

BACKGROUND

CLINICAL BACKGROUND

Intraoperative neurophysiologic monitoring (IONM) is a practice utilizing various procedures to evaluate the integrity of neural pathways during surgery. Techniques used in IONM include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), electroencephalography (EEG), and electromyography (EMG). By monitoring neural activity using these techniques, a neurophysiologist may be able to mitigate adverse effects by identifying and communicating changes to the surgical team.

POLICY AND CRITERIA

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.

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
    - 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	☑		
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	☑		

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:

- 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.

RATIONALE

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 concluded that IONM is sensitive and specific for detecting neurological complications during spinal surgery.[1] 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.[1]

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 evaluated 17 studies

comparing thyroid surgery with and without IONM.[2] 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.[2] Another systematic review reported a slightly lower incidence of RLNP among those who had thyroid surgery with IONM, but this difference was not statistically significant.[3]

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) released an updated position statement on IONM in January 2018. The AANS/CNS concluded that IONM is a reliable diagnostic tool for assessment of spinal cord integrity during surgery, but that there is insufficient evidence of a therapeutic benefit of IONM during spinal surgery.[4] In 2014, an analysis of all spine surgeries performed from 2007-2011 that were included in the Nationwide Inpatient Sample database that included 443,194 spine procedures in which 31,680 cases utilized IONM.[5] Iatrogenic neurological injury was rare, occurring in less than 1% with no difference in cases where IONM was used.[5] A 2015 analysis of a University of Texas Health Science's Center department's spine surgeries completed before and after adoption of a departmental policy limiting IONM use to intradural procedures and those for spinal deformity correction found that while utilization of IONM dropped from 38% of spinal cases to 7%, there was no change in incidence of neurological injury.[6] In fact, the only observed cases of injury occurred in cases utilizing IONM where the monitoring did not alert the surgeon to the injury.[6]

In 2017, "Guidelines for the Use of Electrophysiological Monitoring for Surgery of the Human Spinal Column and Spinal Cord" was approved by both the American Association for Neurological Surgeons and the Congress of Neurological Surgeons.[7] This Guideline was based on review of relevant published literature from 1966-2017. This 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 spinal surgery has not been correlated with improvements in neurological outcome that its expense does not appear justified.[7]

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.[8]

A 2019 Cochrane systematic review performed a comprehensive review and meta-analysis on the use of IONM for adults undergoing thyroid surgery.[9] In that review, authors found no definitive evidence that IONM was superior to visual identification of the recurrent inferior

laryngeal nerve during thyroid surgery. Measured outcomes included permanent RILN palsy (Relative Risk 0.77, 95% CI 0.33-1.77, p=NS), transient RILN palsy (RR 0.62, 95% CI 0.35-1.08, p=NS), and transient hypoparathyroidism (RR 1.25, 95% CI 0.45-3.47, p=NS). There were no significant differences in operative time.[9]

A 2021 Hayes Health Technology Assessment on IONM to detect and prevent surgical manipulations that could cause nerve damage during lumbar spinal discectomy alone or discectomy plus fusion identified 5 studies that evaluated IONM for detection of new neurological deficits and 11 studies that evaluated IONM for intraoperative guidance to prevent new neurological studies.[10] Hayes concludes that the overall body of evidence is very low in quality and not sufficient to make conclusions about the efficacy and safety of IONM for detection and prevention of new neurological deficits in patients undergoing lumbar discectomy or fusion.[10]

CODES

CPT/HCPCS	Description
General neuromonitoring	
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)	
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)	
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
Brainstem auditory evoked potentials (BAEP)	
92585	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive
92586	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited
Electroencephalography	
95822	Electroencephalogram (EEG); recording in coma or sleep only
95955	Electroencephalogram (EEG) during non-intracranial surgery (e.g., carotid surgery)
Electromyography	
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
Experimental and Investigational for Intraoperative Monitoring Use	
95907-95913	Nerve conduction studies
95930	Visual evoked potential (VEP) testing central nervous system, checkerboard or flash
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method

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.

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Northwest Utilization Review

UR 47 Massage (Soft Tissue/Myofascial Manipulation) Medical Necessity Criteria

Department: Utilization Review
Applies to: Kaiser Permanente NW Region
Review Responsibility: UROC
Subject Matter Expert: Lauren Kaplan, DO

Number: UR 47
Effective: 4/99
Last Reviewed: 2/18, 2/19, 3/20, 2/21
Last Revised: 3/17, 3/22, 2/23, 2/20/24

MEDICAL NECESSITY CRITERIA FOR MASSAGE (SOFT TISSUE/MYOFASCIAL MANIPULATION) THERAPY

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

PURPOSE

The purpose of these criteria and policy is to describe the policy and process requirements for massage (soft tissue/myofascial manipulation) and the medical necessity criteria for its coverage as a benefit.

DEFINITIONS

Maintenance Treatment/Therapy: Treatment once the functional status has remained stable for a given condition, without expectation of additional functional improvement; any treatment program designed to maintain optimal health in the absence of symptoms or in chronic conditions without exacerbation of symptoms.

POLICY AND CRITERIA

POLICY

When a member's contract covers massage as a benefit, soft tissue/myofascial manipulation may be applied as part of an integrated physical therapy plan of care for the treatment of musculoskeletal neck and back conditions. A physician referral to physical therapy is required. The physical therapist will perform an evaluation, and designate treatment interventions based on their objective findings. Soft tissue/myofascial manipulation will be included only if determined to be clinically indicated. When included in the plan, soft tissue/myofascial manipulation will be of short duration, and specific to the region being treated.

CRITERIA

A. Appropriate standard medical treatment without significant improvements, will have been attempted.

B. Documentation of previous treatment and functional impairment, including relevant history, physical findings, and evaluation must be documented for determination of appropriateness and/or as part of work-up.

C. Significant, sustainable and measurable improvement must be evident after the initial

trial of Physical Therapy treatments. If objective improvements are evident through documentation, additional Physical Therapy treatments may be clinically indicated. Services are not provided for on-going chronic or maintenance therapy.

D. Soft tissue/myofascial manipulation must be specific to the area involved and will not be applied for stress relief, palliative or maintenance treatment.

CONTRAINDICATIONS

Acutely inflamed joints, phlebitis (inflammation of vein(s)) or lymphangitis (inflammation of lymph vessel(s)) because of danger of embolism (obstruction of blood vessel), burns, acute dermatitis, local malignancy, osteomyelitis (inflammation of bone), local infection, advanced arteriosclerosis (hardening of arteries), advanced nephritis (inflammation of kidney(s)), and increased pain, swelling or stiffness in a joint persisting for more than two hours following the soft tissue/myofascial manipulation.

RATIONALE

EVIDENCE BASIS

A 2020 Agency for Healthcare Research and Quality (AHRQ) systematic review of noninvasive nonpharmacological treatment for chronic pain reports that massage improved function and/or pain for at least 1 month when used for chronic low back pain, neck pain, and fibromyalgia.[1] This review notes that effects across included studies were mostly small and that there was a paucity of long term evidence.[1] Additionally, no evidence suggested serious harms from massage, but data on harms was limited in the included studies.[1] A 2023 update to the Evidence Map of Massage Therapy produced by the VA Evidence-based Synthesis Program reports that 6 reviews published since 2018 show a potential benefit for massage therapy in patients with back pain, fibromyalgia, myofascial pain, and breast cancer-related pain with moderate certainty of evidence, whereas previously published reviews included conclusions of low and very low certainty of evidence, suggesting that conclusions of benefit of massage therapy have a stronger evidence base now than in 2018.[2]

Low Back Pain

A 2015 Cochrane systematic review of the effects of message therapy for people with low-back pain (primarily chronic or sub-acute low back pain) (k=25) reports improvements in pain outcomes and functional outcomes in the short term among those who received massage therapy compared to inactive control.[3] However, the quality of the underlying evidence in this review was judged to be “low” or “very low”, limiting confidence in the true effect of massage therapy for low-back pain.[3]

Neck Pain

A 2012 Cochrane systematic review of the effects of massage on neck pain (k=15) reports that massage may have a more beneficial effect on function and tenderness compared to control.[4] The reviewers rated the underlying evidence as low or very low quality and the majority of included studies did not adequately describe the massage technique and reported outcomes immediately post-treatment, which is too soon to determine clinical change.[4] Additionally, most studies did not report harms from massage and those that reported post-treatment pain, discomfort, and soreness as possible side effects of massage therapy.[4]

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UR 64: Maxillofacial Anomalies Policy & Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Subject Matter Expert: Dana Smith, MD (ENT); Kelly Dezura, DMD; James Rapson, DDS	Number: UR 64 Effective: 01/2013 Last Reviewed/Approved: 1/23, 1/30/24

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

MAXILLOFACIAL ANOMALIES POLICY and MEDICAL NECESSITY CRITERIA

The purpose of these criteria is to define KFHPNW coverage of limited maxillofacial prosthetic services included as part of a medical treatment plan for members with a maxillofacial anomaly when medically necessary to restore function.

ORS 743A.148 and 743.706 require health benefit plans to provide coverage for maxillofacial prosthetic services when necessary for restoration and management of head and facial structures that cannot be replaced with living tissue and are defective because of disease, trauma, or birth and developmental deformities when performed for the purpose of controlling or eliminating infection; controlling or eliminating pain; or restoring facial configuration or function.

Note that separate policies/criteria exist for coverage of:
1. dental and orthodontic services for treatment of craniofacial anomalies (UR 67),
2. general anesthesia for dental procedures performed in an inpatient/ambulatory operating room (UR 56),
3. surgical interventions for temporo-mandibular disorders (UR 49).

DEFINITIONS

Adjunctive treatment (as defined by ORS 743.706): secondary or ancillary prosthetic services provided in conjunction with the primary treatment of a medical condition.

Maxillofacial: related to or involving the bony structures of the upper and lower jaw and the face.

Prosthesis: an artificial replacement or substitute for a body part or function, either internal or external.

CRITERIA: Prosthetic Services for treatment of a MAXILLOFACIAL ANOMALY

NOTE: although dental implants are excluded from medical coverage, prosthetic services (including dental implants) must be covered when **ALL** of the following criteria are met.

1) An anomaly affecting the head and facial structures exists that are defective:
    - Because of disease, trauma, birth or developmental deformity; **AND**
    - Not due to the result of bacterial disease or poor hygiene, i.e. common dental and/or periodontal disease.
2) The requested prosthetic services are a necessary adjunctive treatment for the purpose of:
    - Controlling or eliminating infection
    - Controlling or eliminating pain

- Restoring facial configuration or functions such as speech, swallowing, or chewing, but not including cosmetic procedures rendered to improve the normal range of conditions.
  --a Participating speech pathologist or other appropriate Participating specialist has determined that the **inability to speak or swallow** (or ineffectiveness) is the result of missing teeth; OR
  --an appropriate Participating specialist has determined that the **inability to chew** (or ineffectiveness) is the result of missing teeth.

3) An appropriate Participating specialist agrees that the success and sustainability of the prosthesis is likely and that the prosthesis is expected to improve function (e.g. the bone and/or oral structures can support the prosthesis).

4) The service(s) is not requested in order to alter the alignment of teeth unless necessary for retention of a maxillofacial prosthesis.

5) The requested prosthesis is necessary for restoration and management of head and facial structures that cannot be replaced with living tissue.

6) The requested prosthetic services are the least costly, clinically appropriate treatment as determined by a Participating Provider.

CONTRAINDICATIONS: Bone or tissue cannot sustain a prosthesis

SPECIAL GROUP CONSIDERATIONS

OR/WA Commercial: Applies to all commercial groups

Oregon Medicaid: Criteria apply

Medicare: Criteria do not apply as mandate not applicable to Medicare. Local Coverage Determination L33738 requires coverage of facial prostheses when there is a loss or absence of **facial tissue** due to disease, trauma, surgery or a congenital defect (e.g. obturator and other facial prostheses). See the EOC for coverage of routine dental care, including dentures.

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Most procedures (e.g. advanced imaging and some DME) and levels of care other than office visits require prior-authorization (please refer to members' benefits but examples of exceptions to the above include outpatient labs, xrays, and preventive services).

Washington Medicaid: Criteria apply

REFERENCES:

Commercial Medical EOC EXCLUSIONS: Dental Services. Dental care including dental x-rays; dental services following accidental injury to teeth; dental appliances; dental implants; orthodontia; and dental services necessary for or resulting from medical treatment such as surgery on the jawbone and radiation treatment is limited to: (a) emergency dental services; or (b) extraction of teeth to prepare the jaw for radiation treatment.
The EOC also excludes "dental appliances and dentures" under DME section.

Monitored Anesthesia Care for Gastrointestinal Endoscopic Procedures

Policy Number: 0008
Effective Date: August 1, 2015
Reviewed Date: June 2023
Next Review: June 2024
Clinician Reviewer: Jarrod Larson, MD; Krishna Kasturi, MD

BACKGROUND

CLINICAL BACKGROUND *(extracted from KP MTAT 2010)*

Usual Care for Sedation During Colonoscopy and Routine Upper Endoscopy Procedures
Traditional sedation for routine colonoscopy and upper endoscopy procedures, including esophagogastroduodenoscopy (EGD), has involved a benzodiazepine with or without an opioid. These agents have known antidotes and are usually administered by a registered nurse (RN) under the supervision of an endoscopist.

Administration of Propofol (Source: verbatim from Singh et al., 2008; Vargo et al., 2009)
In recent years propofol (2, 6-di-isopropylphenol) has increasingly been utilized as an alternative method of sedation in endoscopy suites. Propofol was initially introduced in 1989 and has since then been widely used in critical care units and emergency departments for providing sedation. Although propofol is associated with a more rapid onset of action, its use for sedation during endoscopy by non-anesthesiologists in many parts of the world (particularly North America) has been limited by concerns of potential side-effects. This agent has also been administered by anesthesiologists and certified registered nurse anesthetists (CRNAs) within KP SCAL for endoscopy procedures. Emergency medicine physicians also appear to be privileged for at least select medical centers for GI procedures. Unlike other standard sedation agents, propofol does not have an antidote/reversal agent.

There are several key terms and definitions related to methods for the administration of propofol. Several terms and definitions were summarized recently in a position statement from the American Gastroenterological Association (AGA) (Vargo et al., 2009):

Monitored Anesthesia Care (MAC): Monitored anesthesia care (MAC) is the service provided by an anesthesia specialist to the patient undergoing a diagnostic or therapeutic procedure. In many instances, although not all, MAC results in deep sedation, and the normal airway protective reflexes may be lost. MAC can include general anesthesia with endotracheal intubation.

Standard Sedation: Standard sedation refers to the administration of intravenous drugs, usually a benzodiazepine and an opioid, under the supervision of an endoscopist. A level of moderate sedation is usually targeted.

Nonanesthesiologist-administered propofol (NAAP) Administration of propofol under the direction of a physician who has not be trained as an anesthesiologist. Propofol may be used either alone or in combination with 1 or more additional agents. A level of moderate-to-deep sedation is targeted with NAAP.

Nurse-administered propofol sedation (NAPS) Describes the administration of propofol as a single agent under the direction of a physician who has not been trained as an anesthesiologist. A level of deep sedation is targeted with NAPS.

Balanced propofol sedation (BPS) (Source: Vargo et al., 2009) Administration of the combination of a benzodiazepine, and opioid, and propofol under the direction of a physician who is not an

anesthesiologist. The opioid and benzodiazepine are each given as a single dose, which is followed by small incremental doses of propofol administered to achieve a target level of moderate sedation.

Another potential method for administering propofol involves computer assistance.

Computer Assisted Propofol Administration (CAPS) The SEDASYS (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio) system is a computer-assisted personalized sedation that integrates a suite of patient monitors (pulse oximetry, capnometry, EKG, noninvasive blood pressure (NIBP), and patient responsiveness) with oxygen and computer-controlled propofol delivery. Details on the published evidence on computer-assisted personalized sedation (CAPS) can be found in a SCPMG Technology Assessment and Guidelines Unit (TAG) assessment from February 2009.

