Washington State Health Care Authority

May 17, 2024 Meeting Materials
Health Technology Clinical Committee

Spinal cord stimulation and bariatric surgery

Contents

Health Technology Clinical Committee Application for Membership

Washington State Health Care Authority

1 Contact information

First name: Joseph

Middle initial: D

Last name: Strunk

Address: [redacted]

Best method, time to reach you: Email, anytime

Today's date: August 31, 2023

2 Personal information (optional)

Gender:

- ✓ Male
- Female
- X/non-binary[1]

Pronouns (select all that apply)

- She/her
- ✓ He/him
- They/them
- Other (subj./obj.):

Race or Ethnicity

- American Indian or Alaska Native
- Asian or Pacific Islander American
- Black/ African American
- Latino, Hispanic, Spanish
- ✓ White/ Caucasian
- Other:

3 Professional training

Education (list degrees): Bachelors of Science (BS), Doctor of Medicine (MD)

Health care practitioner licenses: Washington State Medical License, MD

Professional affiliations: American Society of Anesthesiologists, American Society of Regional and Pain Medicine

Board certifications, formal training, or other designations: American Board of Anesthesiology; Anesthesiology and Subspecialty Pain Medicine

Current position (title and employer): Anesthesiologist and Pain Physician, Pain Medicine Fellowship Associate Program Director, Virginia Mas

Current practice type and years in practice: Anesthesiology & Pain Medicine; 4 years

Total years as an active practitioner: 4 years

Location of practice (city): Seattle, WA

1 *Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.*

4 Experience

Provide a brief explanation (up to 150 words each) addressing the following:

1) Why you would like to serve on the clinical committee;

My motivation stems from a desire to contribute to the betterment of healthcare systems and patient outcomes. My clinical experience provides me insights into the real-world implications of coverage decisions. I have witnessed firsthand the impact of coverage determinations on patient access to vital treatments and the financial burden it can impose. Additionally, this is an opportunity to engage with fellow experts, and enhance my understanding of healthcare economics and policy. This continuous learning process aligns with my commitment to providing the best possible care to my patients. Lastly, active participation in evidence review is crucial for maintaining the highest standards of care. I am dedicated to the critical evaluation of medical evidence and appropriateness surrounding treatments like spinal cord stimulation.

2) The value of informing health policy decisions with scientific evidence, including any examples incorporating new evidence into your practice;

Evidence based medicine is a cornerstone of our practice at Virginia Mason Franciscan Health. We strive to educate our Pain Medicine fellows in the process of scholarly peer review with the goal to implement the most updated practice guidelines. One example includes the recent review and adoption of the evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimlation therapy for chronic non-cancer pain by H. Shanthanna et al. published in Regional Anesthesia and Pain Medicine earlier this year. Our practice now uses these guidelines for treatment discussions with patients, trainee education, and multidisciplinary team planning.

3) How your training and experience will inform your role on the committee

I trained at Virginia Mason Franciscan Health in Seattle and have continued to practice as clinical faculty of our Pain Medicine training program. Our practice serves a broad mixture of patients with disease processes spanning complex regional pain syndrome, degenerative spine disease, chronic abdominal pain, and cancer pain. Our clinic emphasizes appropriate procedural interventions and coordinations with non-pharmacologic and pharmacologic treatment modalities through our multidisicplinary conferences.

4) Treating populations that may be underrepresented in clinical trials: women, children, elderly, or people with diverse ethnic and racial backgrounds, including recipients of Medicaid or other social safety net programs?

I am dedicated to providing equitable and compassionate healthcare to underserved and vulnerable patient populations. The evidence underscores the pressing need for improved equity in healthcare, particularly in the field of pain medicine, where disparities persist among women, BIPOC individuals, and those with low socioeconomic status. I firmly uphold the fundamental right to quality healthcare for everyone. To achieve this, we must first acknowledge our implicit biases. It is imperative that we give deliberate attention to these patient populations. This entails recognizing and addressing disparities in access and treatment, ensuring that our healthcare systems are inclusive, and working collectively to bridge the existing gaps. Achieving better outcomes for all enrollees hinges on our commitment to equity and a proactive approach to overcoming biases in healthcare.

5 Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year? ✓ Yes ☐ No

Are you willing to commit to the responsibilities of a committee member, including:

- Attending meetings prepared for the topics of the day;
- Actively participating in discussions;
- Making decisions based on the evidence presented and the public interest1? ✓ Yes ☐ No

Could you, or any relative, benefit financially from the decisions made by the HTCC? ☐ Yes ✓ No

6 References

Provide three professional references:

1.
First name: Christine
Last name: Oryhan
Relationship: Colleague
Title: Anesthesiologist & Pain Physician, Pain Medicine
Contact email: [redacted]
Phone number:

2.
First name: Daniel
Last name: Warren
Relationship: Colleague
Title: Anesthesiologist & Pain Physician,
Contact email: [redacted]
Phone number:

3.
First name: Wyndam
Last name: Strodtbeck
Relationship: Colleague
Title: Anesthesiologist and Pain Physician,
Contact email: [redacted]
Phone number:

For your application to be reviewed, please include:

✓ Completed application ✓ curriculum vitae ✓ **conflict of interest disclosure**

Download this form and send the completed version to **shtap@hca.wa.gov**

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

1 *Detailed in Washington Administrative Code (WAC) and committee bylaws*

Joseph D. Strunk, MD

[redacted]

EDUCATION

Years	Degree	Institution (Area of Study)
2006 - 2010	BS	Northwest Nazarene University (Physics) Nampa, ID
2010 - 2014	MD	University of Utah (Medicine) Salt Lake City, UT

GRADUATE MEDICAL EDUCATION

Years	Degree	Institution (Area of Study)
2014 - 2015	Intern	Providence Sacred Heart Medical Center (Transitional Medicine) Spokane, WA
2015 - 2018	Resident	Virginia Mason Medical Center (Anesthesiology) Seattle, WA
2018 - 2019	Fellow	Virginia Mason Medical Center (Pain Management) Seattle, WA

LICENSURE AND CERTIFICATION

MEDICAL LICENSURE

2018 - present	State of Washington Medical License
2015 - 2018	State of Washington Medical License (Training)

BOARD CERTIFICATION

06/2019-12/2029	American Board of Anesthesiology
09/2019-12/2029	American Board of Anesthesiology Pain Medicine

OTHER CERTIFICATIONS

2012 - present	Advanced Cardiovascular Life Support (ACLS) Certification
2012 - present	Basic Life Support (BLS) Certification
2020 – present	Neonatal Resuscitation Program Certification

PROFESSIONAL EMPLOYMENT

08/2018 – 12/2020	Clinical Anesthesiologist Virginia Mason Medical Center, Seattle, WA
01/2021 – present	Academic Anesthesiologist Virginia Mason Medical Center, Seattle, WA

PROFESSIONAL ORGANIZATIONS

American Society of Regional Anesthesia and Pain Medicine

American Society of Anesthesiologists

Washington State Society of Anesthesiologists

PROFESSIONAL ACTIVITIES

2016 – 2018	Virginia Mason Perioperative Services Steering Committee, Member
05/2017	Washington State Delegation to ASA Legislative Conference, Member
2018 – 2021	Comparison of TAP vs IV Lidocaine After Kidney Transplant Surgery Principle Investigator
2019 – present	The Effect of an Opioid Free Anesthetic on Post-Operative Opioid Consumption after Laparoscopic Bariatric Surgery Sub-Investigator
2020 – present	Virginia Mason Department of Anesthesiology, Complex Spine Team, Member
2021 – present	Virginia Mason Department of Anesthesiology, Scheduling Consultant
2021 – present	ASA Summaries of Emerging Evidence, Question Writer
2021 – present	Virginia Mason Pain Medicine Fellowship Program, Associate Program Director

PUBLICATIONS AND PRESENTATIONS

Peer Reviewed Publications

Velagapudi M, Nair AA, Strodtbeck W, Flynn DN, Howell K, Liberman JS, **Strunk JD**, Horibe M, Harika R, Alamdari A, Hembrador S, Kantamneni S, Nair BG. Evaluation of machine learning models as decision aids for anesthesiologists. *J Clin Monit Comput.* 2022 Jun 9. doi: 10.1007/s10877-022-00872-8. Online ahead of print. PMID: 35680771

Hanson, N. A., **Strunk, J**., Saunders, G., Cowan, N. G., Brandenberger, J., Kuhr, C. S., Oryhan, C., Warren, D. T., Slee, A. E., & Strodtbeck, W. (2021). Comparison of continuous intravenous lidocaine versus transversus abdominis plane block for kidney transplant surgery: a randomized, non-inferiority trial. *Regional anesthesia and pain medicine*, rapm-2021-102973. Advance online publication. https://doi.org/10.1136/rapm-2021-102973. PMID: 34417343.

Davis, J. J., Bankhead, B. R., Eckman, E. J., Wallace, A., & **Strunk, J.** (2012). Three-times-daily subcutaneous unfractionated heparin and neuraxial anesthesia: a retrospective review of 928 cases. *Regional anesthesia and pain medicine*, *37*(6), 623–626. https://doi.org/10.1097/AAP.0b013e31826a8d10

Poster Presentations

Strunk, J., Hanson, N., Oryhan, C., Rouse, J., Strodtbeck, W. (2018) *Thoracic Epidural Catheter Removal in a Patient with Heparin Induced Thrombocytopenia on an Argatroban Infusion.* Submitted for presentation at: American Society of Regional Anesthesia, Pain Medicine Meeting; San Antonio, TX.

Strunk J., Porteous G. (2017) *Blood Product Utilization and Outcomes after Implementation of a Massive Transfusion Protocol in a non-trauma hospital.* Poster presented at: Anesthesiology; Boston, MA.

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Conflict of Interest Form

This form must be completed by individuals who are:

- Appointed to, or applying for, the Health Technology Clinical Committee; or
- Are providing certain consultant services.

Depending on the appointment or position, certain interests are permitted, but must be disclosed. In addition to providing disclosure on this form, applicants may be required to affirmatively recuse themselves from discussions or deliberations of a technology topic for which the applicant has an interest. The applicant may not participate in any agenda item for which a conflict of interest is identified and may not vote on any such matter. The applicant's terms of appointment or contract should be consulted for specific dates and limitations.

If a conflict of interest is so great as to make it difficult for an applicant to participate meaningfully in the work to which they have been appointed or contracted for, that member may be asked to resign.

Submission or re-submission of this form is required annually by July 1st. If, during the course of any year, a material change in any of the information occurs, this form should be updated prior to the next public meeting of the committee. It is advised applicants retain a copy of this form for their records.

Definitions

For purposes of this disclosure statement, the following definitions apply:

Business: Any corporation, partnership, proprietorship, firm, enterprise, franchise, association, organization, self-employed individual and any other legal entity operated for economic gain. This does not include income-producing not-for-profit corporations that are tax-exempt under section 501(c) of the Internal Revenue Code with which service is performed in a non-compensated capacity.

Committee: Means the Health Technology Clinical Committee (HTCC) or the consulting service that the person completing this form is applying for, contracting for, or serving on.

Honorarium: A payment or something of economic value given in exchange for services, upon which custom or propriety prevents the setting of a price. Services include, but are not limited to, speeches or other services connected with an event where an appearance is made in an official capacity.

Income: Gross, pre-tax income of any nature, derived from any source, including but not limited to, any salary, wage, advance payment, dividend, interest, rent, honoraria, return of capital, forgiveness of indebtedness, income from government sources (i.e. Social Security, public salary, etc.) retirement income, real estate transactions, inheritance income, or anything of economic value received as income.

Legislative or Administrative Interest: An economic interest, distinct from that of the general public, in one or more bills, resolutions, regulations, proposals or other matters.

Member of Household: Any relative who resides in the household of the person completing this form.

Person: A natural person or a corporation, partnership, joint venture, and any other similar organization or association.

Relative: The spouse of the person completing this form, and any children, siblings or parents whether by birth, adoption or marriage.

Applicant Name	Joseph D. Strunk
Address	[redacted]

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
None	None	None

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
None	None	None

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
American Society of Anesthesiologists: Summaries of Emerging Evidence	1061 American Lane, Schaumburg, IL 60173	Question Writer

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
Virginia Mason Franciscan Health 1100 9th Ave, Seattle WA, 98101	Joseph Strunk	Salary

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
None	None	None

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
None	None	None

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
None	None	None

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
None	None

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name Joseph D. Strunk

Check One: ☒ Committee Member ☐ Subgroup Member ☐ Contractor

[redacted] 09/03/23

Signature Date

Washington State Health Care Authority

Agency medical director comments

Spinal Cord Stimulator: Re-review Follow Up

Christopher Chen, MD, MBA
Medical Director, Medicaid
WA Health Care Authority

February 16, 2024

Options for Committee Deliberation

- Option 1: **Non coverage** for all conditions
- Option 2: **Coverage** with criteria **for certain conditions**, for example:
  - Coverage with criteria for PDN
  - Non coverage for FBSS/CBP, CRPS
- Option 3: **Coverage** with criteria **for all reviewed conditions**

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Agency Medical Director Group
Recommendation

- Spinal Cord Stimulation is not a covered benefit for:
  - Chronic back pain (including FBSS)
  - Painful Diabetic Neuropathy
  - Complex Regional Pain Syndrome

Proposed criteria: development process

- Reviewed other payer policies
- Reviewed inclusion or exclusion criteria from studies included in the evidence review

Proposed criteria: Qualifying Diagnoses

- Qualifying diagnoses (for Options 2 or 3):
  - Failed Back Surgery Syndrome
  - Chronic Regional Pain Syndrome (by Budapest Diagnostic Criteria)
  - Painful Diabetic Neuropathy
- Out of scope:
  - Dorsal root ganglion stimulation

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Proposed exclusion criteria

- Life expectancy < 1 year
- Concurrent substance use disorder (including alcohol or illicit drugs)
- Dependence or addiction to prescription opioids or benzodiazepines
- Related pending or existing worker's compensation claim, or pending or existing litigation
- Substantial pain in other regions that have required treatment in the past year
- Burst stimulation

Proposed coverage criteria

- The patient has moderate to severe (>5 on the VAS pain scale) **neuropathic pain and objective neurologic impairment** with documented pathology related to pain complaint (i.e., abnormal MRI). Neurologic impairment is defined as objective evidence of one or more of the following:
  - Markedly abnormal reflexes
  - Segmental muscle weakness
  - Segmental sensory loss
  - EMG or NCV evidence of nerve root impingement
- Member's functional disability assessed using the Oswestry Disability Index (ODI); member has received an **ODI score greater than or equal to 21%**, AND
- **Psychological evaluation** to rule out substantial mental health disorders, AND
- 12 months of **conservative medical management**, defined as regular attendance, participation and compliance with a multidisciplinary approach including:
  - Full course of physical therapy, AND
  - Cognitive behavioral therapy AND
  - Another modality of conservative management (acupuncture, chiropractic)
- Patient underwent a **7 to 14 day trial** of percutaneous spinal cord stimulation, and
  - Experienced significant pain reduction (50% or more) AND, either:
  - 50% reduction of chronic opioid medications (if applicable) OR
  - Showed objective and clinically meaningful degree of functional improvement

Washington State Health Care Authority

Questions?

More Information:

shtap@hca.wa.gov

HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the

task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Any adverse event		
AEs requiring surgery		
Withdrawal due to AEs		
Durotomy		
Neurologic injury		
Death		
Allergic reaction		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Pain (VAS, NRS etc)		
Function (ODI, etc)		
Opioid use		
ODI		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	**Less** Less cost effective	**Equivocal**	**More** More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is *insufficient* to make a conclusion about whether the health technology is *safe, efficacious, and cost-effective*;
- Evidence is *sufficient* to conclude that the health technology is *unsafe, ineffectual, or not cost-effective*
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for all indicated conditions*;
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for some conditions or in some situations*

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	**Covered unconditionally**	**Covered with conditions**

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

The report "identified no Medicare national coverage determination on the use of SBRT or any local coverage determinations that apply to the state of Washington."

Medicare Coverage

[see page 60 of final report]

- **Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**
  NCD – Electrical Nerve Stimulators (160.7) - There are two types of implantations covered by this instruction: Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered. Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

Clinical Practice Guidelines
[see page 19-24 of final report]

Guideline	Year	Evidence Base	Recommendation	Rating/Strength of Recommendation
American Society of Regional Anesthesia and Pain Medicine	2023	NR	• In patients with chronic low back pain and/or leg pain, limb ischemia due to peripheral vascular disease, painful diabetic neuropathy, and/or CRPS type I or II a trial of SCS should be performed prior to a definitive SCS implant.	• Moderate (US Preventative Services Task Force rating)
Dutch Quality of Healthcare Institute	2022	NR	• Given the high initial costs and the invasiveness, the scientific committee has followed the general rule that primarily more conservative therapies should be used to treat the complaints. If there is insufficient effect and/or if relevant, too many side effects, neurostimulation can be advised. • **FBSS**: In the case of insufficient effect on conservative treatments, minimally invasive treatment can be considered. Treatment with epidural injections with local anesthesia and possibly corticosteroids in a PSPS (FBSS) in which there is scar pain can be considered. In a PSPS (FBSS) in which the neuropathic and/or nociplastic pain is prominent, a pulsed radio frequency of a nerve root can be considered. • **CRPS**: Based on the available literature, combined with the expert opinion, the Scientific Committee recommends considering the following conservative treatments before applying neurostimulation. In the case of insufficient effect on conservative treatments, minimally invasive treatment can be considered. In upper extremity CRPS where vasomotor dysregulation is prominent, a thoracic block(T2–3) with local anesthetic and corticosteroids can be considered. In a residual CRPS situation in which neuropathic and/or nociplastic pain is prominent, a low dose of intravenous ketamine therapy can be considered. • **PDPN**: Based on the available literature, combined with the expert opinion, the Scientific Committee recommends considering conservative treatments before applying neurostimulation. In the case of insufficient effect of conservative treatments, minimally invasive treatment can be considered. Transcutaneous electrical nerve stimulation can	NR

			be considered for a PDPN in which pain is the main focus. In the case of a PDPN in which vasomotor dysregulation is prominent, a sympathetic blockade can be considered.	
European Academy of Neurology	2016	• **Post-surgical chronic leg and back pain (CBLP)**: Spinal cord stimulation added to conventional medical management versus conventional management alone or versus reoperation in post-surgical CBLP: 2 RCTs • **CRPS and PDN**: Spinal cord stimulation added to conventional medical management versus conventional management alone in CRPS and PDN: 2 or 3 RCTs	• **CBLP**: There is weak recommendation for the use of SCS added to conventional medical management versus conventional medical management and for the use of SCS as an alternative to reoperation in post-surgical CBLP • **CRPS and PDN**: There is weak recommendation for the use of SCS added to conventional medical management versus conventional medical management in PDN and CRPS I	• **CBLP**: Moderate (GRADE) • **CRPS and PDN**: Low (GRADE)
Dutch Orthopedic Association and the Dutch Neurosurgical Society	2015	• 2 RCTs	• FBSS: Neuromodulation is recommended for patients with FBSS who have pronounced leg pain and for whom conservative therapy has provided insufficient or no effect.	• **FBSS**: Based on the lack of a scientific conclusion and these other considerations, the task force developed the following positive recommendation for practice (because effectiveness is demonstrated in various RCTs, and the benefits clearly outweigh the risks and burdens)

American Society of Interventional Pain Physicians	2013	• 2 RCTS, 12 NRSIs	• **FBSS**: SCS is indicated in chronic low back pain with low-er extremity pain secondary to FBBS, after exhausting multiple conservative and interventional modalities.	• **FBSS**: The evidence is fair for spinal cord stimulation (SCS) in managing patients with failed back surgery syndrome (FBSS)
Neuropathic Pain Special Interest Group	2013	• **FBSS**: 2 RCTs • **CRPS type I**: 1 RCT, 1 SR, 1 Guideline • **CRPS type II**: NR • **PDN**: 1 NRSI	• **FBSS**: SCS is effective in treating FBSS • **CRPS type I**: SCS is effective in treating CRPS type I • **CRPS type II**: Very limited evidence • **PDN:** Weak evidence with small, positive case series with large effects in refractory DPN over long-term follow-up	• **FBSS**: Quality of evidence: Moderate; Strength of recommendation: Weak • **CRPS type I**: Quality of evidence: Moderate; Strength of recommendation: Weak • **CRPS type II:** Quality of evidence: Low; Strength of recommendation: Inconclusive • **PDN**: Quality of evidence: Low; Strength of recommendation: Inconclusive
Canadian Pain Society	2012	• 2 RCTs, 1 SR, 1 Guideline	• **FBSS**: In patients with FBSS who are not candidates for corrective surgery and who have failed conservative therapy, a SCS trial should be considered • **CRPS**: In patients with CRPS who are not candidates for corrective surgery and who have failed conservative therapy, a SCS trial should be considered	• **FBSS**: Level of evidence: Good; Rating of recommendation: B • **CRPS**: Level of evidence: Good; Rating of recommendation: B
Neuromodulation Access Therapy Coalition	2008 (Incorrectly noted in Deer, 2014)	• 8 RCTs	• SCS is effective in treating chronic neuropathic pain	NR
National Institute for Health and Care Excellence Technology appraisal guidance [TA159],	2008 (Original) 2014 Re-review	• 11 RCTs (3 RCTs in people with neuropathic pain due to FBSS)	• SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain of at least 50mm on a 0–100mm VAS for at least six months despite appropriate conventional medical management, and who have had a successful trial of stimulation.	• NR; no overall description of level of evidence in guideline document. • The Committee noted that only a small

Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin *[2008 original assessment included in prior review]* *See Table 5 for device-specific evaluations by NICE*		• 8 RCTs in patients with ischaemic pain, 4 of which were for treatment of angina	• SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of people with spinal cord stimulation devices, including experience in the provision of ongoing monitoring and support of the person assessed. • When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with SCS. Tests to assess pain and response to SCS should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted. • If different SCS systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered. **2014 Re-review Decision**: The implementation section updated to clarify that spinal cord stimulation is recommended as an option for treating chronic pain of neuropathic or ischemic origin. Nothing new that affects the recommendations in this guidance was identified. This guidance will be reviewed if there is new evidence that is likely to change the recommendations.	number of clinical trials had been identified and that relatively small numbers of people were included in these studies. The Committee accepted that there was some uncertainty about how the effects of pain treatments were sustained over time, but concluded that benefits could be sustained for at least up to 5 years in pain of neuropathic origin (for FBSS, CRPS)

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination
Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no or unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

Washington State Health Care Authority

FINAL Key Questions

Spinal Cord Stimulation

Background

Chronic pain is a leading cause of disability and is an immense public health challenge. Pain is chronic when it occurs for extended periods (usually defined as >3 months), and can affect other aspects of an individual's health and function, including physical, emotional, social, and mental, often leading to a loss in quality of life[1-6]. Treatment of chronic pain aims to improve function and quality of life in addition to pain relief. Primary treatments include disease and injury-specific treatments such as nerve root decompression or reoperation, and other therapies such as pharmaceuticals, physical therapy, behavioral and psychological therapies, and neurostimulation therapies such as transcutaneous nerve electrical stimulation (TENS). Spinal cord stimulation (SCS) may be considered for moderate or severe pain that does not respond to standard therapies. A 2020 U.S. Food and Drug Administration (FDA) communication estimated that 50,000 SCS devices are implanted annually.[7]

SCS was developed in the 1960's based on the Melzack and Wall's gate-control theory and has been used to treat a number of chronic pain issues.[8,9] Mechanisms of pain relief using SCS are not completely understood, although current theories suggest stimulation occurs through a pulse delivering a specific current to dorsal fibers which interfere with or suppress the transmission of pain signals between nerves and the brain.[10-12] Originally, pain relief through parameter changes were completely dependent on user input. Open loop and closed loop systems have been described. *Open loop* (OL) systems ignore external stimuli, such as movement of the spinal cord, heart rate, and respiration.[13,14] In contrast, *closed loop* (CL) systems automatically adapt and modify stimulator settings in response to patient position and activity in real time, maintaining stimulation within an individualized therapeutic range.[13,14] Further details on the mechanism of SCS systems have been described in great detail elsewhere.[11,12,15]

SCS systems involve percutaneous implantation of electrode leads into the epidural space until they reach the dorsal column of the spinal cord. Currently, 16 FDA approved SCS devices are available. Approved musculoskeletal indications generally include Failed Back Surgery Syndrome (FBSS), Complex regional pain syndrome (CRPS) Types I and II, intractable low back pain and leg pain. Other indications include epidural fibrosis, degenerative disc disease, and arachnoiditis. Some SCS devices are approved for treatment of diabetic neuropathy. In 2016 the FDA gave premarket approval (PMA) to the first generation of devices implanted onto the dorsal root ganglion (DRG) of the posterior root to treat CRPS type I or type II, reflex sympathetic dystrophy and causalgia.[16-18] Compared with SCS devices, in which leads are implanted into the epidural space, DRG leads enter the epidural space, exit the neuroforamina, and stimulate the adjacent DRG, potentially providing more focused pain relief through specific targeting, as well as decreased paresthesia.[11,19]

The pulse frequency used in SCS, measured in hertz (Hz), can be adjusted to meet the needs of individual pain thresholds.[11,12] Traditional SCS systems are considered "low-frequency", typically defined as 30 Hz to 200 Hz, but may be as low as 10 Hz or high as 1200 Hz.[12] Low-frequency SCS is often associated with paresthesia, a feeling of tingling or buzzing that is perceived differently depending on the individual, which may or may not bring discomfort. "High frequency" (also referred to as "paresthesia free") SCS systems, often defined as greater than 200 Hz, produce stimulations that are

typically unperceivable by patients, and may be preferred.[20] Currently, the highest frequency available is 10,000 Hz. Additionally, in 2016 the FDA approved a clinician application for SCS systems that provide stimulation in "bursts" rather than constant rates (referred to as tonic stimulation or burst stimulation), which may provide greater relief at lower frequencies.[21-24]

Topic Background

A Health Technology Assessment (HTA) on SCS was performed in 2010 and reviewed by the Washington Health Technology Assessment Program (HTAP). The prior report focused on evidence for the effectiveness of and complications for traditional SCS (dorsal column) in patients with chronic neuropathic pain. Signal updates were performed in 2014, 2016, and 2018, all of which concluded that there was not substantial, high-quality new evidence comparing SCS with medical or surgical interventions that did not involve neuromodulation (e.g., SCS, DRG stimulators, peripheral nerve neuromodulation) to trigger an updated report. The HTAP is interested in re-evaluation of spinal cord stimulation as additional evidence on technical advances related to use of SCSs, including use of high frequency and burst stimulation, may be available. Dorsal root ganglion stimulators will not be included in this review, given differences in lead placement compared with traditional SCS. This is consistent with the scope of the prior report. The proposed assessment update will be restricted to devices approved by the FDA for management of the FDA-approved conditions related to neuropathic and non-neuropathic musculoskeletal pain as described in the PICOTS (Table 1). Comments from the public posting of the KQ and PICOTS and consultation with the HTAP were considered for finalization of the Key Questions and scope.