POLICY AND CRITERIA

Monitored anesthesia care (MAC) is considered medically necessary during gastrointestinal endoscopic procedures when there is documentation by the operating physician and/or the anesthesiologist that demonstrates any of the following higher risk situations exist:

A. Prolonged or therapeutic endoscopic procedure requiring deep sedation; OR
B. A history of or anticipated intolerance to standard sedatives; OR
C. Increased risk for complication due to severe comorbidity. American Society of Anesthesiologists ASA class III physical status or greater; OR
D. Age 30 years or younger; OR
E. Pregnancy; OR
F. History of/or active drug or alcohol abuse; OR
G. Uncooperative or acutely agitated patients (e.g., delirium, organic brain disease, senile dementia); OR
H. Anxiety, defined as a history of excessive nervousness or worry that is difficult to control, causes significant distress and impairment or ICD-10 diagnosis of nervousness or anxiety/anxiety disorder; OR
I. Post-traumatic stress disorder (PTSD); OR
J. History of sexual abuse; OR
K. Hearing impairment; OR
L. Spasticity or movement disorder complicating procedure; OR
M. Increased risk for airway obstruction due to anatomic variant including ANY of the following:
    a. Documented history of previous problems with anesthesia or sedation; OR
    b. History of stridor or severe sleep apnea requiring oxygen and BIPAP; OR
    c. Dysmorphic facial features, such as Pierre-Robin syndrome or trisomy 21; OR
    d. Presence of oral abnormalities including but not limited to a small oral opening (less than 3 cm in an adult), high arched palate, macroglossia, tonsillar hypertrophy, or a non-visible uvula (not visible when tongue is protruded with patient in sitting position, e.g., Mallampati class greater than II), as documented by anesthesia; OR
    e. Neck abnormalities including but not limited to short neck, obesity involving the neck and facial structures, limited neck extension, decreased hyoid-mental distance (less than 3 cm in an adult), neck mass, cervical spine disease or trauma, tracheal deviation, or advanced rheumatoid arthritis as documented by anesthesia; OR
    f. Jaw abnormalities including but not limited to micrognathia, retrognathia, trismus, or significant malocclusion as documented by anesthesia.

GENERAL CLINICAL INFORMATION

1. Prolonged or therapeutic endoscopic procedures requiring deep sedation include:
    a. Endoscopic ultrasound (EUS)
    b. Double balloon enteroscopy (push endoscopy)
    c. Transanal endoscopic microsurgery (TEM)
    d. Endoscopic retrograde cholangio-pancreatography (ECRP)
2. History of or anticipated intolerance to standard sedatives includes:

    a. Patient has allergy to opiates or benzodiazepines
    b. Patient on chronic narcotics and/or benzodiazepines (e.g., using these medications consistently most days in a week, long term)
    c. Patient has an unstable neuropsychiatric disorder which would prevent cooperation
3. ASA class III physical status definition: A patient with severe systemic disease. Adult examples include, but are not limited to:
    a. Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, history (>3 months) of MI, CVA, TIA, or CAD/stents.
4. History of/or active drug abuse:
    a. Heavy Marijuana use: Daily use
    b. Alcohol abuse:
        i. National Institute on Alcohol Abuse and Alcoholism (NIAAA) definition for heavy alcohol use: For men, consuming more than 4 drinks on any day or more than 14 drinks per week. For women, consuming more than 3 drinks on any day or more than 7 drinks per week.

Special Group Considerations

These criteria apply to OR/WA Commercial members.

These criteria apply to Medicare.

RATIONALE

EVIDENCE BASIS

A 2010 Kaiser Permanente review of monitored anesthesia care for gastrointestinal disorders reported findings from systematic reviews, meta-analyses, randomized controlled trials, and published internal data (KP MTAT 2010). Their findings included the following:

"There is good evidence of improved patient satisfaction and reductions in discharge and recovery times with propofol used alone or in combination with other agents compared to standard sedation for colonoscopy exams. There is fair evidence from a KP SCAL-based comparative study of improved cecal intubation rates with propofol used as a single agent for sedation during colonoscopy. The evidence is of insufficient quantity or quality to draw definitive conclusions on differences in polyp detection. There is less comparative data on EGD procedures, but some evidence of improved recovery and patient satisfaction with propofol sedation. The evidence is of insufficient quantity and/or quality to draw definitive conclusions on comparative risk of serious adverse events, including death, neurologic injury, endotracheal intubations, bleeding, and colonic perforations during these procedures. There does not appear to be a significant difference in the risk of cardiopulmonary and respiratory events with propofol compared to standard sedation and no evidence of greater risk for serious adverse events for either colonoscopy or EGD procedures in lower risk patients (ASA I or II).

Following the review of one systematic review and two comparative observational studies, the evidence is of insufficient quantity and quality to draw definitive conclusions on the safety of anesthesiologist- versus non anesthesiologist-directed or administered propofol sedation in GI endoscopy. Controlled prospective studies with standardized protocols, patient selection, and reporting are needed.

Serious Adverse Events: The best available comparative evidence from the United States is a large observational registry study that suggests comparable rates of serious adverse events for anesthesiologist-directed propofol under monitored anesthesia care and gastroenterologist-administered propofol during colonoscopy procedures (0.16% and 0.14%) but a significantly increase risk of serious adverse events with gastroenterologist-administered propofol for upper endoscopy procedures, including EGDs (0.16% vs 0.5%). However, it is likely that these events differentially occurred in higher risk patients

(ASAI III) who were also included in the study. Overall Cardiopulmonary Adverse Events. There is evidence from the same study of a significant increased risk of overall cardiopulmonary events with endoscopic-administered propofol in ASA I or II patients undergoing colonoscopy and upper endoscopy. The majority of the cardiopulmonary events are most likely to be of minor clinical consequence, but the challenge remains to identify which cardiopulmonary events are more likely to result in serious adverse events and what risk factors are specific to upper versus lower endoscopy procedures.

The evidence is of insufficient quantity and quality to draw conclusions on the safety of RN-administered propofol as compared to standard sedation for colonoscopy and EGD in ASA I and II patients. Based on a review of several systematic reviews and randomized controlled trials, there is no evidence of a significant increase in risk of adverse events with propofol compared to standard sedation and the risks appear to be comparable. However, these studies were not adequately sampled to detect or compare rates of serious adverse events. Comparative data from large and well-designed observational studies is needed. The existing series of RN-administered propofol are large and report low rates of adverse events."

A 2020 Kaiser Permanente evidence scan for more recent evidence on monitored anesthesia care for gastrointestinal disorders includes the following findings:

A 2018 systematic review (k=5 studies) of trials and observational studies compares patient safety and procedure quality outcomes following non-anesthesiologist-administered propofol vs. anesthesiologist-administered propofol in routine upper or lower gastrointestinal endoscopy and reports no significant differences in rates of airway intervention, hypotension, gastrointestinal bleeding between groups. Rates of bradycardia and cardiopulmonary events were substantially higher in patients who received non-anesthesiologist administered propofol, however. Studies included in this review primarily included patients meeting ASA class I or II criteria, and where patients meeting ASA class III-IV were included, proportions were not balanced between groups. (Daza et al., 2018)

A 2017 systematic review (k=27 studies; n=2,518 patients) evaluating sedation-related adverse events associated with the use of propofol vs. nonpropofol (i.e., midazolam, meperidine, pethidine, remifentanil, and/or fentanyl) for endoscopic procedures reports no significant differences in pooled odds ratios for rates of hypoxia, hypotension, or arrhythmia by sedation type. An analysis of studies of nonadvanced endoscopy procedures indicates that patients who received propofol were 39% less likely to develop any complications compared to those receiving non-propofol sedation (OR: 0.61; 95% CI: 0.38-0.99). No difference in the complication rate for advanced endoscopy procedures was found between sedation groups. A subgroup analysis comparing complication rates by sedation administration (non-gastroenterologist vs. gastroenterologist) showed no differences in rates of cardiopulmonary complications. (Wadhwa et. al, 2017) A 2019 meta-analysis comparing sedation with propofol to traditional sedatives with or without propofol during endoscopic procedures (k=23 trials; n=3,854) reports no statistical difference in rates of hypotension, oxygen desaturation, and post-procedure anesthetic recovery when propofol is used alone or in combination with benzodiazepines and/or opioids. This review reports greater patient satisfaction among patients who were sedated with benzodiazepines and/or opioids compared to those sedated with propofol alone. This review did not include studies with participants groups with specific comorbidities, including obesity, cardiovascular disease, and pulmonary diseases. (Delgado et al., 2019)

CODES

CPT or HCPCS Code	Description
00740	Anesthesia for upper gastrointestinal endoscopic procedures, endoscope introduced proximal to duodenum
00810	Anesthesia for lower intestinal endoscopic procedures, endoscope introduced distal to duodenum
ICD-10 Code	**Description**
	All diagnoses

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Surgical Revascularization for Moyamoya Disease

Policy Number: 0016
Effective Date: February 4, 2020
Reviewed Date: June 2023
Next Review: June 2024
Clinician Reviewer: Kristophe Karami, DO, Neurosurgery

BACKGROUND

CLINICAL BACKGROUND *(excerpted from Acker 2018)*

"Moyamoya disease (MMD) is a rare cerebrovascular disease which is characterized by bilateral progressive steno-occlusion of basal cerebral arteries with emergence of coexisting abnormal net-like vessels. MMD is most frequent in Asian countries with an incidence ≤0.94/100 000, but an increase in incidence has been reported in non-Asian countries with some ethnic differences in disease characteristics. MMD shows worldwide a bimodal age distribution with a peak each in childhood and adulthood; thus, it is one of the leading causes of stroke in children and young adults. The most frequent initial symptom of MMD adults in Asians and whites is intracranial hemorrhage because of fragile blood vessels and ischemic events, respectively. Children with MMD worldwide frequently experience ischemic events."

POLICY AND CRITERIA

Members may be eligible for revascularization surgery to treat Moyamoya disease when the following criteria are met:

1. Member has definitive Moyamoya disease as defined by ALL of the following angiographic findings:
    a. Stenosis or occlusion of at least one of the following
        i. the terminal portion of the intracranial internal carotid artery;
        ii. the proximal portions of the anterior cerebral artery;
        iii. the middle cerebral artery;
    b. Development of abnormal vascular networks near the occlusive or stenotic lesions in the arterial phase;
    c. Bilateral cerebral lesioning; AND
2. Fulfillment of at least ONE of the following criteria:
    a. Symptoms of cerebral ischemia (e.g., ischemic stroke, transient ischemic attack, cognitive decline); OR
    b. Asymptomatic children (under 18 years of age) with:
        i. Decreased regional cerebral blood flow of less than 14%; OR
        ii. Inadequate perfusion reserve as evidenced by regional transit time greater than 8.0 seconds.

Revascularization may be direct, indirect, or a combination of both, depending upon the member's unique characteristics. Examples of indirect bypass procedures include (but are not limited to): encephaloduroarteriosynangiosis (EDAS), encephalomyosynangiosis (EDAMS), encephaloarteriosynangiosis (EAS), encephalodurogaleosynangiosis (EDGS).

RATIONALE

EVIDENCE BASIS

A comprehensive systematic review and meta-analysis (Ravindran 2019) evaluated methods of surgical revascularization among pediatric patients with Moyamoya disease. Their findings included the following:

"Of the indirect studies, a total of 488 patients were treated via encephaloduroarteriosynangliosis (EDAS), 82 via encephaloduroarteriomyosynangiosis (EDAMS), 410 via EDAS + encephalogaleosynangiosis (EGS), 216 via pial synangiosis, and 107 by dural inversion and EDAS. In the combined and direct cohort, all patients were treated with either superficial temporal artery-middle cerebral artery (STA-MCA) bypass, STA-MCA + encephalomyosynangiosis (EMS), or STA-MCA + EDAMS.

Future Stroke Incidence

The frequencies of future stroke events in patients undergoing either direct bypass alone, combined bypass, or indirect bypass alone were 1 per 190.3 patient-years, 1 per 108.9 patient-years, and 1 per 61.1 patient-years, respectively. The estimated stroke rates were 9.0% with indirect revascularization, 4.5% with direct revascularization alone, and 6.0% with combined revascularization. Stroke events most commonly occurred within the acute postoperative period, up to 7 days from surgery.

When pooling comparative studies, the overall RR of future stroke events after indirect versus combined/direct revascularization did not achieve statistical significance (RR 0.99, 95% CI 0.30–3.24, p = 0.112). On assessing the two comparative studies that included a direct bypass only, the overall RR for future stroke events after indirect versus direct bypass alone similarly did not achieve statistical significance (RR 1.84, 95% CI 0.36–9.40, p = 0.50). After pooling single-arm studies, the overall effect sizes (ESs) of the proportion of patients experiencing future stroke events were the same between combined/direct revascularization and indirect revascularization cohorts (0.04, 95% CI 0.00–0.12, and 0.04, 95% CI 0.02–0.06) and comparable with the direct bypass only cohort (0.07, 95% CI 0.03–0.16). In patients with moyamoya syndrome, the pooled postoperative stroke event rate was 6 of 102 patients (5.9%), as compared to 158 of 1864 (8.5%) in patients with idiopathic moyamoya disease.

Angiographic Outcome

The overall ESs of "excellent" angiographic outcome as designated by Matsushima grade A were 0.58 (95% CI 0.48–0.67) for indirect revascularization and 0.70 (95% CI 0.64–0.75) for combined/direct revascularization.

Complications

A total of 220 complications occurred in 1424 patients treated with indirect revascularization and 48 of 533 patients undergoing combined/direct revascularization. The most common complications in both cohorts were transient ischemic attack (TIA) and infarction within the 30-day postoperative period. Among those undergoing indirect revascularization, the 30-day ischemic infarct rate was 6.9%, relative to 2.1% in the combined/direct group. Hemorrhagic complications were similar between both groups, occurring in 1.9% of patients undergoing indirect revascularization and 0.6% of patients undergoing direct revascularization.

CODES

CPT Code	Description
61711	Anastomosis, arterial, extracranial-intracranial (e.g., middle cerebral/cortical) arteries
64999	Unlisted procedure, nervous system

ICD-10 Code and Description
I67.5 Moyamoya disease

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KAISER PERMANENTE®

Northwest Utilization Review

UR 48 Naturopathy Medical Necessity Criteria

Department: Utilization Review	Number: UR 48
Section: Alternative Medicine	Effective: 7/03
Applies to: Kaiser Permanente Northwest Region	Last Reviewed: 3/20, 2/21, 2/23, 2/20/24
Review Responsibility: UROC	Last Revised: 11/20, 9/21, 2/22
SMEs: Lauren Kaplan, DO	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR NATUROPATHIC SERVICES

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

CRITERIA

I. Naturopathic care is limited to the following conditions:

A. Symptomatic menopause (limited to hot flushes/night sweats), perimenopause, or premenstrual syndrome [1-6]
B. Chronic Irritable Bowel Syndrome [7-11]
C. Headache [12] (episodic or chronic, with symptom onset >3 months ago)
D. Chronic Eczema/Atopic Dermatitis [16-18]
E. Osteoarthritis [19-22]

- Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider

F. Chronic (lasting >3 months) pain syndromes (other than secondary to osteoarthritis or headache) [19-22]

- Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider

G. Chronic Fatigue Syndrome

- Only if patient has been evaluated and failed therapy (in clinic, virtual, or telephonic) through KPNW internal Complementary and Integrative Medicine Clinic, and referral is placed by the clinic provider

2. Recommended standard medical therapies (allopathic care) for the condition must be documented as objectively ineffective.