Final Key Questions and Scope

Key Questions (KQ)
When used in adult patients who have failed other treatment options for pain related to failed back surgery syndrome, chronic back pain, complex regional pain syndrome, or peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia):

Key Question 1:
What is the evidence of short and long-term effectiveness of spinal cord stimulation compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?

Key Question 2:
What is the evidence of the safety of spinal cord stimulation compared with medical and/or surgical treatment (appropriate to condition) that does not include neuromodulation devices?

Key Question 3:
What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub-populations of interest?

Key Question 4:
What is the evidence of cost-effectiveness of spinal cord stimulators compared with other medical or surgical options that do not include neuromodulation?

Table 1. Draft PICOTS Scope

Study Component	Inclusion	Exclusion

Participants	Adults with one of the following: • chronic low back pain, failed back surgery syndrome (low back pain and persistent, significant radicular pain following surgery), complex regional pain syndrome, peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia) Special populations/factors of interest: Sex, age, psychological or psychosocial co-morbidities, diagnosis or pain type, provider type, setting or other provider characteristics, health care system type, including worker's compensation, Medicaid, state, employees	• Children, patients <18 years old • Patients with prior use of SCS • Patients who are pregnant • All other pain conditions (e.g., cancer pain, chronic refractory anginal pain, heart failure, critical limb ischemia, peripheral vascular pain, pain at end of life, MS, fibromyalgia, headache, trigeminal neuralgia, chronic pancreatitis, chronic pelvic pain, chronic abdominal pain, post-stroke pain • Studies in which < 75% of patients have chronic musculoskeletal or neuropathic pain or other included pain conditions
Intervention	FDA-approved spinal cord stimulation (permanently implanted pulse generator systems and radiofrequency receiver systems)	• Temporarily implanted spinal cord stimulation devices • Neurostimulation of other parts of the nervous system (e.g., peripheral nerves, deep brain), dorsal root ganglion stimulation • Transcutaneous electrical nerve stimulation (TENs) • Non-FDA approved devices (unless final, phase III trial) • Intrathecal pumps
Comparators	Medical and/or surgical treatment (appropriate to condition) that does not include comparison of SCS methods/devices or other neuromodulation devices	• Comparisons of SCS devices • Comparison of SCS combined with other interventions vs. the other intervention alone • Comparisons of different types/modalities of SCS (e.g., comparisons of low versus high frequency, burst vs. tonic, etc.)
Outcomes	**Primary Outcomes (SOE)** • Function • Pain • Opioid use • **Complications** and adverse effects (e.g., procedural complications and technical failures, harms, infection, revision, removal, painful paresthesia or loss of paresthesia, mortality, serious adverse events) **Secondary outcomes (No SOE)**	• Non-clinical outcomes • Non-validated measures • Intermediate outcomes • Return to work

	• Health-related quality of life (HR-QoL) • Anxiety and depression • Patient satisfaction • Global perceived effect (GPE)/global impression of change	
Setting	Any	
Study design	• RCTs will be the primary focus; prospective high quality comparative nonrandomized studies of intervention (NRSI) with concurrent controls that control for confounding will be considered if RCTs are not available; question 3 is limited to RCTs • NRSIs including case series designed to evaluate harms with at least 5 years follow-up, or which report on rare harms for question 2 will be considered. • Formal cost-effectiveness analyses assessing initial placement and replacement will be considered for question 4	• Case reports • Case series (for KQ1, 3, 4) • Case series not designed to evaluate harms, those with < 5 years follow-up for question 2 unless they report on rare harms outcomes • Non-clinical studies (e.g., animal studies) • Studies with N < 10 patients total or < 10 per group • Studies not reporting on primary outcomes or harms
Publication	• Studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports • Full formal economic analyses (e.g., cost-utility analyses) published in English in an HTA, or in a peer-reviewed journal published after those represented in previous HTAs	• Abstracts, editorials, letters, books, conference proceedings • Studies without abstracts available online • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • Studies reporting on the technical • aspects spinal cord stimulation • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions/publications • Other types of economic evaluations (e.g., costing studies, cost-minimization analyses, cost-benefit analyses)

DRGS = Dorsal Root Ganglion Stimulation; FDA = Food and Drug Administration; GPE = Global perceived effect; HFSCS = High-frequency spinal cord stimulation; HR-QoL = Health-related quality of life; HTA = Health Technology Assessment; MS = multiple sclerosis; NRSI = Non-randomized studies of interventions; RCT = Randomized Control Trial; SCS = Spinal cord stimulator; SOE = Strength of Evidence; TENS = Transcutaneous electrical nerve stimulation.

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Health Technology Clinical Committee Application for Membership

Washington State Health Care Authority

1 Contact information

First name: Judy

Middle initial: Y

Last name: Chen

Address:

Phone number:

Best method, time to reach you:

Email:

Today's date: 2/7/2024

2 Personal information (optional)

Gender:

☐ Male ☑ Female ☐ X/non-binary[1]

Pronouns (select all that apply)

☑ She/her ☐ He/him ☐ They/them ☐ Other (subj./obj.):

Race or Ethnicity

☐ American Indian or Alaska Native

☑ Asian or Pacific Islander American

☐ Black/ African American

☐ Latino, Hispanic, Spanish

☐ White/ Caucasian

☐ Other:

3 Professional training

Education (list degrees): Medical Doctor

Health care practitioner licenses: DEA

Professional affiliations: University of Washington School of Medicine

Board certifications, formal training, or other designations: American Board of Surgery, American Board of Obesity Medicine, Focused Practice Designation in Bariatric Surg

Current position (title and employer): Associate Professor of Surgery, University of Washington Medical Center

Current practice type and years in practice: Bariatric Surgery 11 years

Total years as an active practitioner: 11 years

Location of practice (city): Seattle, WA

1 *Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.*

4 Experience

Provide a brief explanation (up to 150 words each) addressing the following:

1) Why you would like to serve on the clinical committee;

I would like to participate in the discussion regarding the review in coverage determinations for Bariatric Surgery. I am an expert in obesity health and metabollic surgery.

2) The value of informing health policy decisions with scientific evidence, including any examples incorporating new evidence into your practice;

I am actively involved in the American Society for Metabolic and Bariatric Surgery, specifically as the chair of the State Chapter committee and involved in the Access to Care committee. I participate in research and understand the importance of scientific evidence to guide the practice of obesity and metabolic health care.

3) How your training and experience will inform your role on the committee

I am fellowship trained and a bariatric surgeon at the University of Washington. This practice mostly cares for the medicare and medicaid population in the state of WA and I look forward to working with the HTCC on the goals of the committe to review and provide best coverage determination for obesity health.

4) Treating populations that may be underrepresented in clinical trials: women, children, elderly, or people with diverse ethnic and racial backgrounds, including recipients of Medicaid or other social safety net programs?

As a surgeon at our state hospital, University of Washington Medical Center, I am familiar with these populations and am dedicated to sharing my experience, training, and knowledge.

5 Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year? ☐ Yes ☐ No

Are you willing to commit to the responsibilities of a committee member, including:

- Attending meetings prepared for the topics of the day;
- Actively participating in discussions;
- Making decisions based on the evidence presented and the public interest1? ☑ Yes ☐ No

Could you, or any relative, benefit financially from the decisions made by the HTCC? ☐ Yes ☑ No

6 References

Provide three professional references:

1.
First name: Andrew
Last name: Wright
Relationship: colleague
Title: Professor of Surgery
Contact email:
Phone number:

2.
First name: Saurabh
Last name: Khandelwal
Relationship: colleague
Title: Associate Professor of Surgery
Contact email:
Phone number:

3.
First name: Laura
Last name: Montour
Relationship: colleague
Title: Assistant Professor of Family Medicine
Contact email:
Phone number:

For your application to be reviewed, please include:

☑ Completed application ☑ curriculum vitae ☑ **conflict of interest disclosure**

Download this form and send the completed version to **shtap@hca.wa.gov**

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

1 *Detailed in Washington Administrative Code (WAC) and committee bylaws*

Judy Chen-Meekin, MD, FACS, FASMBS, Diplomate of Obesity Medicine
Assistant Professor of Surgery

Education

Undergraduate

University of Washington,
Sept 1997 – June 2001
Bachelor of Science, Microbiology
Minor in Medical History and Ethics
Magna Cum Laude

Medical School

Stritch School of Medicine, Loyola University,
Sept 2003 – June 2007
Loyola Scholarship Grant
Doctor of Medicine, 2007

Post Graduate Training

Residency	General Surgery July 2007 – July 2012 Boston Medical Center Department of Surgery
Fellowship	Minimally Invasive and Bariatric Surgery August 2012 – July 2013 Brigham and Women's Hospital Harvard Medical School

Professional Summary

Faculty Positions

2012-2013	Clinical Instructor Associate Surgeon Brigham and Women's Hospital, Boston MA
2013-2017	Bariatric Surgeon Swedish Medical Center, Seattle and Issaquah WA

2017-2023 Assistant Professor of Surgery
University of Washington Medical Center, Seattle WA

2019-current Affiliate Faculty
University of Washington Medicine Diabetes Institute, Seattle WA

2021-2023 Montlake Site Director for Surgery Clerkship for Medical Students
University of Washington School of Medicine, Seattle WA

2022-current Affiliate Faculty
University of Washington Division of Healthcare Simulation Science, Seattle WA

2023-current Associate Professor of Surgery
University of Washington Medical Center, Seattle WA

2023-current Associate Clerkship Director of Medical Students
University of Washington School of Medicine, Seattle WA

Hospital Positions

2017-current Director
Adolescent Bariatric Surgery

2018-current Associate Medical Director for Infection Control
University of Washington Medical Center

2019-current Bariatric Coordinator
Center for Weight Loss & Metabolic Surgery

2020-current Associate Medical Director Clinical Resource Management
University of Washington Medical Center

2020-2021 Co-Medical Director
Center for Weight Loss & Metabolic Surgery

2024-current Medical Director for 4NE
University of Washington Medical Center

Honors

1997-2001	Phi Eta Sigma Honors Society 1997-2001
1997-2001	Deans Honor List
1998-2001	Certificate of High Scholarship
2000-2001	Mortar Board Honors Society
2005-2006	Bioethics Honors Program
2005-2006	Surgery Honors Research Society
2006	Loyola Financial Aid Award
2009	Gold Heart VA Award
2010	ABSITE highest score of PGY 3 Boston University Surgery Residents
2015-2023	Seattle Met Top Doctor

Board Certification

National Board of Medical Examiners
American Board of Surgery
General Surgery, 2013 Expires 3/2023
Certificate #057939
Diplomate of the American Board of Obesity Medicine
Obesity Medicine, Expires 4/2022
Focused Practice of Designation, American Board of Surgery
Metabolic Bariatric Surgery, 4/2022
Certificate #000021

Certifications and Courses

Fellow of the American College of Surgeons
Fellow of the American Society of Metabolic and Bariatric Surgery
ASMBS Certificate of Acknowledgement of Satisfactory Training:
Metabolic and Bariatric Surgery for Fellows
Orbera Intragastric Balloon System Certified Surgeon
OverStitch Endoscopic Suturing System Certified Surgeon
WSMA Physician Leadership Course
ACS Improvement Course: The Basics
UW Medicine Quality Improvement Bootcamp
BESAFE: Bariatric Endoscopy Skill Acquisition Focused Evaluation
SAAS: Executive Healthcare Leadership Academy

Licensure

WA State Department of Health Physician and Surgeon License
MD 60370704
DEA License CURRENT: FC3387392, Issued July 2012
National Board of Medical Examiners, USMLE Steps 1,2,3