Standard medical therapies (allopathic care) for the above qualifying conditions to be tried are:

A. For symptomatic menopause, perimenopause, or premenstrual syndrome (PMS):

i. For hot flushes/night sweats associated with menopause:

[Hormone Replacement Therapy (HRT) requirement can be waived if there is documentation of a shared decision making between the appropriate clinician and the patient regarding HRT]

- 1 oral HRT (at least a 2-month trial with at least 1 dose adjustment), AND one or more of the following:
- 1 selective serotonin reuptake inhibitor (SSRI) or serotonin/norepinephrine reuptake inhibitor (SNRI) (at least a 1-month trial), or
- oral Clonidine

ii. For PMS symptoms:
- 3-month trial of SSRI, or
- 3-month trial of continuous oral contraceptive pill (OCP)

iii. For perimenopause bleeding:
- 6-month trial of progestin containing intrauterine device (IUD) or OCP

iv. For perimenopause mood disorder or hot flushes:
- 2-month trial of low dose OCP, or
- 1 SSRI or SNRI (at least a 1-month trial)

B. For Irritable Bowel Syndrome (IBS):

i. IBS-Diarrhea:
- Trials of at least 2 of the following:
  -dairy holiday or lactose-restricted diet
  -loperamide (if bowel movement cluster in the morning, consider a trial of evening dosing)
  -probiotic
  -cholestyramine

ii. IBS-Constipation predominant:
- minimize constipating meds (anti-cholinergics, narcotics), AND
- Trials of at least 2 of the following:
  -fiber (note that psyllium and Metamucil can cause bloating. If prone to bloating try Benefiber, Citrucel)
  -osmotic laxative (Miralax) titrated to effect- start at 17g/day, uptitrate every 3-5 days
  -probiotic

iii. IBS with generalized abdominal pain and cramping:
- Trials of at least 2 of the following:
  -dairy holiday
  -dicyclomine 10mg 4x/day (can increase to 20mg 4x/day if tolerated)
  -FODMAP diet (fermentable oligosaccharides, disaccharides, monosaccharides, and polyols)
  -nortriptyline every evening

C. For Headache (episodic or chronic, with symptom onset >3 months ago)**:**
- Adequate trial of prophylactic treatment:
  -at least 1 antiepileptic medication, or
  -at least 1 medication from another class (tricyclic antidepressant or beta-blocker), or
  -Botox (for migraine headaches only)

Adequate trial= a maximum tolerated dose of the selected medication for at least 2 months.

D. For Chronic Eczema/Atopic Dermatitis
- Failed treatment recommended by a dermatologist

E. For Osteoarthritis:

- at least a 1-month trial of regular (not *as needed*) use of at least 1 non-steroidal anti-inflammatory drug (unless patient refusal or contraindicated) (prescription or over-the-counter), AND
- at least 1 corticosteroid injections per affected joint in the last 24 months (for knee osteoarthritis) (unless patient refusal or contraindicated)

F. Chronic pain syndromes (other than secondary to osteoarthritis or headache): exempt from a trial and failure of standard medical therapies (allopathic care) requirement

G. Chronic Fatigue Syndrome (CFS): exempt from a trial and failure of standard medical therapies (allopathic care) requirement

3. Naturopathic care must be part of an integrated plan of care for a specific medical condition. This condition must be evaluated by the referring clinician face-to-face, telephonically, or via video or email prior to consideration of a referral to a non-plan naturopathic provider.
4. After the initial authorization, additional visits may be authorized when the following circumstances are met:

   A. The primary care clinician's assessment of the patient's condition demonstrates significant documented objective measurable improvement, AND
   B. The Treatment Extension Request provided by the Naturopath includes:
      - the patient's initial and current symptoms. The intensity of the symptoms must be documented in measurable terms.
      - a treatment plan with measurable goals for continued improvement in symptoms and functional status and an identified target date for the conclusion of therapy.
      - documentation by the naturopath that improvement in the patient's symptoms and/or functional status is expected to be sustainable with additional short-term treatment.
      - Treatment must have a direct therapeutic relationship to the patient's referral diagnosis.

ADDITIONAL INFORMATION and REQUIREMENTS

1. The KPNW Complementary and Integrative Medicine (CIM) Clinic can provide patients with advice on diet, behavior modification, herb supplements, and other modalities. The clinic is appropriate for KPNW members with an interest in holistic care who are highly motivated from the standpoint of lifestyle modification.
2. If an external referral is needed, all authorized services for naturopathic care will be provided by a member of NaturoNet through Complementary Healthcare Plans' network.
3. All prescriptions and/or naturopathic services are reviewed for benefit and medical necessity prior to authorization. Herbs and supplements are not covered under the prescription drug benefit. Prescription drugs must be in the Kaiser Permanente formulary to be covered.
4. Procedures, evaluations, and diagnostic testing, including laboratory tests, that are determined by a network provider (MD, DO, NP or PA) to be medically necessary are to be ordered by a network provider.

SPECIAL GROUP CONSIDERATIONS, IF BENEFIT IS COVERED

Commercial: Covered for all Washington groups as a mandate
Medicare: Coverage varies, check CM or EPIC
Washington Medicaid: Check CM or EPIC
Oregon Medicaid: These criteria do not apply to OHP

Evidence/Source Documentation

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KAISER PERMANENTE® Northwest Region Utilization Review

UR 69: Orthognathic Surgery Medical Necessity Criteria

Department: Non-Behavioral Health Section: KPNW Region Applies to: KPNW Region Review Responsibility: Kelly Dezura, DMD; Alexis Kleinman, DMD	Number: UR 69 Effective: 01/2017 Reviewed: 03/17, 3/18, 3/19, 3/21, 3/22, 5/23 Revised: 3/20, 4/20

ORTHOGNATHIC SURGERY MEDICAL NECESSITY CRITERIA

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

PURPOSE

The purpose of these criteria is to define KFHPNW coverage for orthognathic surgery to treat a limited number of medical conditions, as mandated by WAC 284-43-5640.

DEFINITIONS

Orthognathic Surgery- the surgical correction of abnormalities of the mandible and/or maxilla. The underlying abnormality may be present at birth or may become evident as the patient grows and develops or may be the result of traumatic injuries.

Malocclusion- imperfect positioning of the teeth when the jaws are closed. The condition may also be referred to as an irregular bite, crossbite, or overbite.

Congenital- a condition present at birth such as a cleft lip or cleft palate.

CRITERIA

Orthognathic surgery and supplies are covered for any of the following:

1) conditions resulting from a skeletal malocclusion which resulted from TMJ arthritis, ankylosis, trauma or tumor and is not amenable to orthodontic therapy alone.

2) sleep apnea with a referral from a Sleep Medicine specialist. Patient must have documented severe OSA (obstructive sleep apnea) or the patient has documented mild-moderate OSA with severe symptoms (based on Epworth Sleepiness Scale) with an identifiable dentofacial deformity such as maxillary or mandibular hypoplasia. Patient is also either intolerant or unable to use CPAP.

3) a congenital anomaly that is not amenable to orthodontic therapy alone with a referral from a cranio-facial specialist (e.g. ENT, Cranio-facial Surgeon, Oromaxillo-facial Surgeon).

SPECIAL GROUP CONSIDERATIONS

Although this is a WA State mandate, the coverage criteria will be universally applied to all lines of business beginning 1/1/17 except as follows:

Washington and Oregon Medicaid- these criteria do not apply to Medicaid.

Added Choice/POS: members may directly access non-KP providers under their Tier 2 and Tier 3 benefits, without prior-authorization, for office visits that do not include a procedure. Procedures and levels of care other than office visits require prior-authorization.

REFERENCES

WAC 284-43-5640; Essential health benefit categories, section (3)b,iii,B

KAISER PERMANENTE

Northwest Region Utilization Review

UR 20.2 Panniculectomy and Removal of Excess/Redundant Skin Medical Necessity Criteria

Department: Surgery	Number: UR 20.2
Section: Plastic Surgery	Effective: 4/03
Applies to: KPNW Region	Last Reviewed: 2/19, 2/20/24
Review Responsibility: UROC	Last Revised: 4/20, 2/21, 6/21, 2/22, 3/22, 2/23
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; H. Jonathan Chong, MD (Plastic Surgery)	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR PANNICULECTOMY AND REMOVAL OF EXCESS/REDUNDANT SKIN

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

Panniculectomy: The excision of an apron of abdominal tissue overhanging the inguinal crease (panniculus).

Abdominoplasty: Cosmetic abdominal contouring surgery that includes skin removal.

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

CRITERIA FOR ABDOMINAL PANNICULECTOMY CONSULTATION AND/OR SURGERY

Panniculectomy may be considered medically necessary in the following situations:

A. Panniculectomy is being requested by a surgeon because of difficult surgical access, where the panniculus will interfere with surgery,

OR

B. Panniculectomy is being requested by a patient who meets ALL of the following criteria:

1. The panniculus hangs below the level of the mons pubis (hair bearing area) and completely covers the mons pubis on direct (un-angled) frontal view.
2. There is documentation that the panniculus:
   a. interferes with ambulation OR
   b. causes recurrent chronic rashes, infections, cellulitis, or non-healing ulcers under the panniculus with documentation of at least a 3-month trial and failure of treatment with prescribed or over-the counter topical medications.

3. Patient's weight has reached a plateau for at least the last 6 months (within 10 lbs of current weight), AND 1 of the following:

   a. Pt with no history of bariatric surgery.

   b. For patients with history of bariatric surgery, 18 months or more has elapsed following bariatric surgery (total of 18 months from day of surgery, including stable weight during the last 6 months).

4. Members with a history of tobacco products* use must have:

   a. a documented "quit" date >6 months prior to referral for consultation, **or**

   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)

CRITERIA FOR REMOVAL OF EXCESS/REDUNDANT SKIN OR TISSUE CONSULTATION AND/OR SURGERY
(other than abdominal fat/panniculus)

Excess/redundant skin or tissue removal may be considered medically necessary in the following situations:

1. Excess/redundant skin or tissue removal is being requested by a surgeon because of difficult surgical access, where the excess/redundant skin or tissue will interfere with surgery,

OR

2. Excess/redundant skin or tissue removal is being requested by a patient with documented recurrent chronic rashes, infections, cellulitis, or non-healing ulcers under the excess skin or tissue with documentation of at least a 3-month trial and failure of treatment with prescribed or over-the counter topical medications.

AND

3. Members with a history of tobacco products* use must have:

   a. a documented "quit" date >6 months prior to referral for consultation, **or**

   b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff)

**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher.
3. Any other surgical contraindications will be determined by the surgeon.

OTHER REQUIREMENTS

Relevant history and physical findings establishing medical necessity must be documented.

Panniculectomy or abdominoplasty, with or without diastasis recti repair, for the treatment of back pain or knee pain is not considered medically necessary.

Cosmetic services (see definition above) are specifically excluded by the members' benefit coverage. This exclusion does not apply to services that are covered under "Reconstructive Surgical Services" or services that are medically necessary.

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Criteria apply to Commercial members
Criteria do not apply to Medicare for panniculectomy (see Medicare Plastic Surgery LCD 37020)
Oregon Medicaid: subject to eligibility on OHP Linefinder
WA Medicaid/Molina: these criteria do not apply, refer to WA State Health Care Authority Provider Billing Guide

RATIONALE

EVIDENCE BASIS

Panniculectomy:

A 2018 systematic review of the effects of body contouring surgery (including panniculectomy) on post-bariatric patients reports significant improvement in physical functioning, psychological well-being, and global quality of life scores following body contouring surgery.[1]

Tobacco Use:

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following abdominoplasty.[2] These complications include wound healing due to increased incidence of flap necrosis, infection, and wound separation in, all of which were significantly more common among smokers compared to non-smokers.[2] A 2015 systematic review of the association between smoking status and outcomes of plastic surgery reports significantly increased odds of surgical site infections, delayed wound healing, and cutaneous necrosis among patients who were smokers compared to non-smokers.[3]

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Pre-implantation Genetic Testing

Policy Number: 0009
Effective Date: August 1, 2015
Reviewed Date: June 2023
Next Review: June 2024
Clinical Reviewer: Brian Pfeiffer, DO

BACKGROUND

CLINICAL BACKGROUND *(excerpted verbatim from NHS 2013)*

"Preimplantation genetic testing is a technique used in reproductive medicine to identify inherited genetic defects in embryos created through in vitro fertilization (IVF). Preimplantation genetic diagnosis (PGD) can be offered when one or both parents have, or are carriers of, a known genetic abnormality; testing is performed on embryos created through IVF to determine whether they are at risk of genetic disease.

The use of PGD enables couples at risk of passing on an inherited disorder to decrease the risk of having an affected child significantly… PGD represents the only way for parents to have an unaffected child to whom they are both biological parents, without risking the need for termination of pregnancy. PGD is one of several reproductive options available for couples at risk of passing on a genetic condition, but the fact that the technology requires a highly skilled technical team and laboratory set up means it is significantly more expensive than the more common prenatal diagnosis option (PND)… The two commonly used post-conception diagnosis procedures [for PND] are amniocentesis and chorionic villus sampling (CVS) at 16 and 11 weeks, respectively. If the fetus is found to have the genetic condition of concern, the parents have to make difficult decisions about whether or not to opt for termination of the pregnancy. Termination of pregnancy is not an acceptable option for some couples."

DESCRIPTION OF THE TECHNOLOGY

"PGD requires IVF with or without intra-cytoplasmic sperm injection (ICSI), embryo biopsy for DNA sampling, genetic testing, and selected embryo transfer. DNA can be extracted from the oocytes (polar bodies) or from embryonic cells as one blastomere from a cleavage-stage embryo or 5 to 10 trophectoderm cells from a blastocyst-stage embryo. The genetic material is then tested for either single-gene mutations, using molecular biology techniques (PCR, PCR-multiplex), or for chromosomal translocation and de novo aneuploidy, using cytogenetic techniques such as FISH or CCS. The latter is the emerging new cytogenetic technique that consists of identifying the whole chromosomal complement (24 chromosomes). CCS can be accomplished through microarray technology such as aCGH and SNP or through qPCR. As the cells are being tested, the embryos remain in IVF media culture. If the biopsied cell or cells are shown to be unaffected for the genetic disorder in PGD or to carry a euploid embryo in PGS, then that particular embryo is considered an apt candidate for transfer into the uterus." (excerpted verbatim from Dahdouh 2015)

There are multiple types of pre-implantation genetic testing:

- **PGD** is used to identify inherited genetic defects in embryos created through IVF.
- **PGT-M** is used to detect single gene disorders.
- **PGT-SR** is used to detect structural chromosomal abnormalities.
- **PGT-A** is used to detect aneuploidies (presence of extra chromosomes or absence of one or more chromosomes).

POLICY AND CRITERIA

Pre-implantation genetic testing (PGT) is considered medically necessary when BOTH of the following criteria are met:

1. There must be documentation confirming that PGT is medically necessary to detect a single gene disorder (via PGT-M) or structural chromosomal abnormality (via PGT-SR) whose expression in the fetus or child would be expected to have a significant adverse medical impact and that detection in the pre-implantation period would directly affect reproductive decisions; AND
2. One of the following clinical circumstances must be documented:
    a. One genetic parent has a balanced, reciprocal translocation or Robertsonian translocation; OR
    b. One genetic parent has a single gene autosomal dominant disorder; OR
    c. Both genetic parents are known carriers of the same autosomal recessive disorder; OR
    d. The female genetic parent is a known carrier of an X-linked disorder.

The biopsy procedure to obtain a cell sample from an embryo and perform the necessary genetic testing for PGT is covered when the above criteria are met. However, the procedures and services (such as IVF) required to create the embryos to be tested and the transfer of embryos to the uterus after testing, are covered ONLY for members with advanced reproductive technology (ART) benefits and who meet medical necessity criteria for IVF (in vitro fertilization).

PGT is considered NOT medically necessary when the above-outlined criteria are not met.

PGT-A is considered NOT medically necessary for any indication.

RATIONALE

EVIDENCE BASIS

There is moderate strength of evidence that pre-implantation genetic diagnosis may accurately identify the presence of single gene defects in high-risk embryos of couples with a known genetic disorder. Estimates of sensitivity range from 96% to 99%, and estimates of specificity range from 80% to 85%.

There is low strength of evidence that pre-implantation genetic diagnosis does not affect neonatal outcomes such as birth weight.

There is insufficient evidence to estimate the cost-effectiveness of PGD compared to traditional prenatal testing in couples with a known genetic disorder because no studies have formally evaluated this question.

In May 2015, the Society of Obstetricians and Gynaecologists of Canada performed a comprehensive review of the literature regarding preimplantation genetic diagnosis and screening (Dahdouh 2015). The review was conducted to inform SOGC recommendations regarding preimplantation genetic testing, which are outlined under the Guidelines section of this document. The Dahdouh review did not directly report findings regarding the diagnostic accuracy of preimplantation genetic diagnosis. However, the references discussed in the Dahdouh review provided the additional detail needed. The estimated sensitivity of PGD for single gene mutations was between 96.6% and 99.2%, with estimated false negative rates between 0.8% and 3.4%. False positives were more common, with rates between 9.1% and 14.3% (Dreesen 2008 and Dreesen 2013 in Dahdouh 2015).

> “Generally, the most reliable PCR-PGD protocols employ multiplex PCR. In addition to amplification of a DNA fragment encompassing the mutation site, extra fragments containing linked polymorphisms are amplified to avoid misdiagnosis due to ADO, and at least one highly polymorphic marker is amplified to detect possible contamination. Another strategy used to decrease ADO is blastocyst biopsy, with frozen embryo transfer for PGD of monogenic diseases.

It has been associated with higher genotyping and implantation rates and lower amplification failure and ADO than traditional blastomere biopsy."

Eldar-Geva (2014) performed a prospective analysis of 242 children born after PGD, along with 242 born after intracytoplasmic sperm injection (ICSI) and 733 born after spontaneous conception. Authors compared neonatal outcomes and reported that birth weight among babies born after PGD was not significantly different from those born after spontaneous conception. The overall low birth weight rate was 4.4% for PGD (compared to 12.0% for ICSI and 5.7% for spontaneous conception), and intrauterine growth restriction rate was 5.1% for PGD (compared to 9.5% for ICSI and 5.5% for spontaneous conception). Authors made the following conclusion: "Embryo biopsy itself did not cause intrauterine growth restriction or low birth weight compared with SC, despite lower gestational ages with PGD. The worsened outcomes in ICSI compared with PGD pregnancies may be due to the infertility itself."

Dreesen (2014) reported the sensitivity and specificity of PGD for identification of monogenic diseases as part of the ESHRE PGD consortium study. Authors performed a retrospective analysis of 940 untransferred embryos, and estimated sensitivity of 99.2% and specificity of 80.9%. Overall, 93.7% of embryos were correctly classified. Authors noted that diagnostic accuracy was statistically significantly better when PGD was performed on two cells than one cell (p=0.001).

RELEVANT GUIDELINES

American College of Obstetricians and Gynecologists

ACOG issued a committee opinion in March 2020 on preimplantation genetic testing that includes the following recommendations:

- Preimplantation genetic testing comprises a group of genetic assays used to evaluate embryos before transfer to the uterus. Preimplantation genetic testing-monogenic (known as PGT-M) is target to single gene disorders. Preimplantation genetic testing-monogenic uses only a few cells from the early embryo, usually at the blastocyst stage, and misdiagnosis is possible but rare with modern techniques. Confirmation of preimplantation genetic testing-monogenic results with chorionic villus sampling (CVS) or amniocentesis should be offered.
- To detect structural chromosomal abnormalities such as translocations, preimplantation genetic testing-structural rearrangements (known as PGT-SR) is used. Confirmation of preimplantation genetic testing-structural rearrangements results with CVS or amniocentesis should be offered.
- The main purpose of preimplantation genetic testing-aneuploidy (known as PGT-A) is to screen embryos for whole chromosome abnormalities. Traditional diagnostic testing or screening for aneuploidy should be offered to all patients who have had preimplantation genetic testing-aneuploidy, in accordance with recommendations for all pregnant patients.

In March 2017, ACOG issued a committee opinion entitled "Carrier Screening for Genetic Conditions" (ACOG 2017). Specifically with regard to hemoglobinopathies, the authors state the following regarding preimplantation genetic diagnosis:

> "Couples at risk of having a child with a hemoglobinopathy may benefit from genetic counseling to review their risk, the natural history of these disorders, prospects for treatment and cure, availability of prenatal genetic testing, and reproductive options. Prenatal diagnostic testing for the mutation responsible for sickle cell disease is widely available. Testing for α-thalassemia and β-thalassemia is possible if the mutations and deletions have been previously identified in both parents. These DNA-based tests can be performed using chorionic villi obtained by chorionic villus sampling or using cultured amniotic fluid cells obtained by amniocentesis. For some couples, preimplantation genetic diagnosis in combination with in vitro fertilization may be a desirable alternative to avoid termination of an affected pregnancy. Preimplantation genetic diagnosis has been successfully performed for sickle cell disease and most types of β-thalassemia."

In March 2017, ACOG issued a committee opinion titled "Carrier Screening in the Age of Genomic Medicine" (ACOG 2017). This Committee Opinion includes the following recommendations relevant to preimplantation genetic testing:

- If a carrier couple (ie, carriers for the same condition) is identified before pregnancy, genetic counseling is encouraged so that reproductive options (eg, donor gametes, preimplantation genetic diagnosis, prenatal diagnosis) can be discussed.

American Society of Reproductive Medicine

The ASRM issued a practice committee opinion on preimplantation genetic diagnosis. The committee opinion outlines the following as indications for PGD:

> "PGD is indicated for couples at risk for transmitting a specific genetic disease or abnormality to their offspring. For carriers of autosomal dominant disorders, the risk that any given embryo may be affected is 50%, and for carriers of autosomal recessive disorders, the risk is 25%. For female carriers of X-linked disorders, the risk of having an affected embryo is 25% (half of male embryos). PGD also can be performed and may be elected by patients who carry mutations such as BRCA1 that do not cause a specific disease but are thought to confer significantly increased risk for a disease. In some cases, there may be more than one indication for PGD, such as when human leukocyte antigen (HLA) matching is performed in conjunction with testing for a specific mutation.
>
> For individuals who carry a balanced chromosomal translocation, inversion, or other structural chromosomal rearrangement, there is increased risk that their gametes will have an unbalanced genetic composition due to excess missing genetic material. An embryo derived from the union of such an unbalanced gamete with a partner's normal gamete also will have an unbalanced genetic composition and may be identified using telomeric probes specific for the loci of interest that must be selected for individual patients, according to their unique abnormality."

Overall, the ASRM practice committee opinion made the following recommendations regarding PGD (ASRM 2007):

- "Before PGD is performed, genetic counseling must be provided to ensure that patients fully understand the risk for having an affected child, the impact of the disease on an affected child, and the limitations of available options that may help avoid the birth of an affected child.
- PGD can reduce the risk for conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell.
- Prenatal diagnostic testing to confirm the results of PGD is encouraged strongly because the methods used for PGD have technical limitations that include the possibility for a false negative result."

ASRM also issued an ethics committee opinion specifically addressing the use of PGD for serious adult-onset conditions. The committee made the following conclusions:

> "After careful review and consideration, the Committee concludes, based on the arguments outlined above, that PGD for adult-onset conditions is ethically justified when the condition is serious and no safe, effective interventions are available. The Committee further concludes that reproductive liberty arguments ethically allow for PGD for adults-onset conditions of lesser severity or penetrance. In the latter cases, the application of the technology hinges on evidence that PGD is a relatively low-risk procedure; this evidence may change. The complexity of the scientific, psychological, and social issues involved in this arena compels the Committee to strongly recommend that an experienced genetic counselor play a major role in counseling patients considering such procedures."

Society of Obstetricians and Gynaecologists of Canada (SOGC)

The SOGC guideline recommendations are based off the systematic review by Dahdouh and colleagues (2015). Authors made the following recommendations, with the overall quality of the evidence assessment and classification of the recommendation noted in parentheses (see Appendix I for the rating key used by SOGC):

1. Before preimplantation genetic diagnosis is performed, genetic counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the risk of having an affected child, the impact of the disease on an affected child, and the benefits and limitations of all available options for preimplantation and prenatal diagnosis. (III-A)
2. Couples should be informed that preimplantation genetic diagnosis can reduce the risk of conceiving a child with a genetic abnormality carried by one or both parents if that abnormality can be identified with tests performed on a single cell or on multiple trophectoderm cells. (II-2B)
3. Invasive prenatal or postnatal testing to confirm the results of preimplantation genetic diagnosis is encouraged because the methods used for preimplantation genetic diagnosis have technical limitations that include the possibility of a false result. (II-2B)
4. Trophectoderm biopsy has no measurable impact on embryo development, as opposed to blastomere biopsy. Therefore, whenever possible, trophectoderm biopsy should be the method of choice in embryo biopsy and should be performed by experienced hands. (I-B)
5. Preimplantation genetic diagnosis of single-gene disorders should ideally be performed with multiplex polymerase chain reaction coupled with trophectoderm biopsy whenever available. (II-2B)
6. The use of comprehensive chromosome screening technology coupled with trophectoderm biopsy in preimplantation genetic diagnosis in couples carrying chromosomal translocations is recommended because it is associated with favourable clinical outcomes. (II-2B)
7. Before preimplantation genetic screening is performed, thorough education and counselling must be provided by a certified genetic counsellor to ensure that patients fully understand the limitations of the technique, the risk of error, and the ongoing debate on whether preimplantation genetic screening is necessary to improve live birth rates with in vitro fertilization. (III-A)
8. Preimplantation genetic screening using fluorescence in situ hybridization technology on day-3 embryo biopsy is associated with decreased live birth rates and therefore should not be performed with in vitro fertilization. (I-E)
9. Preimplantation genetic screening using comprehensive chromosome screening technology on blastocyst biopsy, increases implantation rates and improves embryo selection in IVF cycles in patients with a good prognosis. (I-B)

European Society for Human Reproduction and Embryology (ESHRE)

In 2011, the ESHRE made recommendations regarding multiple aspects of PGD testing (Harton 2011). Relevant to this review are recommendations made regarding inclusion/exclusion criteria specific to amplification-based PGD:

Inclusion

2.6. Testing can be carried out for confirmed pathogenic germline mutation(s) that have been identified in one parent for dominantly inherited diseases or in each parent for recessively inherited disorders giving a disease recurrence risk of 50 or 25%, respectively.
2.7. The germline mutation(s) is known to be causative of serious health effects that may manifest at birth, in childhood or as an adult.
2.8. For recessive and some X-linked (e.g. Duchenne muscular dystrophy) disorders, where a single germline mutation has been diagnosed in the proband and only one parent, it is acceptable to offer diagnosis if the pathogenic genotype can be attributed to a single gene and there is sufficient family history to identify a haplotype linked to the germline mutation.
2.9. Exclusion testing can be carried out for late-onset disorders, such as Huntington's disease to avoid presymptomatic testing of the partner with a family history of the disease (Sermon 2002; Moutou 2004; Jasper 2006; Pecina 2009 in ESHRE 2011).

Exclusion

2.10. Where the genetic diagnosis is uncertain, for example, owing to genetic/molecular heterogeneity or uncertain mode of inheritance and recurrence risk is low (e.g. 10%).

CODES

CPT or HCPCS Code	Description
88271 – 88299	Molecular cytogenetics
89290 – 89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than, equal or greater than 5 embryos [not covered to enhance delivery rates in advanced reproductive technologies]
S3800	Genetic testing for amyotrophic lateral sclerosis (ALS)
S3840	DNA analysis for germline mutations of the ret proto-oncogene for susceptibility to multiple endocrine neoplasia type 2
S3841	Genetic testing for retinoblastoma
S3842	Genetic testing for Von Hippel-Lindau disease
S3844	DNA analysis of the connexin 26 gene (gjb2) for susceptibility to congenital, profound deafness
S3845	Genetic testing for alpha-thalassemia
S3846	Genetic testing for hemoglobin E beta-thalassemia
S3849	Genetic testing for Niemann-Pick disease
S3850	Genetic testing for sickle cell anemia
S3852	DNA analysis for APOE epsilon 4 allele for susceptibility to Alzheimer's disease
S3853	Genetic testing for myotonic muscular dystrophy
S3854	Gene expression profiling panel for use in the management of breast cancer treatment

ICD-10 Code	Description
D56.0 – D56.9	Thalassemia
D57.0 – D57.819	Sickle-cell disorders
D61.01 – D61.09	Constitutional aplastic anemia
E75.02	Tay-Sachs disease
E75.19	Other gangliosidosis
E75.4	Neuronal ceroid liofuscinosis
E72.00 – E72.9	Other disorders of amino-acid metabolism
E84.0 – E84.9	Cystic fibrosis
G71.0	Muscular dystrophy
G71.2	Congenital myopathies
Q05.0 – Q05.9	Spina bifida
Q06.0 – Q06.9	Other congenital malformations of spinal cord
Q87.40 – Q87.89	Marfan’s syndrome
Q90.0 – Q99	Chromosomal abnormalities, not elsewhere classified
Z14.1	Cystic fibrosis carrier
Z14.8	Genetic carrier of other disease
Z81.0	Family history of intellectual disabilities
Z82.0	Family history of epilepsy and other diseases of the nervous system
Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
Z83.31 – Z83.49	Family history of other endocrine, nutritional, and metabolic diseases
Z82.79	Family history of other congenital malformations, deformations and chromosomal abnormalities
Z84.89	Family history of other specified conditions

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POLICY HISTORY

Date	Action
August 1, 2015	New policy
March 21, 2017	Updated literature search; ACOG 2015 and ACOG 2017 committee opinions added; language revised to specify that “biopsy” procedure is the procedure covered to obtain cells for testing; ICD-9 codes replaced with ICD-10 codes.
April 27, 2018	Updated literature search identified relevant European guidelines regarding best practices for preimplantation genetic diagnosis of cystic fibrosis; no change in policy.
May 31, 2019	Updated literature search; no policy changes.
May 12, 2020	No policy changes; reviewed literature.

KAISER PERMANENTE®

Northwest Utilization Review

UR 43: Physical/Occupational/Speech Therapy Medical Necessity Criteria

Department: Utilization Review	Number: UR 43
Applies To: KPNW Region	Effective: 1/1/08
Review Responsibility: UROC	Last Reviewed: 9/18
SMEs: Kathy Cutter, PT, Therapy Manager;	Last Revised: 8/20, 9/20, 4/21, 1/22, 1/23, 11/23
Lora Clements, MS, OTR/L, MBA, Therapy Director	Page 1 of 8

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Medicare: These criteria apply to all Commercial and Medicare members with a rehabilitation/ habilitation benefit; also, see *SPECIAL GROUP CONSIDERATIONS, MEDICARE* for information added as a result of the *Jimmo v. Sebelius* Settlement Agreement.

FOR POLICY AND PROCESS, PLEASE SEE UR 43, UTILIZATION REVIEW PHYSICAL/OCCUPATIONAL/ SPEECH THERAPY POLICY AND PROCEDURES

PURPOSE: To provide guidelines for the medical necessity of member's outpatient physical therapy, occupational therapy and speech therapy services.

DEFINITIONS

A. **Acute:** less than 30 days.

B. **Acute exacerbation:** A significant increase in frequency, duration, or intensity of symptoms typically associated with a person's existing condition.

C. **Subacute:** 30 to 90 days.

D. **Chronic:** greater than 90 days.

E. **Maintenance Therapy:** any treatment program designed to maintain, prevent, or slow further deterioration of the patient's functional status.

F. **Neurodevelopmental Disorder**: A congenital or acquired neurologically based condition in which a child does not reach developmental milestones at normative times and fails to master age-appropriate acquired skills such as selfcare, gross and fine motor skills, coordination and motor planning skills, communication skills (including speech, speech with augmentative and alternative communication device, language skills, sensory/motor skills, or swallowing and feeding skills). Residual effects can persist into adulthood.

G. **Sustainable:** able to be maintained. For purposes of PT, OT, and ST, progress toward goals can be maintained across visits and following discharge.

H. **Physicians:** for purposes of these criteria, physicians who can refer to PT/OT/ST are (1) a doctor of medicine or osteopathy; (2) a doctor of dental surgery or of dental medicine; (3) a doctor of podiatric medicine; (4) a doctor of optometry; or (5) a chiropractor. See REFERENCES section for entire definition of Physicians, as defined in 1861(r)(1) of the Social Security Act.