Diversity, Equity and Inclusion Activities

2020-current American Society of Metabolic and Bariatric Surgery
Committee on Diversity and Inclusion

2020-22 American Society of Metabolic and Bariatric Surgery
Committee on Bariatric Surgery Training
DEI Liaison to improve diversity representation for Fellowship
Educational Lectures & Learning Objectives Webinars (monthly webinar)
Moderation of F.E.L.L.O.W education program

2021, May Cultural Complications – Stereotypes - obesity bias

Professional Organizations

2012-14 Affiliate Surgeon Member
American Society of Metabolic and Bariatric Surgery

2014-2016 Regular Member
American Society of Metabolic and Bariatric Surgery

2014-current Regular Member
Seattle Surgical Society
2015-current Fellow
American College of Surgeons

2016-current Fellow
American Society of Metabolic and Bariatric Surgery

2016-18 Treasurer
American Society of Metabolic and Bariatric Surgery, WA State Chapter

2018-current Surgeon Member
Society of American Gastrointestinal and Endoscopic Surgeons

2018-20 Vice President
American Society of Metabolic and Bariatric Surgery, WA State Chapter

2019-22 Councilor
American College of Surgeons, WA State Chapter

2019-current Surgeon Member
Society for Asian Academic Surgeons

2019-current Site Surveyor
Metabolic and Bariatric Surgery Accreditation & Quality Improvement Program

2020-2022 President
American Society of Metabolic and Bariatric Surgery, WA State Chapter

2021-2022 Program Committee
American College of Surgeons, Oregon Chapter Conference

2022-2023 President Elect
American College of Surgeons, Washington Chapter

2022-current Bariatric Endoscopy Skill Acquisition Focused Evaluation BE SAFE Subcommittee Chair, Examiner
American Society of Metabolic and Bariatric Surgery and Society of American Gastrointestinal and Endoscopic Surgeons

2023 Program Chair
American College of Surgeons, Washington Chapter Conference

2023-current President
American College of Surgeons, Washington Chapter

Teaching Responsibilities

2017-current ASMBS Endoscopy Course: Bariatric Endoscopy
Faculty

2017-current UW Surgery Science Series
Lecturer and Curriculum creator

2017-2021 How I Do It Lectures
Lecturer

2018-current Surgical Intern Boot Camp
Lecturer

2018-current Surgery O chalk talks
Organizer and Lecturer

2019 Internal Medicine Resident Lecture and Small Group
Lecturer

April 29, 2019 UW Minimally Invasive Surgery Regional Course for Residents (SAGES Mini Fellowship Residents Course)

Course Director (5 residencies)
Lecturer: Bariatric Case and Technical Video: Gastric Bypass

2019-current Education Research Workgroup
Mentor

2019-2021 Capstone Surgery Boot camp for Medical Students
Lecturer

2019 SAGES Hands On Regional Course: Primary Procedures in Bariatric Endoscopy and Endoscopic Management of Complications
Faculty

2020-current Resident Education in Quality & Patient Safety
Director

2020-current Medical Student Site Director, UWMC Montlake
Director

2020-current School of Medicine Energetics and Homeostasis Curriculum - Obesity and Weight Regulation
Lecturer

2020-current Fellowship Educational Lectures & Learning Objectives Webinars (monthly webinar), Bariatric Surgery Training Task Force with ASMBS, creating schedule and monthly moderation of education program
Monthly Moderator
June 4, 2021 Lecturer

2022 ASMBS Bariatric Endoscopy Skills Session
Faculty

2023 Surgical Education Workgroup
Faculty

2023 Program Didactics for Surgery
August 2, Junior Surg Technical Skills
August 9, Stomach
August 9, Quality Assessment and Improvement
September 6, Junior Technical Skills

2024 Program Didactics for Surgery
January 3, Laparoscopic Ventral Hernia Repair
January 17, Small Bowel Anastomosis

Primary Mentor for Trainees in the Past Five Years:

Center for Videoendoscopic Surgery Fellows

2017 Hope Jackson, George Washington Medical Center
2017 Monica Young, Olympia Medical Center
2017-2018 Grace Lopez, Piedmont Healthcare
201-2018 Dustin Cummings, Rutgers Medical Center
2018-2019 Annie Ehlers, University of Michigan VA
2018-2019 Jin-Sol Oh, Northwest Community Healthcare
2019-2020 Colette Inaba, University of Washing Medical Center
2020-2021 Jay Zhu, University of New Mexico Medical Center
2021-2022 Laurel Tangalakis, Ascension Borgess Hospital
2022-2023 Rachel Silcox, George Washington Medical Center
2022-2023 Mary Kate Bryant, Medical University of South Carolina
2023-2024 Alex Lois,

Endocrine Fellow, 2021 Weight Management Surgery Curricula Elective

2021 Kesh Popli, Evergreen Hospital
2023 Kriti Kalra, Kaiser Medical Center

SORCE Research Fellow, 2018-2020

2018-2020 Erin Fennern, Mount Sinai Surgery Residency
2018-2019 Kavita Pandit, University of Washington Surgery Residency

UW Surgical Residents, 2017-present

2018-2019 Ana (Erijia) Bao, left medicine
2019-2020 Peter Park, PMNR Residency
2020-2021 Court Orsborn, Radiology Residency
2021-2022 Connor Mamikunian, General Surgery
2023-2024 Alice Tao, General Surgery

UW Surgical Residents, Education and Simulation Projects

2019-current Jaime Oh – Laparoscopic small bowel anastomosis curriculum
2020-2021 Josh Rosen – Bowel Anastomosis, Wound Closure Suture Practice Kits

Swedish Surgical Residents

2014-2015 Brandon Vanderwel, Eviva Bariatrics
2015-2016 Jose Fernandez, Tacoma General
2016-2017 Emily Kobayashi, Eastern New Mexico Medical Center

Editorial Responsibilities

2015-2018 Reviewer, Obesity Surgery

2018-2021 Editorial Board Member, Obesity Surgery

2021-current Associate Editor, Obesity Surgery

2018-current Reviewer, Surgery for Obesity and Related Diseases

2019- current Reviewer for abstracts, 24th IFSO World Congress

2019-current Reviewer for abstracts, Society for American Gastrointestinal and Endoscopic Surgeons

2022-current Reviewer for abstracts, American College of Surgeons Washington and Oregon Chapters

2023-current Editorial Board Member, Innovative Surgery

2024-current Associate Editor, Bariatric Surgery Practice and Patient Care

National Responsibilities

2017-current SAGES Champion
Society for American Gastrointestinal and Endoscopic Surgeons

2018-2019 Fundamentals of Endoscopic Surgeries (FES) Committee
Society for American Gastrointestinal and Endoscopic Surgeons

2018- current Diversity and Inclusion Committee
American Society of Metabolic and Bariatric Surgery

2018-2021 Resident and Fellow Training Committee
Society for American Gastrointestinal and Endoscopic Surgeons

2018-current Metabolic and Bariatric Surgery Committee
Society for American Gastrointestinal and Endoscopic Surgeons

2018-current Committee on Pediatric Surgery
American Society of Metabolic and Bariatric Surgery

2018-current Committee on Bariatric Surgery Training
American Society of Metabolic and Bariatric Surgery

2019 **Liason** with Emergency Department Resource Work Group
American Society of Metabolic and Bariatric Surgery

2019-current **Site Surveyor**

Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program

2021-current Healthcare-Associated Infections and Antimicrobial Resistance Advisory Committee
Office of Communicable Disease Epidemiology
Washington State Department of Health

2022-current **Chair Subcommittee** of BESAFE Bariatric Endoscopy Skill Acquisition Focused Evaluation
Society for American Gastrointestinal and Endoscopic Surgeons

2022-current **Proctor** BE-SAFE Bariatric Endoscopy Skill Acquisition Focused Evaluation
American Society of Metabolic and Bariatric Surgery
Society for American Gastrointestinal and Endoscopic Surgeons

2022-current **Co-Chair** of State & Local Chapters Committees
American Society of Metabolic and Bariatric Surgery

2023 **Program Chair** WA and OR ACS State Chapter Conference
American College of Surgeons WA and OR State Chapter

2023-2024 **Chair** of State & Local Chapters Committees
American Society of Metabolic and Bariatric Surgery

2024-current Committee on Flexible Endoscopy
Society for American Gastrointestinal and Endoscopic Surgeons

National Conferences

2015-18 ASMBS WA/OR Session, **Program Chair**
ACS WA/OR Annual Conference

2018-19 ASMBS Welcome Event at SAGES, **Program Chair**
Seattle 2018, Baltimore 2019, Cleveland 2020 (cancelled for COVID)

2019 ACS Clinical Congress Scientific Forum e-Poster, **Moderator**
ACS, Oct 28, 2019

2020 Building a Comprehensive Weight Loss Center, **Session Chair**
SAGES, August 12, 2020

2021 Devils in the Details for Rural Surgeon, **Session Co-Chair**
SAGES, June 16, 2021

2021 MBSAQIP Site Verification: The New Virtual Norm, **Speaker** Re-Vision ASMBS Conference, January 29, 2021

2022 How I Deal with Complications in Bariatric Surgery **Session Co-Chair**, SAGES, March 18, 2022

2022 WA and OR ACS Chapter Conference, **Program Committee and Moderator,** June 9-11, 2022

2022 University of Washington Healthcare Simulation Symposium, **Technical Session Co-Chair,** September 30, 2022

2023 Seattle Surgical Society Annual Meeting, **Discussant**
Seattle Surgical Society, February 10, 2023

2023 Your Bariatric Patient has Regained Weight, Now What? **Session Co-Chair**
SAGES, March 30, 2023

2023 Bariatric Endoscopy Lab, **Lab Faculty**
ASMBS, June 25, 2023

2023 Bariatric Endoscopy Didactic, **Session Chair**
ASMBS, June 25, 2023

2023 State Chapter Advocacy Summit: An Update on Recent Policy Changes and How They Affect MBS, **Course Co-Director**
ASMBS Weekend, October 5, 2023

2023 The Basics of Therapeutic Endoscopy, **Lab Faculty**
ACS, October 24, 2023

Local Administrative Responsibilities

2010-12 Member, Surgical Site Infection Task Force
Boston Medical Center

2015-16 Member, Digestive Health Network Committee
Swedish Medical Center

2016 Member, Venous Thromboembolism Prophylaxis
Swedish Medical Center

2016 Member, Glycemic Team
Swedish Medical Center

2017-current **Chair**, Surgical Infection Prevention Task Force
University of Washington Medical Center

2017 Communications Liason
Department of General Surgery

2017-current **Chair**, Perioperative Glycemic Committee
University of Washington Medical Center

2018-current Senate Member
Faculty Senate, University of Washington

2018-21 Surgeon Champion, Sepsis Committee
University of Washington Medical Center

2018-22 Member, Infection Control Committee
University of Washington Medical Center

2018-19 Member, Surgery Core Group
University of Washington Medical Center

2018-20 Member, Women in Academia
Faculty Senate Committee, University of Washington

2019-current **Faculty Lead**, Quality Assessment and Improvement Forum
Department of General Surgery

2019 Search Committee for Medical Director of Infection Prevention & Control
University of Washington Medical Center, Montlake and Northwest

2019-current Member, WISH Simulation Interest Group
Division of Healthcare Simulation Sciences

2020-21 Member, UW General Surgery Program Virtual Recruitment Committee,
Department of General Surgery

2022 Program Committee, Healthcare Simulation Symposium Program
Division of Healthcare Simulation Sciences

2022-current Member, UW Surgery Education Working Group
Department of General Surgery

2022-current Member, UW School of Medicine Department of Surgery Medical Student

Surgical Career Counseling Committee

Research Funding/Grants

Feb 14, 2019 SAGES Grant for Regional Resident Laparoscopy Course
$5,000

Bibliography Peer reviewed manuscripts

1. 2012-2013 **Chen JY**, Ardestani A, Tavakkoli A. Brigham and Women's Hospital, Department of Surgery, Boston, MA
   Laparoscopic Adrenalectomy for Metastatectomy: Appropriate, safe and feasible. Surgical Endoscopy: Volume 28, Issue 3 2014, pages 816-820.
   PMID: 24337189

2. 2013-2014 Bradley DD, Louie BE, **Chen JY**, Aye RW, McMahon R, Farivar AS. Swedish Medical Center, Seattle, WA
   The Effect of Concurrent Esophageal Pathology on Bariatric Surgical Planning. Journal of Gastrointestinal Surgery: Volume 19, Issue 1 2015, pages 111-115.
   PMID: 25213580

3. 2016 Pernar LI, Lockridge R, McCormack C, **Chen JY**, Shikora SA, Spector D, Tavakkoli A, Vernon A, Robinson M. Brigham and Women's Hospital, Boston, MA
   An Effort to Develop an Algorithm to Target Abdominal CT Scans for Patients After Gastric Bypass. Obesity Surgery. (10):2543-6.
   PMID: 27523471

4. 2020 Ehlers AP, Sullivan KM, Stadeli KM, Monu JI, **Chen JY**, Khandelwal S. University of Washington, Department of Surgery, Seattle WA
   Opiod Use Following Bariatric Surgery: Results of a Prospective Survey. Obesity Surgery. 2020 Mar;30(3):1032-1037.
   PMID: 31808115

5. 2020 Fennern EB, Farjah F, **Chen JY**, Verdial FC, Cook SB, Wolff EM, Khandelwal S. University of Washington, Department of Surgery, Seattle WA
   Use of post-discharge heparin prophylaxis and the risk of venous thromboembolism and bleeding following bariatric surgery. Surg Endosc. 2020 Oct 6.
   PMID: 33025253

6. 2021 Inaba, C, **Chen JY**, Yates R, Khandelwal S, Oelschlager B, Wright A. University of Washington, Department of Surgery, Seattle WA
   Characteristics and Outcomes of Patients Undergoing Paraesophageal Hernia Repair with Selective Use of Biologic Mesh. Surg Endosc. 2021 Jun 2.