MEDICAL NECESSITY CRITERIA FOR PHYSICAL, OCCUPATIONAL and SPEECH THERAPY

Initiation Criteria

Outpatient physical therapy, occupational therapy and speech therapy are considered medically necessary when all of the following criteria are met:

A. For initial evaluation
   1. the member is referred by an examining *physician, physician assistant, or nurse practitioner
      *See REFERENCES section for definition of *Physicians*, as defined by the Social Security Act
   2. the member's condition is acute, subacute, neurodevelopmental, an acute exacerbation of a chronic condition or a function-limiting chronic condition,
   3. the member's condition can be expected to show measurable, significant, sustainable functional improvement within a reasonable and generally predictable period of time as a result of the prescribed therapy

B. For initiation of therapy treatment
   1. the prescribed therapy services are of the complexity and nature to require that they be performed by a licensed PT, OT, or ST provider,
   2. the therapy plan of care includes the member's diagnosis, initial objective status, with planned treatment interventions to address the identified impairments, treatment frequency and duration; measurable, time-specific, functional goals for therapy; and expected potential for achievement of goals.
   3. Treatment does not duplicate services provided by other types of therapy, or services provided in multiple settings, including but not limited to those provided as part of an individual educational plan (IEP) or an individual service plan (ISP).
   4. For pediatric members (also see **Special Group Considerations** below):
      a. when the member falls below the 16th percentile (1.0 SD below the mean) on a standardized test that requires clinician-observed member performance and is consistent with professional standard of practice. For those members whose deficits negate the validity of a standardized test, they must demonstrate, through clinician-observed member performance, a clinically significant impairment using a norm-referenced developmental assessment (e.g. Rosetti or Vineland-3.) Clinically-based surveys that do not require observation by a skilled provider cannot be the sole determining factor in qualifying for therapy treatment approval, however will be considered in the overall determination of medical necessity.

b. for Pediatric Speech/Articulation disorder, the evaluating Speech Language Pathologist has determined that the articulation deficits are not expected to improve with normal maturation.

NOTE: If a referral is made to a PT/OT/ST provider outside of KP, or out of the plan service area, it must be authorized by the Regional Referral Center.

Continuation Criteria

Continued outpatient physical therapy, occupational therapy and speech therapy are considered medically necessary when all of the following criteria are met:

1. Member continues to meet initiation criteria
2. Documentation establishes evidence of clinically significant objective measurable improvement AND evidence of observable improvement in functional task performance in at least 75% of established goals, as compared to most recent reporting period.
3. There is documented evidence that the member and/or caregiver are participating in and adhering to a home exercise program (HEP).
4. Member has not yet met discontinuation criteria.

Therapy extension requests require the following documentation to be submitted in order for requests to be reviewed:

1. Progress report that addresses each treatment goal, with inclusion of member's initial status, last reporting period status and current reporting period status, with specific reference to the parameters outlined in previous status. Objective measure parameters must be consistent across reporting periods.
2. Planned treatment techniques and interventions are detailed including amount frequency and duration required to achieve ongoing progress toward functional, measurable goals.
3. Identification of any health conditions or other factors which could impede the member's ability to benefit from treatment.
4. Summary of member's response to therapy, with documentation of any issues which have limited progress
5. Brief prognosis statement with clearly established discharge criteria
6. An explanation of any significant changes to the member's Plan of care, and the clinical rationale for revising the treatment plan.
7. Reevaluation
   a. For pediatric members: Retesting with norm referenced or criterion-reference standardized tools for re-evaluations is required annually for chronic or developmental conditions. Tests must be age appropriate for the child being tested and providers must use the same testing as used in the initial evaluation. If re-use of the initial testing instrument is not appropriate ie due to change in client status or restricted age range of the testing tool, the provider must justify the change.

Discontinuation of Therapy

Continued outpatient physical therapy, occupational therapy and speech therapy are considered not medically necessary in the following situations:

- Member no longer demonstrates functional impairment or has achieved goals set forth in the POC or has returned to their prior level of function

- Member has adapted to impairment with assistive/adaptive equipment or devices
- Member has been receiving services over an extended period and it cannot be determined whether the progress is due to therapeutic intervention or natural development
- Member is unable to participate in the plan of care due to medical, psychological, or social, complications
- Member (and/or family/caregiver) is non-compliant with Home Exercise Program and/or lacks participation in scheduled therapy appointments
- For Pediatric members, if the member scores equal to, or less than 1.0 standard deviation below the mean on a standardized test that is consistent with professional standard of practice.
- Member does not meet continuation criteria

Determination for consideration of a new episode of therapy intervention

The member may be eligible for a new evaluation/reassessment no sooner than 3 months following the end of the prior episode of care unless there has been a significant change in member's condition that justifies additional consideration for therapy services.

Non-Covered Services

Physical, Occupational, and Speech Therapy services are not covered in the following circumstances:

- For maintenance therapy for chronic conditions **except for members on a Washington group or Washington individual contract with a neuro-developmental condition. For these members, maintenance therapy is covered when, in the judgment of a KP practitioner, the condition would result in significant deterioration without such treatment. Neuro-developmental disorders include a broad spectrum of disabilities, delays in normal development and/or impairments in functional activity.**
- For drills, techniques, and exercises after completion of medically necessary therapy. This includes sports-enhancement therapy. The member is responsible for practicing independent community program, including learned drills, techniques, and exercises to preserve or enhance the present level of function and prevent regression of that function.
- For instruction of a secondary language. Included in this would be the acquisition of a secondary language including instruction of a new secondary grammar structure, vocabulary and accent.
- Self-correcting disorders (e.g. natural dysfluency or articulation errors that are self-correcting)
- Support groups
- A member whose impairments/goals are related to skills that are routinely taught as part of a school curriculum will be deemed educationally, rather than medically necessary, and the member will be referred to the School/District to obtain services, regardless of IEP status
- Summer programs for therapy normally provided by school districts during the school year
- Any service, program, or procedure performed in a non-conventional setting (this includes, but is not limited to camps, educational, vocational, or recreational settings.)
- Any treatment that is considered investigational or unproven within the professional community.

There will be no PT/OT/ST visit limits applied when treatment is associated with a mental health diagnosis and is medically necessary. Although these are most often Autism and/or Pervasive Developmental Disorder diagnoses, identified by the following diagnosis codes, this applies to all mental health diagnoses.

ICD-10 Codes

- F84.0 Autistic disorder
- F87.5 Asperger's syndrome
- F84.8 Other pervasive developmental disorders
- F84.9 Pervasive developmental disorder, unspecified

SPECIAL CONSIDERATIONS:

AQUATIC THERAPY

Aquatic therapy is a type of physical therapy or occupational therapy intervention. Scope of services will be limited to development of an independent pool therapy program that the member (and caregiver, as indicated) can perform upon discharge from skilled services.

To be considered for authorization for aquatic based therapy, the member must have demonstrated an inability to tolerate exercise for rehabilitation under gravity-based weight bearing conditions (land-based therapy) according to the following criteria:

1. Failed trial of land-based therapy*:
   - trial of at least 6 sessions within 3 consecutive WITH:
     - documented insufficient progress towards therapy goals as evidenced by therapist documentation over the previous 3-month period

   AND
     - Recommendation for Aquatic Therapy

       *A licensed Physical Therapy or Occupational Therapy provider may request an exception of the stated visit requirement for land-based therapy should they determine, during the course of such intervention, that further participation in land-based program would be detrimental to member's rehabilitation process, and that aquatic therapy is clinically indicated. Such exceptions are subject to UM review.

SPECIAL GROUP CONSIDERATIONS

Commercial: These criteria apply to all commercial groups with a PT/OT/ST benefit

NOTE: In response to the Washington Supreme court ruling in the O.S.T. v. Regence case, the OIC had instructed carriers to amend their 2015 filings to remove the age limits for neurodevelopmental therapies related to conditions found in DSM.

NOTE: Due to the legal, Federal and State guidance on the PPACA and Mental Health parity, therapies for the treatment of Autism Spectrum Disorder and Pervasive Developmental Disorders (PDD), such as Sensory Integration (SI), are considered an essential health benefit (EHB) and will no longer have any annual visit limits applied to therapy services.

Medicare: These criteria apply to all Medicare with a PT/OT/ST benefit; also, added as a result of the ***Jimmo v. Sebelius*** Settlement Agreement: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical

condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively using *nonskilled* personnel.

Washington Medicaid: Check **WAC 182-545-200 (7))**

Oregon Health Plan members (assigned to Health Share of Oregon or Pacific Source): Check LineFinder for members 21 years old and older to determine whether diagnoses are funded and pair with the requested therapy; use UR 43 to determine medical necessity of therapy. For members under 21 years of age, no LineFinder review is needed; use UR 43 to determine medical necessity of therapy.

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(1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1101(a)(7)),
(2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions,
(3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1814(a), 1832(a)(2)(F)(ii), and 1835 but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them,
(4) a doctor of optometry, but only for purposes of subsection (p)(1) of this section and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or
(5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of sections 1861(s)(1) and 1861(s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided.
For the purposes of section 1862(a)(4) and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1862(a)(4)) are furnished.

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KAISER PERMANENTE®

Northwest Utilization Review

UR 12.2: Pulmonary Rehabilitation Medical Necessity Criteria

Department: KPNW Utilization Review	Number: UR 12.2
Applies to: KPNW Region	Issued: 11/03
Review Responsibility: UROC	Last Reviewed: 5/16
SME: Dr. Eric Bonura (Pulmonology)	Last Revised: 6/17, 3/18, 3/19, 3/20, 4/21, 5/22, 6/22, 7/23

DEFINITIONS

Pulmonary Rehabilitation is a multidisciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and independence.

POLICY AND CRITERIA

MEDICAL NECESSITY CRITERIA

A. Diagnosis of moderate to very severe chronic obstructive pulmonary disease (COPD), defined as GOLD classification II, III and IV, when referred by the physician treating the chronic respiratory disease; or,

B. Preoperative or postoperative for lung transplant or resection; or,

C. Interstitial lung diseases (e.g. idiopathic pulmonary fibrosis); or,

D. Bronchiectasis; or,

E. Pulmonary arterial hypertension; or,

F. CT scan determined severe emphysema; or,

G. Confirmed or suspected COVID-19 with persistent symptoms that include respiratory dysfunction for at least 4 weeks; or,

H. For other diagnoses for which pulmonary rehab may be indicated, the pulmonologist will provide evidence-based references supporting its approval; or,

I. Referral from pulmonology.

OTHER REQUIREMENTS:

Pulmonary Rehabilitation Programs must include the following components:

a. Physician-prescribed exercise. Some aerobic exercise must be included in each pulmonary rehabilitation session (Respiratory Therapists who see patients under case management may order Pulmonary Rehab under the Pulmonology doctor-of-the-day);

b. Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling;

c. Psychosocial assessment;

d. Outcomes assessment; and

e. An individualized treatment plan detailing how components are utilized for each patient.

Pulmonary rehabilitation items and services are typically furnished in a physician's office or a hospital outpatient setting with a physician immediately available and accessible for medical consultations and emergencies at all times during which items and services are being furnished under the program.

CONTRAINDICATIONS (THESE ARE NOT MEDICARE APPROVED, APPLY TO COMMERCIAL MEMBERS ONLY)

NOTE: Coverage for pulmonary rehabilitation cannot be denied for a **Medicare** member based on the existence of a contraindicated situation/condition. When medical necessity criteria and the facility/program requirements are met, coverage for Medicare members must be authorized. It is up to the prescribing practitioner to determine if a co-existing condition contraindicates the provision of pulmonary rehabilitation.

a. The patient has not quit smoking or will not participate in smoking cessation activities prior to or during the course of pulmonary rehabilitation services (including tobacco, marijuana and vaping);
b. The patient is not physically able, motivated or willing to participate;
c. There is no expectation of measurable improvement in a reasonable and predictable time frame;
d. Presence of unstable cardiac disease;
e. Presence of active pulmonary infection (excludes COPD exacerbation) unless ordered/approved by a pulmonologist;
f. Presence of unstable pulmonary hypertension.

SPECIAL GROUP CONSIDERATIONS

Medicare: **There is currently no National or Local Coverage Determination addressing pulmonary rehabilitation.**

As specified at 42 CFR 410.47(f), pulmonary rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary. Contractors shall accept the inclusion of the KX modifier on the claim lines as an attestation by the provider of the service that documentation is on file verifying that further treatment beyond the 36 sessions is medically necessary up to a total of 72 sessions/condition for that beneficiary.

Note: Beneficiaries with moderate to very severe COPD (defined as GOLD classification II, III, and IV) who have completed pulmonary rehab (PR), may participate in PR again if they had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks. Similarly, beneficiaries who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks and complete PR, may participate in PR again if they have moderate to very severe COPD (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease.

RATIONALE

EVIDENCE BASIS

COPD

A 2015 Cochrane systematic review evaluated pulmonary rehabilitation for COPD and reports moderately large or clinically significant improvements in dyspnea, fatigue, emotional function, and enhanced sense of control individuals have over their condition following pulmonary rehabilitation.[1] The review also indicates that

pulmonary rehabilitation is beneficial in improving health-related quality of life and exercise capacity.[1] A 2016 Cochrane review of pulmonary rehabilitation after exacerbations of COPD reports moderate to large effects of pulmonary rehabilitation on health-related quality of life and exercise capacity in patients with COPD after an exacerbation.[2] This review evaluated the effect of pulmonary rehabilitation on hospital readmissions and reports that moderate-quality evidence indicates that pulmonary rehabilitation reduced hospital readmissions, but results across studies were heterogenous.[2] The heterogeneity in these findings may be explained by variation in the extensiveness of pulmonary rehabilitation programs evaluated in the included studies.

Interstitial Lung Disease

A 2021 Cochrane systematic review of pulmonary rehabilitation for interstitial lung disease indicates that functional exercise capacity, dyspnea, and quality of life are likely improved by pulmonary rehabilitation in the short-term and that these benefits were sustained longer term.[3] Due to issues of study quality, such as inadequate reporting of methods, lack of outcome assessment blinding, and heterogeneity in results, the certainty of this evidence was rated as low to moderate.[3]

COVID-19

A 2021 ECRI Clinical Evidence Assessment of rehabilitation for patients with post-acute sequela of COVID-19 notes that available clinical evidence demonstrates significant improvements in pulmonary function following rehabilitation.[4]

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KAISER PERMANENTE® Northwest Region Utilization Review

UR 20.1 Breast Reduction (Mammoplasty) Female Medical Necessity Criteria: Commercial Members

Department: Surgery	Number: UR 20.1
Section: Plastic Surgery	Effective: 2/00
Applies to: KPNW Region	Last Reviewed: 2/20, 2/20/24
Review Responsibility: UROC	Last Revised: 2/21, 3/22, 2/23
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; H. Jonathan Chong, MD (Plastic Surgery)	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR FEMALE REDUCTION MAMMOPLASTY FOR COMMERCIAL LINES OF BUSINESS

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

Note that separate policies/criteria exist, when applicable, for coverage of:

1. Breast Reconstruction (UR 20.6)
2. Gender-Affirming Procedures (UR 65)

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* may vary within the Exclusions section of the EOC documents.

POLICY AND CRITERIA

A. CRITERIA FOR BREAST REDUCTION/PLASTIC SURGERY CONSULTATION

Relevant history and physical findings must establish medical necessity, including all of the following:

1. The member must have two or more of the following conditions present for at least 6 months, with documented failed therapeutic measures i.e. weight loss strategies, supportive garments, and dermatologic measures: [13]
   a. Upper back pain, from breast size
   b. Persistent breast pain (not relieved with hormonal adjustments or analgesics)
   c. Rash under breast (unresolved with dermatologic therapies)
   d. Painful bra strap grooves
   e. Shoulder pain from breast size
   f. Neck pain from breast size
   g. Arm pain from breast size
2. Breast size D cup bra size or above.
3. Body Mass Index (BMI) less than or equal to 34.

4. Must have a normal mammogram within the past year in women 40 years or older.
5. Members with a history of tobacco products* use must have:
    a. a documented "quit" date >6 months prior to referral for consultation, **or**
    b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to referral for consultation.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

B. CRITERIA FOR BREAST REDUCTION SURGERY (POST-CONSULTATION).

In addition to pre-consultation criteria (section A), the following must be met:

1. Predicted removal of the following:
    a. minimum of 200 grams of breast tissue from the larger of the two breasts when BMI is <25.
    b. minimum of 250 grams of breast tissue from the larger of the two breasts when BMI 25-30.
    c. minimum of 450 grams of breast tissue from the larger of the two breasts when BMI is >30.
2. Body Mass Index (BMI) less than or equal to 34.
3. Must have a normal mammogram within the past year in women 40 years or older.
4. No diagnosis of diabetes mellitus or diabetes mellitus with A1c <8.0 within the last 3 months.
5. Members with a history of tobacco products* use must have:
    a. a documented "quit" date >6 months prior to consideration for surgery, **or**
    b. a negative urine anabasine test (level below 3 ng/dl) within the last 30 days if quit ≤6 months prior to consideration for surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).