PMID: 34076763

7. 2021 **Chen JY**. Comment on: Effects of Bariatric Surgery on Reproductive Function of Obese Women without Polycystic Ovary Syndrome: A Systematic Review and Meta-analysis. Surgery for Obesity and Related Diseases. 2021 Nov 11.
   PMID 34857456

8. 2022 Rubinow KB, Zhong G, Czuba LC, **Chen JY**, Williams E, Parr Z, Khandelwal S, Kim D, LaFrance J. Evidence of Sex- and Depot-specific Regulation of all-trans-Retinoic Acid Biosynthesis in Human Adipose Tissue. Clinical and Translational Science. 2022 Feb 25.
   PMID: 35213790

9. 2022 Zhu J, Lois AW, Gitonga B, **Chen-Meekin JY**, Williams EJ, Khandelwal S, Carrera Ceron R, Oelschlager BK, Wright AS. The impact of socioeconomic status on telemedicine utilization during the COVID-19 pandemic among surgical clinics at an academic tertiary care center. Surg Endosc. 2022 Mar 24:1-9.
   PMID: 8945866

10. 2022 **Chen JY**, Nassereldine H, Cook SB, Thornblade LW, Dellinger EP, Flum DR. Paradoxical Association of Hyperglycemia and Surgical Complications Among Patients With and Without Diabetes. JAMA Surgery. 2022 Jun 15.
    PMID: 35704308

11. 2023 Silcox R, Khandelwal S, Bryant MK, Vierra B, Tatum, R, Yates R, **Chen JY**. Preoperative esophageal testing predicts postoperative reflux status in sleeve gastrectomy patients. Surg Endosc. 2023 Aug; 37(8):6495-6503.
    PMID: 37264227

12. 2023 Silcox R, Blaustein M, Khandelwal S, Bryant MK, Zhu J, **Chen JY.** Telemedicine Use Decreases the Carbon Footprint of the Bariatric Surgery Perioperative Evaluation. Obes Surg. 2023 Aug;33(8):2527-2532.
    PMID37407773

Collaborative Authorship

None

MedEDPortal

None

Book chapters

2016 Chapter 17. Shikora S, **Chen JY.** "Long Term Complications of Bariatric Surgery." *Bariatric Surgery, What Every Provider Needs to Know.* Eds. R Armour Forse, Caroline M Apovian. Pages 193-211. SLACK Publisher.

2020 Chapter: Cardiac Prehabilitation. **Chen JY.** "Metabolic and Bariatric Surgery Examination and Board Review." Eds. Robert Lim. McGraw Hill Publishing is currently pending.

2020 Curriculum: Obesity and Weight Regulation. Energetics and Homeostasis UW School of Medicine Curriculum. **Chen JY.** Tylee T.

2021 Curriculum: Medical Complications of Weight. Energetics and Homeostasis UW School of Medicine Curriculum. **Chen JY.** Weaver K.

Published Books or other publications

None

Abstracts/Presentations

Apr 2013 **Chen JY**, Ardestani A, Tavakkoli A. Brigham and Women's Hospital,
Laparoscopic Adrenalectomy for Metastatectomy: Appropriate, safe and feasible.
Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Baltimore MD

Nov 2016 VanderWel B, **Chen JY**, Lovell MM, Schembre D.
Tortuous Gastric Obstruction after Laparoscopic Adjustable Gastric Band Converted to Gastric Sleeve.
Poster Abstract. American Society for Metabolic and Bariatric Surgery, Atlanta GA.

Feb 2018 Lopez RG, **Chen JY.**
Cardiac Trauma caused by Nathanson Retractor during Laparoscopic Vertical Sleeve Gastrectomy.
Podium Presentation. Seattle Surgical Society, Seattle WA

Jun 2018 Lopez RG, **Chen JY,** Khandelwal S.
Axios Stent in Roux en O Patient.
Podium Presentation. Washington and Oregon ASMBS Chapter Meeting. Bend OR.

Jun 2018 Ehlers A, **Chen JY.**
Death after Intragastric Balloon.
Podium Presentation. Washington and Oregon ASMBS Chapter Meeting. Bend OR.

Mar 2019 Pandit KP, Thornblade LW, Cook T, **Chen JY,** Dellinger EG, Flum DR.
The Hyperglycemic Paradox of Surgical Complications.
Podium Presentation. University of Washington, 25th Annual Helen & John Schilling Lecture, Seattle WA.

Mar 2019 Fennern, E, **Chen JY,** Khandelwal S, Verdial F, Cook T, Wolff E, Farhood F.
Post- Discharge Heparin Prophylaxis, Venous Thromboembolism and Bleeding Following Bariatric Surgery: A Population-Based Study.
Poster Presentation. University of Washington, 25th Annual Helen & John Schilling Lecture, Seattle WA.

Apr 2019 Ehlers A, Khandelwal S, **Chen JY,** Wright A.
Implementation of an ERAS Pathway for Gastric Bypass Results in Improved Costs and Reduced Length of Stay.
Poster Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Baltimore MA.

Apr 2019 Minneman J, **Chen JY**, Ehlers A, Nieblas-Bedolla E, Hale M, Cruz M, Wright A, Khandelwal S. *High Prevalence of Asymptomatic Esophageal Motility Disorders and GERD in a Bariatric Surgery Population*.
Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Baltimore MA.

Jun 2019 Fennern EB, **Chen JY**, Khandelwal S, Verdial FC, Cook TB, Wolff EM, Farjah F.
Post-Discharge Heparin Prophylaxis Use and Risk of Venous Thromboembolism and Bleeding Following Bariatric Surgery: A Population-Base Study.
Podium Presentation. American College of Surgeons, WA/OR State Chapter Meeting, Chelan WA.

Jun 2019 Lois AW, Oh J, **Chen JY**, Khandelwal S. *Laparoscopic Reversal of Vertical Band Gastroplasty. Podium Presentation.* American College of Surgeons, WA/OR State Chapter Meeting, Chelan WA.

Jun 2019 Minneman J, **Chen JY**, Ehlers A, Nieblas-Bedolla E, Hale M, Cruz M, Wright A, Khandelwal S. *High Prevalence of Asymptomatic Esophageal Motility Disorders and GERD in a Bariatric Surgery Population*.
Podium Presentation. American Society for Metabolic and Bariatric Surgery, WA/OR State Chapter, Chelan WA,

Aug 2020 Inaba CS, Oelschlager BK, Yates RB, Khandelwal S, Minneman J, **Chen JY**, Wright, AS. *Characteristics and Outcomes of Patients Undergoing Paraesophageal Hernia Repair with Selective Use of Biologic Mesh.*

Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Virtual Conference, Cleveland OH.

Feb 2021 Zhu J, Gitonga B, Carrera R, Petersen R, **Chen JY,** Khandelwal S, Oelschlager B, Wright A. *Telemedicine Utilization Among UW Surgical Clinics during Covid-19.*
Podium Presentation. Seattle Surgical Society, Virtual Conference, Seattle WA.

April 2021 Atkinson S, Marquardt D, Kim S, Zern N, Berfield K, **Chen JY**, Langdale L, Tatum R. *So You Want(ed) To Be A Surgeon? The Covid Effect.*
Abstract. Association for Surgical Education Annual Meeting. Virtual Conference.

Jun 2021 Zhu J, **Chen JY**, Khandelwal SK, Oelschlager, B, Wright, A. *Telemedicine Utilization in Surgical Clinics.*
Podium Presentation. Annual Department of Surgery Education Conference, Virtual Conference.

Jun 2021 Zhu, J **Chen, JY** Khandelwal SK. *Management of Intraoperative Hemorrhage During Laparoscopic Sleeve Gastrectomy.*
Podium Presentation. American Society of Metabolic and Bariatric Surgery, Virtual Conference.

Sept 2021 Zhu, J **Chen JY,** Khandelwal SK, Oelschlager, B, Wright A. *Telemedicine Utilization in Response to COVID-19 Among Surgical Clinics at an Academic Tertiary Care Center.*
Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Las Vegas NV.

Mar 2022 Tangalakis L, Carrera R, Inaba C, **Chen JY,** Khandelwal S. Oelschlager B, Wright A. *Extensive Esophageal Mobilization in PEHR: How Protective is it?*
Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Denver CO.

June 2022 Clark N, Woode D, **Chen JY**, McIntyre L, Maine R.
Experience and Opportunities for Education and Quality Improvement: Optimization of Morbidity and Mortality Conference.
Podium Presentation. American College of Surgeons, WA and OR Chapter Conference, Bend OR.

Sept 2022 Oh J, Ward B, Wright A, **Chen JY.**
Laparoscopic Bowel Anastomosis: Improving Resident Education and Preparedness.
Podium Presentation. The Society for Asian Academic Surgeons Annual Meeting. Honolulu HI.

Feb 2023 Silcox R, Khandelwal S, Bryant MK, Vierra B, Tatum R, Yates R, **Chen JY**. *Does Preoperative Esophageal Testing Predict Postoperative GERD Status in Sleeve Gastrectomy Patients?*
Podium Presentation. Seattle Surgical Society Annual Meeting.
Seattle WA.

April 2023 Bryant MK, Wright A, **Chen JY**. *Revision of sleeve to RYGB for patient with Scleroderma and sleeve obstruction.*
Video Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Montreal Canada.

April 2023 Silcox R, Khandelwal S, Bryant MK, Vierra B, Tatum R, Yates R, **Chen JY**. *Does preoperative esophageal testing predict postoperative GERD status in sleeve gastrectomy patients?*
Podium Presentation. Society of American Gastrointestinal and Endoscopic Surgeons, Montreal Canada.

June 2023 Silcox R, Blaustein M, Khandelwal S, Bryant MK, Zhu J, **Chen JY.** *Telemedicine use decreases the carbon footprint of the bariatric preoperative evaluation.*
Poster Presentation. American Society of Metabolic and Bariatric Surgery, Las Vegas NV.

Sept 2023 Silcox R, Bryant MK, Vierra B, Tatum R, Yates R, **Chen JY**. *Abnormal preoperative esophageal testing predicts unresolved postoperative reflux after Roux-en Y gastric bypass.*
Podium Speaker, Session: Metabolic Surgery/GERD and Hiatal Hernia. International Federation Society of Obesity, Naples Italy.

Sept 2023 Lois A, **Chen JY**, Khandelwal S. *Early Internal Hernia*
Podium Speaker, ASMBS WA and OR Chapter Meeting, Chelan WA.

Social Media
Long-term weight-loss is seen with gastric bypass. By Brian Donohue UW Medicine Newsroom Oct 3, 2017
https://newsroom.uw.edu/postscript/long-term-weight-loss-seen-gastric-bypass

Bariatric Surgery: An Effective Treatment for Type 2 Diabetes. By Crystal Wong. Endocrinology Advisor. Nov 14, 2017
https://www.endocrinologyadvisor.com/home/topics/diabetes/type-2-diabetes/bariatric-surgery-an-effective-treatment-for-type-2-diabetes/

Is BMI Accurate – and What Does It Really Say About Your Health. By Angela Cabotaje. Right as Rain. Oct 10, 2019
https://rightasrain.uwmedicine.org/body/healthy-weight/what-is-bmi

The Good Luck Rituals of Medical Experts. By Angela Cabotaje. UW Huddle. Jan 20, 2020
https://huddle.uwmedicine.org/the-good-luck-rituals-of-medical-experts/

COVID-19 is not a Chinese virus, nor an Asian virus. It is a human virus. By Katharine Liang. Kevin MD. May 24, 2020
https://www.kevinmd.com/blog/2020/05/covid-19-is-not-a-chinese-virus-nor-an-asian-virus-it-is-a-human-virus.html

What you need to know about the Dr. Now diet. By Ruben Castaneda. US News and World Report. June 6, 2022
https://health.usnews.com/wellness/food/articles/dr-now-diet-and-how-to-follow-it

Women Share Their Experiences in Male-Dominated Fields. By Huddle Editorial Team. The Huddle. March 20, 2023
Trailblazing Women | UW Medicine Huddle

Medication or surgery for obesity care?
UW Medicine/Newsroom. May 31, 2023
https://newsroom.uw.edu/resource/medication-or-surgery-obesity-care

WA Health Leaders debate Prescriptions vs Surgery to treat Obesity.
KEPR. June 4, 2023
https://keprtv.com/news/local/wa-health-leaders-debate-prescriptions-vs-surgery-to-treat-obeisty?

National and International Lectures
November 7, 2019
OESO World Conference on Esophagus Diseases: Post-Graduate Course
Procedure Selection in Bariatric Surgery
Beijing, China

August 21, 2020
ACS Quality & Safety Conference
Metabolic Bariatric Surgery Accreditation Quality Improvement Program
Chicago, IL (cancelled due to covid)

June 4, 2021
ASBMS Fellowship Educational Lectures and Learning Webinar: The Fellows Project
Management of Complex Situations in Metabolic Surgery
National Virtual Platform

August 20, 2021

Asian Pacific Digestive Week
Barrett's Esophagus in Bariatric Patients
Kuala Lumpur, Malaysia (virtual)

June 5, 2022
ASMBS Conference
Endoscopy Equipment and Tools
Dallas, TX

September 23, 2022
The Cleveland Clinic: Obesity Summit
Intragastric Balloons: Indications and Outcomes
Cleveland, OH

November 11, 2022
The Cleveland Clinic Endoscopy Course
EDGE Procedure with Remnant Stomach GI Bleed
Dubai, UAE (virtual)

March 31, 2023
SAGES Endoscopic Solutions for the Bariatric Surgeon
Bariatric Endoscopy is Here: How do I Learn it? Skills Acquisition and Credentialing.
Montreal Canada

March 31, 2023
SAGES Masters Bariatrics: Addressing Reflux Before and After Bariatric Surgery.
It`s a Wrap: Handling Previous Anti-reflux Surgery and Avoiding Technical Pitfalls in Bariatric Patients with Reflux.
Montreal Canada

October 5, 2023
ASMBS Weekend: Focus Practice Designation.
Surgical Indications for Obesity and Type 2 Diabetes.
New Orleans LA

October 6, 2023
ASMBS Weekend: When and How to Operate on Complex Cardiac Patients.
Operative Considerations in High-Risk Cardiac Patients.
New Orleans LA

Regional Lectures

June 6, 2018
American College of Surgeons WA and OR Chapter Meeting, Bend Oregon

Cancer or Obesity. Which one do I treat first?

September 12, 2018
University of Washington's Department of Family Medicine 46th Annual Advances in Family Medicine and Primary Care
Update on Bariatric Surgery: Effects on Co-Morbid Conditions like Type 2 Diabetes
Seattle, WA

January 5, 2019
University of Washington Endocrine Update for Primary Care, Seattle WA
Metabolic Surgery and Adverse Metabolic Complications

May 16, 2019
CME Dinner Symposium, Seattle WA
Diabesity

June 15, 2019
ASMBS WA/OR Chapter Conference: Revisions Panel: What the Integrated Health Team Should Know
Revisions: Surgical and Medical Management
Chelan, WA

October 14, 2021
Washington Medical Case Management Association, Seattle WA
Care of Patients with Obesity Issues: From Medical Therapy to Bariatric Surgery

September 13, 2023,
University of Washington 51st Annual Advances in Family Medicine and Primary Care, Seattle WA
Obesity Medicine Treatment Options: How does bariatric surgery fit in a world with new nutrient-stimulating hormone therapy?

Institutional Lectures and Grand Rounds

October 13, 2017
University of Washington Video Spot
Obesity and Sugar

November 7, 2017
Morning CME Webinar
Update on Bariatric Surgery: Effects on Co-Morbid Conditions like Type 2 Diabetes

October 18, 2018
Endocrinology, Fellow Education
Bariatric Surgery
January 8, 2019
UWMC Roosevelt Grand Rounds
Update on Bariatric Surgery: Continuing Care of the Post Bariatric Surgery Patient

January 17, 2019
Family Medicine, Northgate
Metabolic Surgery

May 2, 2019
Internal Medicine Residency Program
Obesity and the Role of the PCP

September 4, 2019
UWMC Orthopedic Surgery Grand Rounds
Metabolics and Weight Loss Bariatric Surgery

April 27 and 28, 2020
UW School of Medicine
Energetics & Homeostasis: Obesity and Weight Regulation

June 30, 2020
Department of Surgery Medical Student Virtual Lectures, 2020-21
Bariatric Surgery

March 4, 2021
Endocrine Fellows
Care of Bariatric Surgical Patient and Metabolic Adverse Complications

January 19, 2022
Valley Medical Center Grand Rounds
Obesity Medicine

Other employment

None

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporory capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.
Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financiol, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name:
Judy

Middle initial:
Y

Last name:
Chen

Phone number:
[redacted]

Email:
[redacted]

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as on independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
C	Novo Nordisk stock	75,795	Self	✓ Family
C	Gilead Science stock	6,957	Self	✓ Family
C	Abbvie	2,105	Self	✓ Family
C	Eli Lilly	3,626	Self	✓ Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

No

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

[redacted]

Date

2/7/2024

Download this form and send the completed version to shtap@hca.wa.gov.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Metabolic and Bariatric Surgery: New Populations and Procedures

Judy Zerzan-Thul, MD, MPH

Chief Medical Officer

Health Care Authority

Washington State Health Care Authority

Background

- 2015 coverage determination 18+ covered with conditions
- Since then
  - Obesity growing problem
  - New procedures
  - New evidence including adolescents
  - New data on effectiveness
  - New medications which are not included in this review

8 Procedures Endorsed by American Society of Metabolic and Bariatric Surgery

- Adjustable gastric banding*
- Biliopancreatic diversion (with or without duodendal switch)*
- One-anastomosis gastric bypass
- Roux-en-Y gastric bypass*
- Single-anastomosis duodenal ileostomy with sleeve gastrectomy
- Sleeve gastrectomy (open* or endoscopic)
- Intragastric balloon

* = covered under 2015 decision

Agency Medical Director Concerns

Safety = Medium

Efficacy = Low

Cost = Medium

Medicaid Utilization 2019

	Number	Total Paid	Average Paid per Client
MCO		$2,959,270.61	$16,349.56
FFS		$318,757.21	$35,417.47
Total	190	$3,278,027.82	$17,252.78

UMP Utilization

- E66.01 Morbid (severe) obesity due to excess calories
- E66.09 Other obesity due to excess calories
- E66.8 Other obesity

DRG 619, 620, 621 (inpatient):

Year

	2019	2020	2021	2022
Male, n	13	18	22	16
Total paid	$392,407	$456,163	$498,916	$418,611
Female, n	98	125	140	139
Total paid	$2,420,181	$3,367,362	$3,463,271	$3,967,388
Total, n	**111**	**143**	**162**	**155**
Total paid	$2,812,588	$3,823,525	$3,962,188	$4,385,998
Average paid	**$25,804**	**$26,926**	**$24,919**	**$28,667**

Key Questions

1. What is the comparative clinical effectiveness of MBS procedures currently covered vs conventional weight loss management in children and adults?
2. What is the comparative clinical effectiveness of MBS procedures not currently covered vs conventional weight loss management in children and adults?
3. What is the short and long term safety of MBS procedures?
4. What is the differential effectiveness and safety of MBS procedures according to patent and clinical factors?
5. What are the costs and cost-effectiveness of the major MBD procedures in this review?

Current State Agency Policies

- PEBB/SEBB
- Apple Health Managed Care and Fee For Service only 18+
- Labor and Industries
  - Not covered because obesity does not meet the definition of an industrial injury or occupational disease

Other Payers

Coverage Criteria	Medicare	Oregon Medicaid	Aetna	Cigna	Regence	Current HTA
Approved populations						
BMI < 30 (any circumstances)	X	X	X	X	X	X
BMI 30 to 34.9 only with comorbidities	X	✓	X	X	X	X
BMI 35 to 39.9 only with comorbidities	X	X	✓	✓	✓	✓
BMI ≥ 35 only with comorbidities	✓	X	X	X	X	X
BMI ≥ 30	X	X	X	X	X	X
BMI ≥ 35	X	✓	X	X	X	X
BMI ≥ 40	X	X	✓	✓	✓	✓
Adolescents (age < 18 years)	*N/A*	✓	✓	✓	✓	X ✓
Approved procedures						
AGB	✓	X	✓	✓	X	✓
BPD	✓	✓	✓	✓	✓	✓
Gastric plication[a]	X	X	X	X	X	X
IGB[a]	X	X	X	X	X	X
OAGB[a]	X	✓	X	X	X	X
RYGB	✓	✓	✓	✓	✓	✓
SADI-S[a]	X	✓	✓	✓	X	X
SG	✓	✓	✓	✓	✓	X
VBG[a]	X	X	✓	✓	X	X
Revisional MBS	X	X	✓	✓	✓	✓
Other requirements						
Trial of medical weight-loss program	✓	X	✓	✓	✓	✓
MBSAQIP accreditation	X	✓	X	X	X	X
Multidisciplinary evaluation	X	✓	✓	✓	✓	✓

22 Practice Guidelines Since 2019

- Without comorbidity
  - BMI => 40 (9)
  - BMI => 35 (1)
- At least 1 comorbidity
  - BMI =>35 (11)
  - BMI =>30 (2)
- With type 2 DM
  - BMI =>30 (8)
- Adolescents BMI => 40 or =>35 with one comorbidity (3)

Evidence for Procedures Currently Covered

- BMI => 30-35
  - 2 RCTs AGB
    - low certainty decreased metabolic syndrome, high cholesterol, health related QoL
- BMI =>25-30 with type 2 DM
  - 1 RCT ABG – lost more weight but no differences in long term sustained remission of DM, BP, lipids, health related QoL

Evidence for Procedures Not Covered

- Endoscopic SG, OAGB, SADI-S, IGB – 8 trials no RCT of SADI-S
- 3 OAGB vs other covered MBS: no differences
  - Wt loss, rates of remission of chronic disease, improvement of QoL
- 3 Endoscopic SG, OAGB or IGB with lifestyle: surgery is better
- 2 IBG with sham surgery – 6mo and 1 yr
  - Wt loss, other changes not clinically meaningful

Evidence for Adolescents

- 3 small RCTs – Roux-en-Y or SG
  - Wt loss – mean 20 kg
    - Starting average weight: 122.6 kg, 128.8 kg, 118 kg
  - Resolution of high cholesterol
  - Remission of type 2 DM 86-100% in long term follow up

Safety – Evidence Considerations

- Reviewed pt level data in registry
  - Deaths very low (0.08%)
    - 58% considered related to the procedure
    - Higher BPD and Roux-en-Y
  - Readmissions in 30 days low (3%) 95% N/V, nutritional depletion, abd pain
    - 79% related to procedure
    - Higher in BPD, Roux-en-Y, SADI-S
  - ED visit in 30 days low (7%)
    - Higher in Roux-en-Y, BPD, SG
  - Reoperation rate in 30 days 1%
    - Higher BPD and Roux-en-Y

Safety –Evidence from Systematic Reviews

- Adult all cause deaths 3% with class 3 obesity with MBS vs. 13% medical care
- Deaths related to cancer reduced 65-75% with MBS
- Adolescents 90% resolution type 2 DM, 77% high cholesterol, 81% HTN; mortality <1%

Safety - Benefits

- Life expectancy after bariatric surgery in the Swedish Obesity Subjects study NEJM Oct 14, 2020 (reference 39)
- Bariatric surgery (2007) vs. usual care (2040) vs. general population (1135)
- Median follow up 24 yrs for mortality
- Mean life expectancy 3.0 yrs longer in surgery vs. usual care
  - Hazard ratio for CV death 0.70 (95% CI, 0.57 to 0.85)
  - Hazard ratio for cancer death 0.77 (95% CI, 0.61 to 0.96)

Cost Effectiveness

- Very low certainty
  - Endoscopic SG cost effective compared to semaglutide and lifestyle
  - SG was cost effective compared to semaglutide
- IBGs (Orbera) were not cost effective

Ongoing Studies

- 24 ongoing studies including 3 in teens
  - Head to head trials
    - 11 RCTs
    - 3 nonrandomized
  - Compared to lifestyle
    - 6 RCTs
    - 4 nonrandomized

Agency Medical Directors Recommendations: Cover with Conditions

Procedures

- Adjustable gastric bands
- Sleeve gastrectomy
- Roux-en-Y
- Biliopancreatic diversion with or without duodenal switch
- Single anastomosis duodenal ileostomy with sleeve gastrectomy
- One-anastomosis gastric bypass

Criteria

- Adults BMI =>35 and Asian descent =>32.5
- Adults with DM2 =>30
- Adolescents with bone maturity (13+) and BMI =>40 or =>35 with one obesity related complication
- MBSAQIP accreditation