CONTRAINDICATIONS (TO BE DETERMINED BY THE SURGEON)

1. Nicotine use, including tobacco products* and nicotine replacement therapy (NRT) products** within the 30 days prior to surgery.

*tobacco products: cigarettes, cigars, pipe tobacco, e-cigarettes, smokeless tobacco (chewing tobacco and snuff).
**NRT products: nicotine gum, lozenges, sublingual tablets, transdermal patch, nasal spray, inhaler.

2. Uncontrolled diabetes as indicated by a HbA1c of 8.0 or higher. Members with a HbA1c in the 7-8 range may be assessed for relative contraindications on a case-by-case basis.

3. Obesity is also a risk factor for poor surgical outcome. Members who are obese but otherwise meet the above medical necessity criteria will be assessed on a case-by-case basis.

4. Any other surgical contraindications will be determined by the surgeon.

SPECIAL GROUP CONSIDERATIONS

Policy applies to all Commercial groups

This policy does not apply to OR or WA Medicaid

This policy does not apply to Medicare (see Medicare Plastic Surgery LCD 37020)

RATIONALE

EVIDENCE BASIS

Reduction Mammoplasty:

Recent systematic reviews have investigated the benefits and harms of reduction mammoplasty in individuals with macromastia and consistently report improved outcomes among those who received reduction mammoplasty compared to those who did not. A 2021 systematic review of randomized controlled trials reports a significant improvement in health-related quality of life (HRQoL) at 4-6 months post-procedure among participants with macromastia who had reduction mammoplasty compared to participants who had non-surgical interventions.[1] Another 2021 review of the risks and benefits of reduction mammoplasty to treat breast hypertrophy reports improved HRQoL and a significant reduction in pain after reduction mammoplasty.[2] A 2020 systematic review reports an overall statistically significant improvement in back pain following reduction mammoplasty among patients with macromastia.[3] A 2019 systematic review of the effect of reduction mammoplasty on the spine of patients with breast hypertrophy reports a substantial reduction in pain among those who underwent reduction mammoplasty compared to those who did not.[4] A 2019 systematic review of patient-reported outcomes following reduction mammoplasty indicates an overall satisfaction rate of 90.3% among patients with macromastia whose satisfaction was directly measured following the procedure.[5] The underlying body of evidence included in these reviews had some methodological limitations that hinders determinations related to patient selection for reduction mammoplasty. One review noted that studies on reduction mammoplasty for breast hypertrophy don't report a definition for breast hypertrophy or detail the indications for reduction mammoplasty that were used.[2]

Tobacco Use

A 2018 systematic review of the effect of smoking on post-operative outcomes in patients who had common elective procedures in plastic surgery reports that tobacco use was associated with a significant increase in the total number of post-operative complications following reduction mammoplasty.[6] These complications include skin necrosis, infection, wound separation, delayed wound healing and need for reoperation, all of which were significantly more common among smokers compared to non-smokers.[6]

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Routine Foot Care (NON-MEDICARE)

Policy Number: UR2a
Effective Date: March 31, 2020
Reviewed Date: July 2023
Next Review: July 2024
Specialist Reviewer: Ryan Downey, DPM; Bennie Patmon, DPM

BACKGROUND

CLINICAL BACKGROUND

Individuals with compromised circulation or sensation of the lower extremity are at high risk for causing themselves serious injury when performing routine foot care on their own. These individuals may have difficulty sensing or healing an injury to their feet that may result in painful ulcers or ultimately loss of the limb. Provision of routine foot care services by a medical professional can help prevent adverse outcomes. Routine foot care may include services such as cutting or removal of corns and calluses; trimming, cutting, or debriding nails; hygienic and preventive maintenance foot care (e.g., soaking, applying lotion). Services may be performed in a physician's office, an outpatient setting, or an individual's home. While diabetes mellitus is a risk factor for foot ulcers, non-diabetic individuals with vascular disease and/or neuropathy are also at increased risk.

POLICY AND CRITERIA

1. Routine foot care services may be considered medically necessary when ANY of the following conditions are present:
    a. significant circulatory insufficiency due to a peripheral vascular disease as evidenced by ANY of the following:
        i. absent posterior tibial pulse by palpation;
        ii. absent dorsalis pedis pulse by palpation;
        iii. lower extremity vascular claudication;
    b. peripheral neuropathy resulting in loss of protective sensation in the feet (as indicated by an absence of sensation at two or more sites out of five tested on either foot when tested with a monofilament*);
    c. previous non-traumatic lower extremity amputation (patients qualify for routine foot care of affected or unaffected lower extremity after partial or complete amputation of foot/toes);
    d. The member is undergoing other treatment for which the foot care is a necessary component (e.g., treatment of warts, fitting for a cast).

INFORMATIONAL ONLY: expected/typical frequency for routine foot care services is no more often than every 60 days. Greater frequency report to Regional Referral Center leadership.

*a standard monofilament is the 5.07 Semmes-Weinstein monofilament

SPECIAL GROUP CONSIDERATIONS

- This policy applies to commercial plans. For Medicare plans, see separate criteria under UR5b.
- Oregon Medicaid: Check LineFinder.
- Washington Medicaid: See Molina Provider Handbook.
    - for clients under 21 years non-experimental medically necessary services are covered through the early and periodic screening, diagnosis, and treatment (EPSDT) program -

WAC 182-534-0100 - EPSDT, https://www.hca.wa.gov/health-care-services-supports/program-administration/wac-182-534-0100-epsdt ;

- for clients 21 years of age and older - see WAC 182-531-1300 https://apps.leg.wa.gov/wac/default.aspx?cite=182-531-1300 and WAC 182-531-0150 (1)(n)) https://apps.leg.wa.gov/wac/default.aspx?cite=182-531-0150

RATIONALE

EVIDENCE BASIS

In their review on prevention of foot ulcers and other serious foot lesions, CMS evaluated primarily evidence related to diabetic foot ulcers. However, other disease processes resulting in peripheral neuropathy and/or peripheral vascular disease face similar potential for benefit. Findings from the CMS review are provided below:

"Comprehensive, multifaceted approaches incorporating multiple interventions that promote greater attention to foot care have been shown to be effectively reduce foot ulcers and other serious foot lesions. Specifically, Litzelman and colleagues were able to reduce serious foot lesions in a randomized controlled trial by utilizing multiple interventions (see Table 3). The intervention was based on two observations (1) basic efforts on the part of the health care provider or patient can reduce the likelihood of subsequent amputation due to diabetes-associated foot disease; and (2) many of these basic procedures are not being systematically applied by health care providers or patients. Over the course of the 12-month study, patients received foot care education and entered into behavioral contracts for desired self-care, which was reinforced with telephone calls and post card reminders. Practice guidelines and informational flow sheets on amputation risk factors were provided to health care providers. Also, patients who received the intervention had special identifiers on their charts to prompt foot examinations and to provide foot care education.

The intervention group (patients in the group that received education on appropriate foot care and whose providers had chart reminders to prompt foot examinations and referral recommendations) was less likely than the control group to have serious foot lesions [baseline prevalence, 2.9%, OR 0.41 (95% CI=0.16-1.00), P = 0.05]. Intervention patients were also more likely to report appropriate self-foot-care behavior, to have foot examinations during office visits (68% compared with 28%; P < 0.001), and to receive foot care education from health care providers (42% compared with 18%; P < 0.001). Finally, physicians in the intervention group were more likely than their control counterparts to examine patients' feet for ulcers, pulses, and abnormal dermatologic conditions and to refer patients to podiatry clinic (10.6% compared with 5.0%; P = 0.04).

In addition, Bild and colleagues noted three studies in which multidisciplinary interventions reduced the frequency of LEAs. In Atlanta, Grady Memorial Hospital instituted an integrated inpatient/outpatient diabetes unit, which included comprehensive podiatry services, nurse clinicians and an extensive education program. The annual number of LEAs in this largely African American and indigent cohort decreased by almost 50%, from 172 in 1973 to an average of 92 per year from 1973 to 1982 among 8000 clinic patients.

In London, England a diabetes foot clinic at Kings College Hospital added podiatrists and shoe fitters to the diabetes foot clinic. Over a two-year period emphasizing podiatric care, antibiotic therapy, and specially constructed shoes, the amputation rate declined 44%. The effect of specially fitted footwear on recurrent ulcers was particularly dramatic. Patients receiving specially fitted footwear had an ulcer recurrence rate of 26%, compared to 83% among those with regular shoes.

Similarly, at the University Hospital of Geneva an 85% reduction in below knee amputations was observed over a 4-year period after the initiation of patient education and training in foot care for people with diabetes. He concluded that the results support the notion that comprehensive foot care, including podiatric care, education and specially fitted shoes[15], can reduce LEAs in individuals with diabetes.[16]

As with the Patout study, the observational nature of each of these studies raises doubts about the true magnitude of any beneficial effect. In addition, it is noteworthy that all of these studies addressed multidisciplinary or multifactorial interventions for diabetic feet. Patient education, for example may be a critical component, and was included in most of these programs."

CODES

CPT Code	Description
11055-11057	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus)
11719	Trimming of nondystrophic nails, any number
11720-11721	Debridement of nail
G0127	Trimming of dystrophic nails, any number

ICD-10 Code and Description	
A52.16	Charcot's arthropathy (tabetic)
B35.1	Dermatophitosis (Tinea unquium)
B37.2	Candidiasis of skin and nail
B52.0	Plasmodium malariae with neuropathy
E08.00 – E13.9	Diabetes Mellitus
O24.011 – O24.93	Diabetes mellitus in pregnancy
G13.0 – G13.1	Systemic atrophy and neuropathy
G6281 – G65.2	Polyneuropathies
G73.3	Myasthenic syndromes in other diseases classified elsewhere
G90.09	Peripheral neuropathy
G99.0	Autonomic neuropathy
I70.201 – I70.799	Atherosclerosis of arteries, lower extremities
I73.00 – I79.8	Peripheral vascular disease
I80.00 – I80.3	Phlebitis and thrombophlebitis, lower extremities
I82.501 – I87.9	Chronic embolism and thrombosis, lower extremities
I89.0	Lymphedema
I99.8	Circulatory system disorder
L02.415 – L03.129	Infections of skin and subcutaneous tissue, lower limb
L11.0	Acquired keratosis follicularis
L60.0 – L60.9	Nail disorders
L84 – L85.2, L86, L87.0, L87.2, L97.501 – L97.529	Disorders of skin and subcutaneous tissue
M05.571 – M05.59	Polyarthropathies
M14.671 – M14.69	Arthropathies, Charcot's joint, ankle and foot
M20.10 – M02.12	Hallus valgus
M34.83	Systemic sclerosis with polyneuropathy
M90.561 – M90.59	Osteonecrosis, lower ley, ankle and foot
M90.861 – M90.89	Osteopathy, lower leg, ankle and foot
Q82.0	Hereditary lymphedema
R20.0 – R20.9	Disorders of skin and subcutaneous tissue
R60.0 – R60.9	Edema

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Northwest Region Utilization Review

UR 20.3 Scar Revision and Medical Tattoo Medical Necessity Criteria

Department: Surgery
Section: Plastic Surgery
Applies to: KPNW Region
Review Responsibility: UROC
Subject Matter Experts: Jennifer Murphy, MD; Patricia Sandholm, MD; H. Jonathan Chong, MD (Plastic Surgery)

Number: UR 20.3
Effective: 8/00
Last Reviewed/Approved: 1/23, 1/30/24

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SCAR REVISION AND MEDICAL TATTOO

Medical necessity criteria and policy are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

DEFINITIONS

See the Evidence of Coverage (EOC) as definitions of *Cosmetic Services* vary within the Exclusions section of the EOC documents.

CRITERIA FOR SCAR REVISION AND MEDICAL TATTOO

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	For Medical Tattooing apply: 140.2 – Breast Reconstruction Following Mastectomy
Local Coverage Determinations (LCD)	For Scar Revision apply: L37020 "Plastic Surgery"
Local Coverage Article	For Scar Revision: A57222 "Billing and Coding: Plastic Surgery"
Kaiser Permanente Medical Policy	For Medicare lines of business, apply the criteria in the NCD for medical tattooing and the criteria in the LCD for scar revision.

For Non-Medicare Members

When the criteria below are met for a scar revision or a medical tattoo, these services will be covered as a form of reconstructive surgery.

1. Scar, discoloration or deformity is a result of an injury or medically necessary surgery
2. Scar, discoloration or deformity duration:
   - If scar is not hypertrophic or keloid, scar has been present for 1 year or more
   - If scar is hypertrophic or keloid, any duration is acceptable
   - For medical tattoo referrals, age of scar, discoloration or deformity is not relevant

3. Scar, discoloration or deformity causes signs or symptoms, as indicated by **1 or more** of the following:
    - Loss of range of motion of joint
    - Pain
    - Significant disfigurement, distortion of adjacent structures and/or scars or discoloration in a cosmetically sensitive area, i.e. face (the decision regarding the significance of the scar and the eligibility of scar removal will be determined on a case-by-case basis by the plastic surgeon)

OTHER REQUIREMENTS

- Cosmetic services (see member's EOC for definition) are specifically excluded by the members' benefit coverage. This exclusion does not apply to services that are covered under "Reconstructive Surgical Services" or services that are medically necessary.

- See UR 20.6 Breast Reconstructive Surgery Criteria for information regarding surgical services related to breast reconstruction.

- See the EOC for other inpatient and outpatient reconstructive surgery services related to congenital hemangioma (port wine stains on the face), correction of significant disfigurement resulting from an injury or from medically necessary surgery and correction of congenital defects, disease, or anomalies in order to produce significant improvement in physical function.

- See UR 65 Gender-Affirming Procedures Medical Necessity Criteria for more information regarding gender-affirming areola tattooing.

SPECIAL GROUP CONSIDERATIONS for the criteria, which applies if a group has the benefit coverage:

Policy applies to all Commercial and Federal groups, WA Medicaid
Oregon Medicaid: subject to eligibility on OHP Linefinder
Medicare: apply the criteria in the NCD and LCD, as defined in the chart above

CLINICAL

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Northwest Utilization Review

UR 7 Skilled Nursing Facility Medical Necessity Criteria

Department: Continuing Care	Number: UR 7
Section: Skilled Nursing	Effective: 2/04
Applies to: KPNW Region	Last Reviewed: 4/20, 5/22, 4/23
Review Responsibility: UROC	Last Revised: 3/18, 4/19, 10/19, 4/21, 3/24
SME: Preston Peterson, MD, SNF Medical Director; Marie Vasquez, RN, CCS	

MEDICAL NECESSITY CRITERIA AND OTHER REQUIREMENTS FOR SKILLED NURSING FACILITY CARE FOR COMMERCIAL, MEDICAID, AND MEDICARE BUSINESS-see Special Group Considerations for Medicare and Washington Medicaid specific information

DEFINITIONS

Definitions of Skilled Nursing Facility

1. An institution or distinct part of an institution that is primarily engaged in providing skilled nursing care and related services for the rehabilitation of injured, disabled or sick persons, and meets the requirements for participation in # 1819 of the Social Security Act and in regulations 42CFR part 483.
2. For Medicare purposes, the term SNF does not include any institutions that are primarily for the care of mental disease or tuberculosis.

Definition of Benefit for Skilled Services

1. Post-hospital extended care services furnished to inpatients of a skilled nursing facility are covered under the Part A hospital insurance program, commercial plans, and under Oregon and Washington Medicaid benefits.
2. Patients with hospital insurance coverage are entitled to have payment made on their behalf for the reasonable cost of covered extended care services furnished by a skilled nursing facility, or by a hospital with which the facility has a transfer agreement.
3. Part A covers up to 100 days of skilled nursing facility services per each benefit period. Oregon Medicaid Health Plan (OHP) covers up to 20 days of skilled nursing services per each benefit period. Commercial plans have various benefit periods. A benefit period begins with the first day of a Medicare covered inpatient skilled nursing stay, and ends with the close of a period of 60 consecutive days during which the member was neither an inpatient of a hospital or a SNF. As long as the beneficiary continues to be entitled to Part A, or OHP, there is no limit on the number of benefit period(s) he/she may have. There is no limit to the amount of skilled benefit days for Washington Medicaid members as long as they meet medical necessity criteria.
4. Beginning the benefit period: A benefit period begins upon admission to a qualified SNF for skilled care, even though payment for the services cannot be made because the prior hospitalization or transfer requirement has not been met.

5. See Waiver of a Three Day Stay Admission Criteria below for details on the waiver of a three-day qualifying stay.
6. Prolonging a benefit period: Beneficiaries who continue to require skilled care after exhausting their 100 days of covered Part A coverage until the close of a period of 60 consecutive days during which the beneficiary was neither an inpatient of a hospital or a SNF at a skilled level of care.

Covered Services in a Skilled Nursing Facility

1. Skilled nursing care.
2. Bed and board.
3. Physical Therapy (PT), Occupational Therapy (OT), Speech Therapy (ST).
4. Respiratory services (RT).
5. Medical/Social Services
6. Drugs and biologicals. (See below)
7. Medical services of interns and residents (see regulations for details).
8. Other health services necessary to the health of patients as are generally provided by SNFs (e.g., labs, x-ray, routine personal hygiene items and services).
9. Medical equipment, both standard and complex.
10. Medically necessary ambulance services.

Covered Drugs and Biologicals

1. During a covered skilled stay, prescribed drugs and biologicals that are ordinarily furnished by the facility are covered. Three requirements for coverage are:
   a. Must represent a cost to the institution, AND
   b. Must be included in the US Pharmacopoeia, the National Formulary, or the US Homeopathic Pharmacopoeia; or, except for those unfavorably evaluated, in AMA Drug Evaluations Accepted, AND
   c. Must be reasonable and necessary.
2. Drugs not included in the compendia are nevertheless covered if such a drug:
   a. Was furnished during the patient's prior hospitalization, AND
   b. Was approved by the hospital's drug therapeutic committee, AND
   c. Is required for the continued treatment in the SNF.
3. Drugs used outside the facility:
   a. If the drug or biological is deemed medically necessary to permit the patient's departure from the facility, and a supply is required until he/she can obtain a continuous supply, the drugs or biologicals would be covered as an extended care service of the SNF.

CRITERIA

Extenuating circumstances around pre-authorization and admission notification is based on the Best Practice Recommendations (BPR) put forth by the Washington Healthcare Forum operated by OneHealthPort but are applicable to all lines of business in Oregon and Washington. Please see associated Regional UM Policy:

UR 70: Extenuating Circumstances Policy at http://internal.or.kp.org/utilization/.

Pre-Admission Qualifying Criteria (Medicare Part A and Commercial)

A. Entitlement to Part A Medicare or Commercial Kaiser Permanente Health Plan (KPHP) coverage.
B. SNF day(s) available.
C. Care is reasonable and necessary.
D. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).
E. Prior hospitalization: Part A - The patient must have been an inpatient of a hospital for a medically necessary stay of at least three consecutive days. (See Waiver of a Three Day Stay Admission Criteria regarding waiver of this and associated requirements).
F. In addition, the patient must have been either:
   a. transferred to a participating SNF within 30 days after discharge from the hospital (the day of discharge is not counted); or
   b. if period of more than 30 days has elapsed, and the patient's condition makes it medically inappropriate to begin and achieve a course of treatment within 30 days after hospital discharge AND it is medically predictable at the time of hospital discharge that such care will be required within a pre-determinable time period.
G. The care is related to prior hospitalization (NOTE: "related to" means the condition requiring skilled care was treated during the hospitalization), or
H. The patient has been evaluated by a physician within the last 7 days in a clinic, emergency room, or in Home Health and skilled care is required to prevent hospitalization.
I. Skilled services (nursing or rehabilitation) must be needed and provided on a "daily basis" i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.

Waiver of Three Day Stay Admission Criteria (Medicare Part A)

A. A number of Kaiser Foundation Health Plans have elected to waive the 3-day qualifying stay requirement allowing patients to be directly admitted to a SNF when medically appropriate.
B. This waiver means that a SNF stay not preceded by a qualifying stay for the 1876 Cost member must be billed to KFHP not Medicare.
C. Medicare Advantage member admissions are always billed to KFHP.
D. If the Kaiser Permanente (KP) SNF benefit waives the qualifying stay, the 30-day transfer rule and the requirement for the SNF care to be related to the preceding hospital care is also waived.

Pre-Admission Qualifying Criteria (Washington Medicaid)

A. Entitlement with Medicaid managed care organization (MCO).
B. Washington Medicaid covers costs when the patient is not covered by Medicare, another primary insurance, or third party insurance. Medicaid is the payor of last resort.

C. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.

D. Care is reasonable and necessary. Covered when the Plan determines that nursing facility care is more appropriate that acute hospital care.

E. The need for skilled services is certified/re-certified by a physician (MD), nurse practitioner (NP) or Clinical Nurse Specialist (CNS) (see Timing of Certifications and Re-certifications for frequency).

F. Skilled services (nursing or rehabilitation) must be needed and provided on a "daily basis" i.e., on essentially a 7-day-a-week basis, a patient whose inpatient stay is based solely on the need for skilled rehabilitation services would meet the daily basis requirement when services are needed and received on at least 5 days per week.

G. Services are not covered by DSHS Aging and Long Term Supports Administration.

H. Services are not covered if it is determined to not be medically necessary for rehabilitation.

I. The Plan shall coordinate with the Skilled Nursing facility to provide prescription medications, durable medical equipment, therapies, intravenous medications, and any other medically necessary service or product.

Pre-Admission Qualifying Criteria (Oregon Medicaid)

A. The post hospital extended care benefit must be authorized by pre-admission screening for individuals not enrolled in managed care.

B. SNF days available.

C. Must be receiving Oregon Health Plan benefits and not Medicare eligible.

D. Have a medically necessary, qualifying hospital stay, not including a hold bed, observation bed, or emergency room bed. The stay must consist of three or more consecutive days, not counting the day of discharge.

E. Transfer to a nursing facility within 30 days of discharge from the hospital.

F. Need skilled nursing or rehabilitation services on a daily basis meeting Medicare skilled criteria that may be provided only in a nursing facility.

G. All members are required to have a Preadmission Screening and Resident Review Level I screening (PASRR). This screening looks for indicators of an intellectual disability or a serious mental illness.

Criteria for Skilled Care under Medicare Part A, Commercial and Oregon and Washington Medicaid

A. Skilled means:

1. The patient requires skilled nursing or skilled rehabilitation services (PT, OT, ST) and meets medical necessity criteria.
2. These services require the skills of technical or professional personnel and are furnished directly by, or under the supervision of such personnel.
3. These services are required on a daily basis (skilled nursing 7 days per week; skilled therapies at least 5 days per week).
4. As a practical matter, considering economy and efficiency, the daily skilled services can only be provided on an inpatient basis in a SNF.

5. The services delivered are reasonable and necessary for the treatment of the patient's illness or injury. The services must also be reasonable in terms of duration and quantity.

B. Specific categories of skilled services are:
    1. Direct care.
    2. Management and evaluation of a patient's care plan.
    3. Observation and assessment of a patient's condition.
    4. Teaching and training services.

OTHER CLINICAL REQUIREMENTS

Physician Services in SNF

A. A physician must approve, in writing, a recommendation that an individual be admitted to a facility.
B. Each resident must remain under the care of the physician.
C. Visits: Physician must:
    1. Review the total program of care at each visit.
    2. Write, sign and date progress notes at each visit.
    3. Sign and date all orders.
    4. Frequency: Beneficiary must be seen once every 30 days for the first 90 days after admission and at least once every 60 days thereafter. The visits must be timely which means the visit occurs no later than 10 days after the required visit date.
D. The physician must make the initial visit. Thereafter he/she may elect to alternate between personal visits and visits by a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) as permitted by State Law.
E. Physician must be available for emergency care.
F. Physician must certify and/or re-certify to the skilled level of care (also see Physician Delegation below).

Physician Delegation of Tasks in SNF

All required physician visits must be made by the physician personally except at the option of the State, the physician may delegate these tasks/visits to a NP, CNS, or PA who is not an employee of the facility, but who is working in collaboration/association with the physician, and is acting within their scope of practice.

Note: A Physician Assistant is not permitted to sign certifications/re-certifications.

Discharge Planning

1. The resident must have a discharge summary that includes a post-discharge plan of care that is developed with the participation of the resident and his/her family, and that will assist the resident to adjust to his or her new living environment.
2. DME may be delivered to a facility that does not qualify as the patient's home, up to 2 days prior to discharge for the purposes of fitting or training. However, suppliers may only bill from date of discharge.

OTHER ADMINISTRATIVE REQUIREMENTS

Certification General Requirements

A. A physician must approve in writing a recommendation that an individual be admitted to a facility.
B. Each resident must remain under the care of a physician.
C. Certification: A physician must certify in writing that:
    1. The beneficiary needs daily skilled nursing or rehabilitation services which can only be provided in a SNF on an inpatient basis for either the condition for which he/she received inpatient hospital services, or for a condition which arose after transfer while in the SNF for treatment of a condition for which he/she received inpatient hospital services, OR
    2. The individual has been correctly assigned to one of the RUGs designated as representing the required level of care (Part A).

Re-Certification General Requirements

A. Re-certification: The physician must recertify to:
    1. The reasons for the continued need for post-hospital SNF care.
    2. The estimated time the individual will need to remain in the SNF.
    3. Plan for home care, if any.
    4. If appropriate, that continued services are needed for a condition that arose after admission to the SNF and while the individual was still under treatment for the condition for which he/she had received inpatient hospital services.

B. There is no requirement for a specific procedure or form as long as the approach permits verification that the certification and re-certification requirement is met. They may be entered in forms, notes, or other records that a physician normally signs in caring for the patient, or on a separate form.

Certification and Re-certification:

A. The attending physician or a physician on the staff who has knowledge of the case signs certifications and re-certifications.
B. The physician may delegate certification/re-certification to a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with the physician.

Note: Per regulation, Physician Assistants may not sign certifications/re-certifications.

Timing of Certifications and Re-certifications

A. Certification: First certification must be made at the time of admission or as soon thereafter as is reasonable and practical.
B. Re-certifications: No later than the 14th day of post-hospital SNF care. Subsequent recertification must be made at intervals not exceeding 30 days.

Change From Skilled to Custodial Level or Exhausted Benefit

A. Beneficiaries who are in a skilled Medicare Part A covered SNF stay, whose physician determines that they no longer require skilled care must be notified in writing via a Medicare Notice of Non-Coverage (NOMNC) prior to discharge to the non-skilled level (Form CMS 10123-NOMNC).
B. Beneficiaries who exhaust their Medicare Part A 100-day benefit and continue to require skilled care are not considered custodial, and must receive a Medicare Notice of Denial of Payment (CMS-10003-NDMCP).

C. Beneficiaries who are in a skilled commercial covered SNF stay, whose physician determines that they no longer require skilled care and the beneficiary disagrees, or who have exhausted their benefit must be notified in writing via a Concurrent Care Claim Denial Notice.

D. Beneficiaries who are in a Washington Medicaid skilled covered SNF stay, whose physician determines that they no longer meet medical necessity criteria for skilled care, must be notified in writing via a Notice of Denial of Services (Notice 17-2921) if the patient does not agree with the discharge.

E. Beneficiaries who are in an Oregon Medicaid skilled covered SNF stay, whose physician determines that they no longer require skilled care or have exhausted their 20-day benefit, must be notified in writing via a Notice of Action.

Minimum Data Set (MDS)/Resident Assessment (Part A)

A. In October 2019, the Patient Driven Payment Model (PDPM) was established by CMS. Under the PDPM model, each patient is classified into a group for each of five case-mix adjusted components: PT, OT, Speech, Nursing and a comorbidity score. SNFs are paid a case mix based upon the components in a covered Part A stay. Under PDPM, an adjustment factor is applied and changes the per diem rate over the course of the stay.
B. The SNF is required to complete an assessment that is both scheduled and unscheduled, with a variety of rules that govern timing, interaction among assessments and combining assessments. The assessments are entered into the Minimum Data Set (MDS) system according to Medicare assessment schedule if they are billing Medicare directly. If the SNF is billing Kaiser Foundation Health Plan, Inc., the first MDS is not due until the 14th day of SNF stay.

Billing Rules (Medicare Part A)

A. Care must be ordered and directed by a physician, AND
B. The care must be furnished for a condition for which the beneficiary received inpatient hospital care, or which arose while receiving inpatient hospital care (see Waiver of Three Day Stay).
C. Under the PDPM System, when the SNF bills Medicare directly, the clinical criteria for covered skilled care must include documentation per the Minimum Data Set assessment and assignment to a payable PDPM classification.
D. Patients assigned to one of the five case-mix categories are PRESUMED to be receiving daily skilled services.
E. Services which are not included in the SNF PPS and for which separate Part B payment must be made:
    1. Cardiac catheterization
    2. CT (computerized tomography)
    3. MRI (magnetic resonance imaging)
    4. Ambulatory surgery
    5. Emergency services
    6. Radiation therapy
    7. Angioplasty
    8. Lymphedema and venous insufficiency
    9. Physician services
F. Medicare Advantage Contract billing requirements:
    1. SNFs bill KFHP
    2. Payment based on contract terms
    3. MDS not required until the 14th day
G. #1876 Cost Contract billing requirements:
    1. SNFs bill Medicare directly

2. SNFs must abide by Medicare PPS and consolidated billing rules, i.e., MDS assessment schedule and RUG assignment.

Contracts (Medicare Part A and Commercial) KFHP must use a Medicare-certified provider. The SNF must have an active state license.

(Oregon and Washington Medicaid) KFHP must use a Medicaid-certified provider.

SPECIAL GROUP CONSIDERATIONS, WHEN GROUP HAS A SNF BENEFIT

Commercial, FEDs, Oregon Medicaid: these criteria apply;

Medicare: January 2014 revisions to the Medicare Benefit Policy Manual related to Skilled Nursing facility, Home Health and Outpatient skilled care clarified that a beneficiary's lack of restoration potential cannot serve as the basis for denying coverage in this context. Rather, such coverage depends upon an individualized assessment of the beneficiary's medical condition and the reasonableness and necessity of the treatment, care, or services in question. Moreover, when the individualized assessment demonstrates that skilled care is, in fact, needed in order to safely and effectively maintain the beneficiary at his or her maximum practicable level of function, such care is covered (assuming all other applicable requirements are met). Conversely, coverage in this context would not be available in a situation where the beneficiary's maintenance care needs can be addressed safely and effectively through the use of *nonskilled* personnel.

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8, Coverage of Extended Care (SNF) Services
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 or LCD, Kaiser Permanente has chosen to use this document, "Skilled Nursing Facility Medical Necessity Criteria", which are based on the Medicare Policy Manual, for medical necessity determinations.

Washington Medicaid: Skilled Nursing care is covered for members that meet Milliman Care Guidelines (MCG) for skilled nursing care instead of Medicare criteria. There is no limit to the number of days in a benefit period. The coverage of skilled care will continue as long as the care is medically necessary.

REFERENCES

MEDICARE

Criteria are based on Medicare Benefit Policy Manual, Chapter 8, Coverage of Extended Care (SNF) Services (Rev. 10/5/23).

Note: Kaiser Foundation Health Plan (KFHP) of the Northwest does not require a 3-day hospital stay prior to admission to a Skilled Nursing Facility (SNF).

Non-Pharmacological Treatments for Tinnitus and Hyperacusis

Policy Number: 0019
Effective Date: March 1, 2021
Reviewed Date: June 2023
Next Review: June 2024
Specialist Reviewer: John Goddard, MD

BACKGROUND

CLINICAL BACKGROUND *(excerpted from Fuller 2020)*

Tinnitus is defined as the perception of sound in the absence of a corresponding auditory source (Jastreboff 2004). It is typically described by those who experience it as a ringing, hissing, buzzing or whooshing sound and is thought to result from abnormal neural activity and connectivity in auditory and non-auditory pathways, which is interpreted by the brain as sound (Elgoyhen 2015, Shore 2016). Tinnitus can be either objective or subjective. Objective tinnitus is estimated to occur in up to 10% of people with tinnitus seeking help (Kircher 2008) and refers to the perception of sound that can also be heard by the examiner (Roberts 2010). Objective forms include heartbeat synchronous pulsatile tinnitus, and they usually have a detectable cause such as arteriovenous malformation, carotid stenosis or dissections (Langguth 2013).