Coverage Criteria	Medicare	Oregon Medicaid	Aetna	Cigna	Regence	AMD recommendations
Approved populations						
BMI < 30 (any circumstances)	X	X	X	X	X	X
BMI 30 to 34.9 only with comorbidities	X	✓	X	X	X	✓
BMI 35 to 39.9 only with comorbidities	X	X	✓	✓	✓	X
BMI ≥ 35 only with comorbidities	✓	X	X	X	X	X
BMI ≥ 30	X	X	X	X	X	X
BMI ≥ 35	X	✓	X	X	X	✓
BMI ≥ 40	X	X	✓	✓	✓	✓
Adolescents (age < 18 years)	*N/A*	✓	✓	✓	✓	✓
Approved procedures						
AGB	✓	X	✓	✓	X	✓
BPD	✓	✓	✓	✓	✓	✓
Gastric plication[a]	X	X	X	X	X	X
IGB[a]	X	X	X	X	X	X
OAGB[a]	X	✓	X	X	X	✓
RYGB	✓	✓	✓	✓	✓	✓
SADI-S[a]	X	✓	✓	✓	X	✓
SG	✓	✓	✓	✓	✓	✓
VBG[a]	X	X	✓	✓	X	X
Revisional MBS	X	X	✓	✓	✓	✓
Other requirements						
Trial of medical weight-loss program	✓	X	✓	✓	✓	X
MBSAQIP accreditation	X	✓	X	X	X	✓
Multidisciplinary evaluation	X	✓	✓	✓	✓	✓

Washington State
Health Care Authority

Washington State Health Care Authority

Bariatric surgery

Order of scheduled presentations:

No scheduled comments

Day of comments:

	Name
1	
2	
3	

Metabolic and Bariatric Surgery: New Populations and Procedures

Washington State Health Technology Clinical Committee Meeting

May 17, 2024

Presented by Shannon Robalino, MSc

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Overview

- Background
- Evidence findings
  - Adults
  - Children
  - Economic analyses
- Clinical Practice Guidelines
- Conclusions

Abbreviations

Metabolic and Bariatric Surgeries

- AGB: adjustable gastric band
- BPD: biliopancreatic diversion, with or without duodenal switch
- ESG: endoscopic sleeve gastroplasty
- IGB: intragastric balloon
- OAGB: one-anastomosis gastric bypass
- RYGB: Roux-en-Y gastric bypass
- SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy
- SG: sleeve gastrectomy

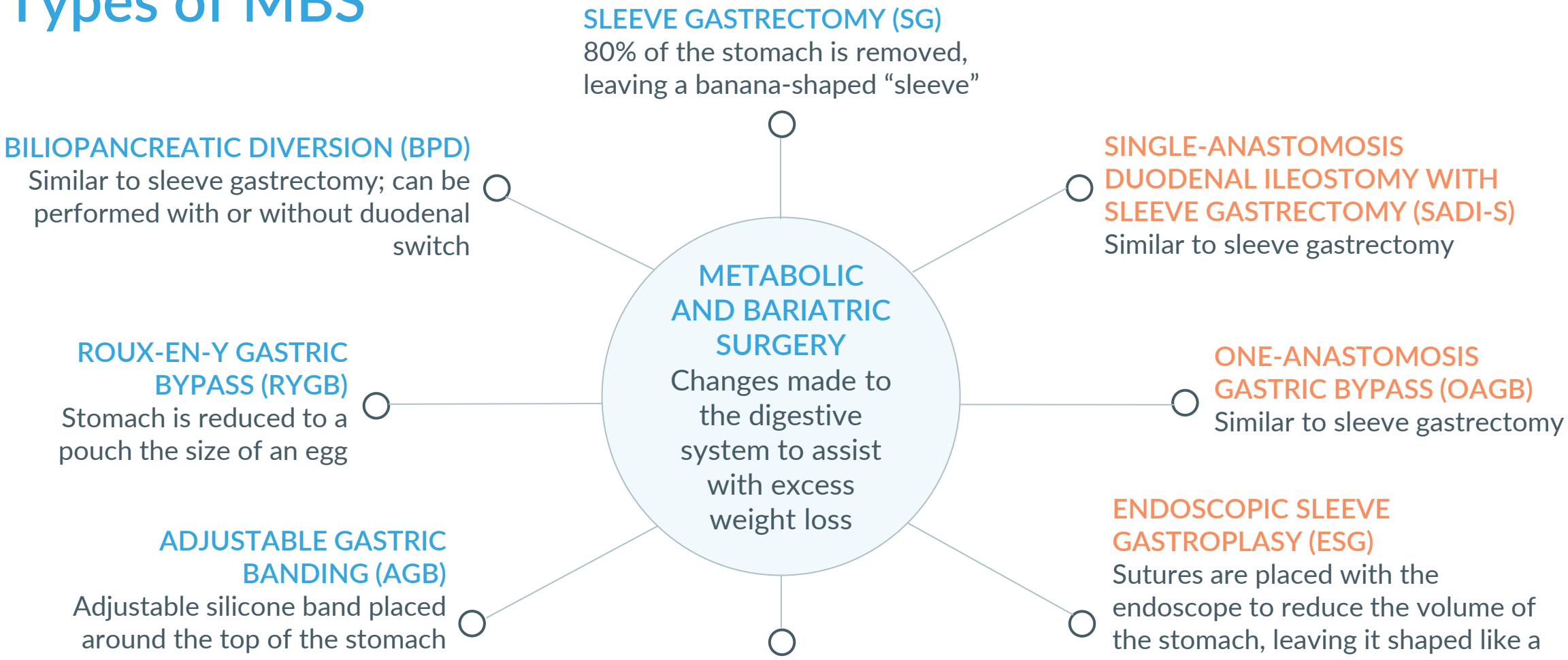
Additional Abbreviations

- BMI: body mass index
- CoE: certainty of evidence
- GRADE: Grading of Recommendations, Assessment, Development, and Evaluation
- MBS: metabolic and bariatric surgery
- RCT: randomized controlled trial
- T2DM: type 2 diabetes mellitus

Background

Technologies of interest and current coverage criteria

Types of MBS



Blue text indicates MBSs reviewed in 2015;
orange text indicates MBSs not reviewed in 2015.

2015 Washington Coverage Determination

- MBS is a **covered** benefit for adults (≥ 18 years of age) with:
  - BMI ≥ 40 kg/m^2, regardless of comorbidity status
  - BMI 35 to < 40 kg/m^2, and ≥ 1 obesity-related comorbidity
  - BMI 30 to < 35 kg/m^2, and T2DM
- MBS is **not covered** for:
  - Children and adolescents (< 18 years of age)
  - Adults with a BMI < 30 kg/m^2
  - Adults with a BMI 30 to < 35 kg/m^2, without T2DM or other obesity-related comorbidities

Overview of Differences Between 2015 and 2024 Reviews

BMI	Covered Under 2015 Criteria	Reviewed in 2015[a]	Reviewed in 2024[b]
≥ 40 kg/m^2 with or without a comorbidity	Yes	Yes	• Only for ESG, IGB, OAGB, and SADI-S
≥ 35 to ≤ 40 kg/m^2 with or without a comorbidity	Partially; patients must have ≥ 1 comorbidity	Yes	• Yes, for ESG, IGB, OAGB, and SADI-S • Yes, for those without a comorbidity for AGB, BPD, RYGB, and SG
≥ 30 to ≤ 35 kg/m^2 with or without a comorbidity	Partially; patients must have T2DM	Yes	Yes
< 30 kg/m^2	No	No	Yes

Notes. [a] The 2015 review focused on the 4 most common MBS procedures performed in US (i.e., AGB, BPD, RYGB, and SG). [b] The 2024 review included all MBS procedures currently practiced in the US (i.e., AGB, BPD, ESG, IGB, OAGB, RYGB, SADI-S, SG) though previously reviewed MBS procedures were only evaluated in the 2024 review for populations not currently covered for MBS under the 2015 Washington coverage determination.
Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic duodenal switch; BMI: body mass index; ED: emergency department; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI-S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

Rating the Evidence

Risk of Bias and Certainty of Evidence

Risk of Bias Assessment for Published Studies

- *Low*

  Clear reporting of methods and mitigation of potential biases and conflicts of interest

- *Moderate*

  Incomplete information about methods that might mask important limitations or a meaningful conflict of interest

- *High*

  Clear flaws that might introduce serious bias

GRADE Certainty of Evidence Ratings

Outcomes rated: weight, cardiovascular risk factors (e.g., T2DM status), HRQoL, safety

- **High** *(RCTs start here)*
  Very confident that the estimate of effect of intervention on outcome lies close to the true effect
- **Moderate**
  Moderately confident in estimate of effect of intervention on outcome; true effect is likely close to estimate, but possibly different
- **Low** *(nonrandomized studies start here)*
  Little confidence in estimate of effect of intervention on outcome; true effect may be substantially different from estimate
- **Very Low**
  No confidence in estimate of effect of intervention on outcome; true effect is likely substantially different from estimate

Abbreviations. GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HRQoL: health-related quality of life; RCT: randomized controlled trial; T2DM: type 2 diabetes mellitus.

Findings

Effectiveness and Safety

Adults Not Currently Covered for MBS Under the 2015 Washington Coverage Determination

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Adults Not Currently Covered Under 2015 Criteria

Report pages 38-45

AGB vs. LIFESTYLE + ORLISTAT (O'Brien, 2006)

BMI ≥ 30 to < 35 kg/m^2 with ≥ 1 obesity-related issue or comorbidity[a]

- 80 participants
- Baseline means
  - Age, 41.2 years
  - BMI, 33.6 kg/m^2
  - Weight, 94.8 kg
- Duration, 2 years + 8 years follow-up
- *Moderate* risk of bias

AGB vs. MULTIDISCIPLINARY DIABETES CARE (Wentworth, 2014)

BMI ≥ 25 to < 30 kg/m^2 with T2DM[b]

- 51 participants
- Baseline means
  - Age, 53.0 years
  - BMI, 29.0 kg/m^2
  - Weight, 82 kg
- Duration, 5 years + 5 years follow-up
- *Low* risk of bias

Note. [a] Currently adults with a BMI of ≥ 30 to < 35 kg/m2 (Class I obesity) are covered for MBS under the 2015 Washington coverage determination only if they have T2DM; individuals non-T2DM obesity-related comorbidities are not currently covered for MBS. [b] Currently adults with a BMI of ≥ 25 to < 30 kg/m2 (i.e., overweight) are not covered for MBS under the 2015 Washington coverage determination.

GRADE for Adults Not Currently Covered Under 2015 Criteria

Based on the studies included in this review for adults who are not currently eligible for MBS under the 2015 Washington criteria:

- Adults with a BMI ≥ 30 to < 35 kg/m^2 and an obesity-related comorbidity
  - **AGBs are more effective** than a very-low-calorie diet plus orlistat (*very low* to *moderate* CoE; 1 RCT)

- Adults with T2DM and a BMI ≥ 25 to < 30 kg/m^2
  - **AGBs are more effective** than multidisciplinary care (*very low* to *low* CoE; 1 RCT)

MBS Procedures Not Reviewed in 2015

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MBS Procedures Not Reviewed in 2015 vs. RYGB or SG

Report pages 45-57

OAGB vs. RYGB (RYSA study)

- 121 participants
- BMI ≥ 35 kg/m^2
- Baseline means
  - Age, 46.5 years
  - BMI, 43.8 kg/m^2
  - Weight, 126.9 kg
- Duration, 1 year
- *Moderate* risk of bias

OAGB vs. SG (Seetharamaiah, 2010)

- 214 participants
- BMI ≥ 30 kg/m^2
  - ≥ 1 obesity-related comorbidity for BMI ≥ 32 to < 35 kg/m^2
  - ≥ 2 obesity-related comorbidity for BMI ≥ 30 to < 32 kg/m^2
- Baseline means
  - Age, 38.9 years
  - BMI, 41.7 kg/m2
  - Weight, 108.9 kg
- Duration, 1 year + 4 years follow-up
- *Moderate* risk of bias

OAGB vs. RYGB (YOMEGA study)

- 253 participants
- BMI ≥ 35 kg/m^2
  - ≥ 1 obesity-related comorbidity for BMI ≥ 35 to < 40 kg/m^2
- Baseline means
  - Age, 43.5 years
  - BMI, 43.8 kg/m^2
  - Weight, 120.6 kg
- Duration, 2 years
- *Moderate* risk of bias

MBS Procedures Not Reviewed in 2015 vs. Lifestyle Interventions

ORBERA IGB + LIFESTYLE vs. LIFESTYLE ALONE (IB-005 study)

- 317 participants
- BMI ≥ 30 to < 40 kg/m^2 + 2-year history of obesity
- Baseline means
  - Age, 31.9 years
  - BMI, 35.0 kg/m^2
  - Weight, 98.0 kg
- Duration, 1 year
- *High* risk of bias

OAGB vs. DIET (LIFEXPE-RT study)