Specific medication or surgical treatment can lead to the cessation of the objective tinnitus percept (Kleinjung 2016). Most commonly, however, tinnitus is subjective, meaning that the sound is only heard by the person experiencing it and no source of the sound can be identified (Jastreboff 1988). Subjective tinnitus (the focus of this review) is estimated to affect up to 21% of the general adult population, increasing to as many as 30% of adults over 50 years of age (Davis 2000, Gallus 2015, Kim 2015). It can be experienced acutely, recovering spontaneously within minutes to weeks. However, it can become chronic and is unlikely to resolve spontaneously when experienced for three months or more (Hahn 2008, Hall 2011, Rief 2005). In 1% to 3% of the population tinnitus causes severe problems with daily life functioning (Davis 2000, Kim 2015). Although a range of psychological, sound, electrical and electromagnetic therapies have been developed, currently there is no reliable cure for subjective tinnitus.

POLICY AND CRITERIA

Cognitive-behavioral therapy (CBT) for tinnitus may be considered medically necessary for individuals scoring a minimum of 18 on the tinnitus handicap inventory (THI).

All other non-pharmacological treatments for tinnitus are considered experimental and investigational, including (but not limited to) patient education, masking, and biofeedback.

All treatments for hyperacusis in the absence of comorbid tinnitus are considered experimental and investigational.

RATIONALE

EVIDENCE BASIS

A 2020 Cochrane review analyzed the findings of 28 studies relevant to treatment of tinnitus with cognitive-behavioral therapy. That high-quality review reported that CBT may effectively improve quality of life in the short term, but long-term data is lacking. Adverse events were found to be uncommon. Evidence for other outcomes, including anxiety, was insufficient. CBT was more effective than no treatment, based on an average 10 point decrease on the tinnitus handicap inventory (THI), for which a

decrease of 7 or more points is considered to be clinically significant. Compared to other interventions for tinnitus, CBT was more effective than audiological care (5 point greater decrease on THI), tinnitus retraining therapy (15 point greater decrease on THI), and other active controls (including relaxation and support groups). The authors' conclusions are outlined below:

"The main results of this review indicate that cognitive behavioural therapy (CBT) may be effective in reducing the impact of tinnitus on quality of life at the end of treatment, and that there are few if any adverse effects from receiving CBT (although further research on this is recommended below). These results provide further evidence or justification for recommendations made in two prominent clinical guidelines endorsing the provision of CBT for patients with chronic bothersome tinnitus (Cima 2019; Tunkel 2014). Consequently, policy-makers and service providers should feel confident that CBT for tinnitus is beneficial for patients at least in the short term. This is not to say, however, that CBT is an easy form of treatment to engage in; it is often personally challenging and can require a considerable investment of time and money from the patient (assuming that CBT is even available and/or covered by insurance in a given country).

CBT for tinnitus appears to have some benefit for people who also experience depression, but the effects are small and there are some concerns with regards to the quality of the evidence. Thus, in addition to receiving tinnitus-specific CBT, people with co-morbid depression should also seek depression-specific treatment. Overall, there is either low-certainty evidence, small effects and/or an insufficient amount of evidence currently to recommend CBT for tinnitus if the primary intention is to improve anxiety or general quality of life, or to change negatively biased interpretations of tinnitus.

CBT for tinnitus delivered in person and delivered via the Internet, with some additional email communication from a professional, appear similarly effective, as does CBT delivered individually and group-wise. Alternative modes of delivery should be considered depending on patient preference, accessibility and cost.

There is insufficient evidence to support a recommendation for whom should provide CBT for tinnitus, although it is noted that psychologists and/or psychiatrists were involved in the design, conduct and/or supervision of all CBT treatments.

The results from this review are relevant to tinnitus patients with varying levels of hearing loss and thus they should also be eligible to access treatment. We do not know, however, to what extent the study populations represent the whole patient population.

It is important to keep in mind that approximately half of the included studies in the review only reported group-level data/ analyses. This means that the results represent an average of the outcomes for participants in the study. In other words, on average, people improved receiving CBT compared with waiting for it (tinnitus) to get better, or another available treatment. It is likely that individual patients might respond better or worse than the average treatment effects reported here and that patients should make informed choices aligned with personal preference where possible."

A 2021 assessment of the effectiveness of Tinnitus Retraining Therapy (TRT) produced for KP Southern California's Medical Technology Assessment Team (MTAT) identified 7 studies (5 RCTs and 2 quasi-experimental clinical studies) involving 620 patients. The report concludes that these studies suggest a benefit of TRT for improving tinnitus symptoms, severity, and function compared to partial TRT, structured counseling, tinnitus education, or provision of resources as part of standard care. MTAT indicates that the findings should be interpreted with caution because the overall quality of the evidence was rated "low" for all key outcomes. All identified studies were determined to be at serious risk of bias due to lack of well-described random sequence generation, allocation concealment, and/or blinding. Additionally, across the studies there was substantial heterogeneity regarding TRT directive counseling protocols in addition to the magnitude and significance of estimated effects (SCPMG Evidence-Based Medicine Services 2021).

CODES

CPT Code	Description
90832-90840	Psychotherapy

ICD-10 Code and Description
H93.1 Tinnitus
H93.11 Tinnitus, right ear
H93.12 Tinnitus, left ear
H93.13 Tinnitus, bilateral
H93.19 Tinnitus, unspecified ear
H93.A Pulsatile tinnitus
H93.A1 Pulsatile tinnitus, right ear
H93.A2 Pulsatile tinnitus, left ear
H93.A3 Pulsatile tinnitus, bilateral
H93.A9 Pulsatile tinnitus, unspecified ear
H93.23 Hyperacusis
H93.231 Hyperacusis, right ear
H93.232 Hyperacusis, left ear
H93.233 Hyperacusis, bilateral
H93.239 Hyperacusis, unspecified ear

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KAISER PERMANENTE®	**Northwest Region Utilization Review UR 49: Temporomandibular Disorders (TMD) Surgical Intervention Medical Necessity Criteria**
Department: Utilization Review Applies to: Kaiser Permanente NW Region Review Responsibility: UROC Subject Matter Experts: Dana Smith, MD; Kelly Dezura, DMD	Original Date 4/08 Last Reviewed: 10/20, 10/21, 10/22, 10/23 Last Revised: 10/19

Medical necessity criteria are applied only after member eligibility and benefit coverage is determined. Questions concerning member eligibility and benefit coverage need to be directed to Membership Services.

SURGICAL INTERVENTION MEDICAL NECESSITY CRITERIA

DEFINITIONS

Temporo-mandibular Disorders (TMD) are muscular-skeletal disorders that are medical, not dental, in nature.

Temporomandibular disorders (TMD) are a heterogeneous group of pathologies affecting the temporomandibular joints, the masticatory muscles, or both. The most frequent signs and symptoms are pain or tenderness in the preauricular area or in the masticatory muscles, an alteration of the range of joint motion, and articular sounds, such as click or crepitus, during mandibular movements. For diagnostic purposes, TMD has been classified into 3 groups: muscle disorders, internal derangement (disk displacement), and other joint disorders, such as arthralgia, osteoarthritis, and osteoarthrosis. Anxiety, depression, somatization disorders, and headaches have been associated with TMD symptoms.

POLICY

TMD treatment is non-dental, non-orthodontic, non-occlusal and generally non-surgical in its approach. Characteristics of TMD:

A. TM Joint popping; clicking; grinding; catching; and locking
B. Facial pain that is not tooth related and is aggravated with use of the jaw
C. Facial pain which appears related to clenching and bruxing

Diagnostic tests that may help identify TMD:

1. Range of motion (ROM): Restricted; deviates; pain active and/or passive; limited lateral motion; roughness of motion.
2. Compressive loading—biting on tongue blade, first one side, then the contralateral side.
3. Resistive loading—asking the patient to hold, in turn, the variety of mouth positions against resistance provided by the examiner's hand.
4. Palpation over lateral poles and intra-meatally to elicit pain and/or determine irregularities

MEDICAL NECESSITY CRITERIA

Surgical intervention is a consideration when pain and dysfunction are persistent and the following are unresponsive to the non-surgical treatments below:

1. recurring and/or persistent lock of TM joint
2. persistent painful popping of TM joint
3. Osteoarthritis of TM joint

OTHER CONSIDERATIONS

Non-surgical treatment to consider prior to surgical intervention:

1. Physical therapy- rest and reassurance; exercise; stretching; use of heat and cold; avoidance of aggravating factors
2. Analgesics, anti-inflammatory medications
3. Soft diet (nothing firmer than consistency of scrambled eggs)
4. Moist heat if muscle; cold, if joint
5. Bite splints

SPECIAL GROUP CONSIDERATIONS: Check individual benefits in CM
GROUP COMMERCIAL: None
OREGON MEDICAID: Check the Prioritized List
WASHINGTON MEDICAID:-Use Molina's definition for medical necessity
MEDICARE: TMJ services related to splint fabrication and fitting are only covered if the TM disorder is directly attributable to a medical condition (e.g., direct result of arthritis) or accidental injury (e.g. dislocation of jaw, closed or open).

CLINICAL
ADA Presidents Council Guidelines
Guidelines of Oregon and Washington State Board of Dentistry

TRIGGER POINT INJECTIONS FOR MYOFASCIAL PAIN

Policy Number: 0003
Effective Date: March 19, 2016
Reviewed Date: July 2023
Next Review: July 2024
Clinical Reviewer: John Borgoy, MD

BACKGROUND

CLINICAL BACKGROUND *(extracted verbatim from Hayes 2013)*

"Myofascial pain syndrome is a chronic condition affecting the connective tissue (i.e., fascia) surrounding the muscles that is characterized by pain and inflammation. A key characteristic of this condition is the presence of one or more myofascial trigger points (TPs) that are located in the muscle or muscle fascia. TPs are hyperirritable and exquisitely tender spots found in a taut, palpable band of skeletal muscle. Stimulation of TPs by either firm compression (palpation) or needle penetration can elicit local pain and tenderness, as well as motor dysfunction and autonomic dysfunction. However, palpation or other stimulation of TPs may also cause a pattern of referred pain that spreads or radiates distally to a target area that is characteristic of each muscle. Snapping (or rapid) palpation at or fast needle insertion into a TP may elicit a local twitch response (LTR), or a brisk contraction of the muscle fibers in and around the TP. Patients may have active TPs, or active and latent TPs. Active TPs cause pain at rest whereas latent TPs do not produce spontaneous pain, but instead may limit movement and cause muscular weakness.

TPIs involve the injection of a solution via a needle directly into the myofascial TP. The injectate may contain a local anesthetic, steroid, botulinum toxin, nonsteroidal anti-inflammatory drug (NSAID), 5-HT antagonist, or a combination of these substances. The goal of TPI therapy is to alleviate pain and restore function by inactivating the TP."

POLICY AND CRITERIA

Trigger point injections of anesthetic and/or corticosteroid for myofascial pain may be considered medically necessary when the following criteria are met:

- Local pain lasting longer than 3 months with all of the following:
  - Tenderness and/or weakness; AND
  - Motion restriction; AND
  - A palpable band that produces referred pain when compressed
- Documented failure or contraindication to standard conservative management (e.g., physical therapy, pharmacotherapy, or cardiovascular exercise); AND
- Injections are provided as part of a comprehensive, multidisciplinary pain program; AND
- No more than 4 injections are provided per session.

Those who exhibit at least 50% improvement in pain level and at least three months of improved function may be eligible for up to 4 sessions per year, at least 3 months apart. Additional injections are considered NOT medically necessary if these criteria are not met.

RATIONALE

EVIDENCE BASIS

Northwest Permanente Evidence-based Medicine Services reviewed the evidence on trigger point injections for myofascial pain in 2015. A recent, good quality technology assessment from Hayes

provided most findings from the evidence base (Hayes 2013). A bridge search from the date of the Hayes report through May 2018 was conducted. Six additional relevant studies were identified, including four randomized trials, one non-randomized trial, and one systematic review. Findings in subsequently published studies did not significantly differ from those reported in the Hayes review, and conclusions regarding the safety and efficacy of trigger point injections for myofascial pain remain the same.

Findings and conclusions of the Hayes review were as follows:

"The literature search identified 1 prospective study with 193 patients that investigated factors associated with the outcome of TPI for myofascial pain syndrome (Hopwood 1994). Thirty-one factors were identified for analysis based on published literature of mixed groups of pain patients, physicians' views of clinical importance, and ease of assessment in a typical clinical setting. Factors were analyzed via univariate and logistic regression analyses both for independent association with short-term treatment outcome and for magnitude of risk of failure associated with each factor following adjustment for other factors. The univariate analysis determined that an elevated risk of treatment failure was associated with unemployment arising from pain, inability of analgesic medication to provide pain relief, constant pain, high levels of pain-at-its worst and pain at-its least, extended duration of pain, alterations in social pursuits, and lower ability to cope with pain. Alcohol use was associated with lower risk for treatment failure according to the univariate analysis. The logistic regression analysis found that only unemployment, prolonged pain duration, and change in social activities were independently associated with treatment outcome.

In a randomized, double-blind trial, Hong (1994) compared lidocaine TPI and dry needling for relief of myofascial trigger points in patients that did or did not exhibit a local twitch response (LTR). Patients that showed an LTR during treatment exhibited statistically significant improvements from baseline in pain intensity, pressure pain threshold (PPT), and range of motion (ROM) immediately after treatment. However, for those patients that did not display an LTR, there was no change from baseline in pain intensity, PPT, or ROM. Thus, the beneficial effects of TPI and dry needling appear to depend upon the elicitation of an LTR during treatment.

Comparative Efficacy of TPI Versus Dry Needling: Three of the reviewed studies compared TPI therapy to dry needling for treatment of myofascial pain syndrome (Hong 1994; Ay 2010; Eroglu 2013). Findings from all 3 studies suggest that TPI is not superior to dry needling for reducing pain intensity and improving range of motion.

Duration of Treatment Benefit: Limited evidence pertaining to the duration of treatment benefit of TPI was available. Follow-up duration only extended up to 3 months following cessation of treatment. Only 4 studies reported data from more than 2 follow-up assessments after the end of treatment (Ferrante et al., 2005; Göbel 2006; Ozkan 2011; Seo 2013); 3 of these studies evaluated BTX-A TPIs and 1 study (Ozkan 2011) evaluated TPIs with lidocaine. The final follow-up assessment in 3 studies was 12 weeks after end of treatment, with 3 to 6 in-person total assessments (excluding baseline) depending on the outcome measure and the study (Ferrante 2005; Göbel 2006; Ozkan 2011). The fourth study included a total of 8 assessments up to 16 weeks posttreatment (Seo 2013). This evidence was insufficient to draw any conclusions about how long treatment efficacy persists after TPI therapy.

Trigger Point Injections as an Adjunct to Other Pain Management Strategies: In a systematic review of TPI for chronic nonmalignant pain, the authors note that most of the studies included in the review evaluated TPI as a stand-alone treatment. However, they indicate that the procedure is routinely used as an adjunctive to other therapies in clinical practice and the effectiveness of TPI may be underestimated in research studies where TPI is a stand-alone therapy (Scott 2009)."

RELEVANT GUIDELINES

The American Society of Anesthesiologists (ASA) and American Society of Regional Anesthesia and Pain Medicine (ASRA) Task Force on Chronic Pain Management evaluated the efficacy of TPIs for patients with chronic pain. The guideline concluded that there was insufficient literature to determine efficacy but

concluded that TPIs may be considered for treatment of myofascial pain when included as part of a multimodal pain management program due to evidence from observational studies.

The Colorado Division of Workers' Compensation issued a guideline entitled "Chronic pain disorder medical treatment guidelines" that addressed trigger point injections for myofascial pain. The guideline notes that "trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other active treatment modalities." The guideline also states that "patients should be reassessed after each injection session for an 80% improvement in pain (as measured by accepted pain scales) and evidence of functional improvement for 3 months. A positive result would include a return to baseline function, return to increased work duties, and measureable improvement in physical activity goals including return to baseline after an exacerbation." The guideline specifies that optimum treatment consists of 4 sessions per year, with no more than 4 injections per session.

CODES

CPT or HCPCS Code	Description
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20553	Injection(s); single or multiple trigger point(s), three or more muscles

ICD-10 Code	Description
M79.1	Myalgia (excl. myositis)

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