- 60 participants
- BMI ≥ 30 to < 50 kg/m^2 + metabolic syndrome
- Baseline means
  - Age, 44.8 years
  - BMI, 40.8 kg/m2
  - Weight, 113.0 kg
- Duration, 1 year
- *Moderate* risk of bias

ESG vs. LIFESTYLE (MERIT study)

- 253 participants
- BMI ≥ 30 to < 40 kg/m^2
- Baseline means
  - Age, 41.5 years
  - BMI, 31.9 kg/m^2
  - Weight, 88.4 kg
- Duration, 2 years + 8 years follow-up
- *Moderate* risk of bias

MBS Procedures Not Reviewed in 2015 vs. Sham Surgery

IGB (TRANSPYLORIC SHUTTLE) vs. SHAM SURGERY (ENDOBESITY II study)

- 270 participants
- BMI ≥ 30 to < 40 kg/m^2
  - BMI ≥ 30 to < 35 kg/m^2 with ≥ 1 obesity-related comorbidity
- Baseline means
  - Age, 43.3 years
  - BMI, 36.6 kg/m^2
  - Weight, 100.4 kg
- Duration, 1 year
- *Moderate* risk of bias

OBALON IGB vs. SHAM SURGERY (SMART study)

- 430 participants
- BMI ≥ 30 to < 40 kg/m^2 with T2DM
- Baseline means
  - Age, 42.6 years
  - BMI, 35.3 kg/m^2
  - Weight, 98.4 kg
- Duration, 5 years + 5 years follow-up
- *High* risk of bias

GRADE for MBS Procedures Not Reviewed in 2015

Based on the studies included in this review, we identified limited evidence on the effectiveness of MBS procedures not included in the 2015 review:

- Adults with a BMI ≥ 30 kg/m^2, with or without an obesity-related comorbidity
  - **One-anastomosis gastric banding (OAGB) is similarly or more effective** than Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG)
    (*moderate* to *high* CoE; 3 RCTs)

- Adults with a BMI ≥ 30 to < 50 kg/m^2, with or without an obesity-related comorbidity
  - **Adjustable gastric bands (AGBs) are more effective** than multidisciplinary diabetes care
    (*very low* to *low* CoE; 1 RCT)

- Adults with a BMI ≥ 30 to < 40 kg/m^2
  - **IGBs (Obalon and TransPyloric Shuttle) are more effective** than sham surgery, with or without a lifestyle intervention
    (*moderate* CoE; 2 RCTs)

30-day Morbidity and Mortality Across all MBS Procedures Among Adults

30-day All-Cause Mortality in Adults, 2016 through 2022

Appendix L

Procedure	Patients, n	Deaths, n	Proportion, %
AGB	8,973	1	0.01
BPD	11,180	31	0.28
ESG	1,480	0	0
IGB	3,072	1	0.03
OAGB	7,630	13	0.17
RYGB	273,474	347	0.13
SADI-S	2,394	4	0.17
SG	765,770	462	0.06
Total	**1,089,905**	**901**	**0.08**

Source. Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Registry.
Note. Blue text indicates the procedure with the highest proportion of patient deaths.
Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic duodenal switch; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy.

30-day Reoperations, Readmissions, and ED Visits in Adults, 2016 through 2022

Procedure	Patients, n	Reoperations, n (%)	Readmissions, n (%)	ED Visits, n (%)
AGB	8,973	71 (0.79)	148 (1.64)	360 (4.01)
BPD	11,180	314 (2.81)	656 (5.86)	901 (8.06)
ESG	1,480	8 (0.54)	38 (2.57)	58 (3.92)
IGB	3,072	34 (1.11)	52 (1.69)	124 (4.04)
OAGB	7,630	140 (1.83)	403 (5.28)	820 (10.75)
RYGB	273,474	5,497 (2.01)	14,495 (5.30)	27,347 (9.99)
SADI-S	2,394	49 (2.05)	102 (4.26)	197 (8.23)
SG	765,770	5,590 (0.73)	19,834 (2.59)	50,464 (6.59)
Total	**1,089,905**	**11,654 (1.07)**	**35,728 (3.28)**	**80,271 (7.36)**

Source. Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Registry.
Note. Blue values indicate the procedure with the highest proportion of patients who experienced the outcome.
Abbreviations. AGB: adjustable gastric band; BPD: biliopancreatic duodenal switch; ED: emergency department; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; OAGB: one-anastomosis gastric bypass; RYGB: Roux-en-Y gastric bypass; SADI S: single-anastomosis duodenal ileostomy with sleeve gastrectomy; SG: sleeve gastrectomy.

MBS Procedures for Children and Adolescents

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MBS in Children and Adolescents

Report pages 57-64

RYGB *or* SG vs. LIFESTYLE (AMOS2 study)

- 50 participants
- BMI ≥ 35 kg/m^2
- Baseline means
  - Age, 15.7 years
  - BMI, 42.6 kg/m^2
  - Weight, 122.6 kg
- Duration, 2 years
- *Moderate* risk of bias

AGB vs. LIFESTYLE (BASIC study)

- 59 participants
- BMI ≥ 35 kg/m^2 with ≥ 1 obesity-related comorbidity
- Baseline means
  - Age, 15.7 years
  - BMI, 44.1 kg/m2
  - Weight, 128.8 kg
- Duration, 1 year
- *Moderate* risk of bias

AGB vs. LIFESTYLE (O'Brien 2010)

- 50 participants
- BMI > 35 kg/m^2
- Baseline means
  - Age, 16.5 years
  - BMI, 41.3 kg/m^2
  - Weight, 118.0 kg
- Duration, 2 years
- *Moderate* risk of bias

GRADE for MBS Procedures in Children and Adolescents

Based on the studies included in this review, we identified limited evidence on MBS in children and adolescents:

- Adolescents aged 13 years and older
  - **Adjustable gastric bands (AGBs), Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy (SG) are more effective** than the lifestyle interventions that include reduced calorie intake, exercise, and behavior therapy (*low* to *moderate* CoE; 3 RCTs)
- Children aged less than 13 years
  - No eligible studies were identified

30-day Morbidity and Mortality Across all MBS Procedures Among Adolescents

30-day Mortality in Adolescents, 2016 through 2022

Appendix L

Procedure	Patients, n	Deaths, n	Proportion, %
RYGB	184	0	0
SG	1,943	2	0.10
Total	**2,127**	**2**	**0.10**

Source. Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Registry.
Abbreviations. RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy

30-day Reoperations, Readmissions, and ED Visits in Adolescents, 2016 through 2022

Procedure	Patients, n	Reoperations, n (%)	Readmissions, n (%)	ED Visits, n (%)
RYGB	184	2 (1.09)	7 (3.80)	14 (7.61)
SG	1,943	8 (0.41)	49 (2.52)	98 (5.04)
Total	**2,127**	**10 (0.47)**	**56 (2.63)**	**112 (5.26)**

Source. Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program Registry.
Abbreviations. ED: emergency department; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Costs and Cost-Effectiveness

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Costs and Cost-Effectiveness of MBS

Report pages 67-74

COST-EFFCTIVENESS ANALYSIS OF THE ORBERA IGB IN ADULTS (Finkelstein, 2019)

- vs. commercial lifestyle programs, commercial food replacement programs, and antiobesity medication
- Age, ≥ 18 years
- BMI, ≥ 25 kg/m^2
- Perspective, payer
- Time horizon, 4 years
- Discount rate, 3.5%
- US dollar year, 2018
- *High* risk of bias

COST-EFFECTIVENESS ANALYSIS OF SG AND ESG IN ADULTS (Saumoy, 2023)

- vs. semaglutide and a lifestyle intervention
- Age, 40 years
- BMI, 33, 37, or 44 kg/m^2
- Perspective, health care sector
- Time horizon, 30 years
- Discount rate, 3%
- US dollar year, 2021
- *Moderate* risk of bias

Cost-Effectiveness of Metabolic and Bariatric Surgery

Economic findings for populations and MBS procedures not currently eligible under the 2015 coverage determination include:

- Adults aged 40 with BMI ≥ 30 to < 35 kg/m^2
  - **ESG was cost-effective** when compared with semaglutide and lifestyle interventions (*very low* CoE; 1 cost-effectiveness analysis)
- Adults aged 40 with BMI ≥ 35 kg/m^2
  - **SG was cost-effective** when compared with semaglutide and lifestyle interventions (*very low* CoE; 1 cost-effectiveness analysis)
- Adults with BMI ≥ 25 kg/m^2
  - **IGBs were not cost-effective** at any willingness-to-pay threshold compared with commercially available, nonsurgical weight-loss interventions (*moderate* CoE; 1 cost-effectiveness analysis)

Clinical Practice Guidelines

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Summary of Clinical Practice Guidelines for Adult Populations

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BMI, kg/m^2	CPGs Recommending MBS
With or without a comorbidity	
≥ 40	9
≥ 35	1
≥ 30 to ≥ 37.5 in people of Asian background	4
With ≥ 1 comorbidity	
≥ 35	11
≥ 30	2
≥ 27.5 to ≥ 32.5 in people of Asian background	5
With T2DM	
≥ 30	8
≥ 27.5 in people of Asian background	6

Abbreviations. BMI: body mass index; CPG: clinical practice guideline; T2DM: type 2 diabetes mellitus.

Summary of Clinical Practice Guidelines for Pediatric Populations

Report pages 76-77

BMI, kg/m^2	CPGs Recommending Coverage
With or without a comorbidity	
≥ 40 or 140% of the 95th percentile	4
With ≥ 1 comorbidity	
≥ 35 to < 40 or 120% of the 95th percentile	4

Abbreviations. BMI: body mass index; CPG: clinical practice guideline.

Clinical Practice Guidelines (1 of 4)

Appendix G

- American Society for Metabolic and Bariatric Surgery Position Statement on One-anastomosis Gastric Bypass (2024)
- NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)
- NICE Guideline: Overweight and Obesity Management: Draft for Consultation (Expected 2024)
- American Academy of Pediatrics Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity (2023)
- 2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)
- Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)

Note. Blue text indicates guidelines that solely address, or include, pediatric populations

Clinical Practice Guidelines (2 of 4)

- American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (2022)
- European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022 European Guideline on Obesity Care in Patients with Gastrointestinal and Liver Diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology Guideline (2022)
- Metabolic Surgery in Treatment of Obese Japanese Patients with Type 2 Diabetes: A Joint Consensus Statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity (2022)
- Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)

Clinical Practice Guidelines (3 of 4)

- American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)
- American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)
- IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (2021) Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)
- Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)
- Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020 (2021)
- Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020

Clinical Practice Guidelines (4 of 4)

- Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/ American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists (2020)
- Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)
- VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)
- Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery (2019)
- Clinical Practice Guideline for the Diagnosis and Treatment of Pediatric Obesity: Recommendations from the Committee on Pediatric Obesity of the Korean Society of Pediatric Gastroenterology Hepatology and Nutrition (2019)

Note. Blue text indicates guidelines that solely address, or include, pediatric populations

Conclusions

Summary of New Evidence Identified for 2024 Review

BMI	Covered Under 2015 Criteria	New Evidence Identified in 2024
Adults		
BMI ≥ 40 kg/m^2 with or without a comorbidity	Yes	• OAGB with metabolic syndrome
≥ 35 to ≤ 40 kg/m^2 BMI with or without a comorbidity	Partially; patients must have ≥ 1 comorbidity	• ESG, IGB (Orbera and TPS), OAGB • Obalon IGB with T2DM
BMI ≥ 30 to ≤ 35 kg/m^2 with or without a comorbidity	Partially; patients must have T2DM	• IGB (Orbera), ESG • AGB, OAGB, IGB (TPS) with ≥ 1 comorbidity • IGB (Obalon) with T2DM
BMI < 30 kg/m^2	No	• AGB with T2DM
Children and adolescents		
Children and adolescents	No	• Adolescents age ≥ 13 years with BMI ≥ 35 kg/m^2: AGB, RYGB, SG

Abbreviations. AGB: adjustable gastric band; BMI: body mass index; ESG: endoscopic sleeve gastroplasty; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus; TPS: TransPyloric Shuttle.

Conclusion

- **MBS continues to be safe and effective** to reduce excess weight and resolve obesity-related comorbidities across a spectrum of BMIs
- **MBS evidence in pediatric populations remains limited**, but the available **evidence supports selected use**
- **Serious adverse events and deaths are rare**
- MBS is **generally cost-effective** compared with nonsurgical interventions
- Clinical practice **guidelines have expanded eligibility criteria**, partially in recognition of differences in BMI and comorbidities across races and ethnicities

Questions?


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Methods

PICOS, contextual questions, key questions, and methods

PICOS: Populations

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- Adults with:
  - BMI ≥ 30 to < 40 kg/m^2, without an obesity-related condition
  - BMI ≥ 30 to < 35 kg/m^2, without T2DM
  - BMI < 30 kg/m^2
  - Overweight or obesity, with or without an obesity-related condition, **for uncovered procedures only**
- Children and adolescents with overweight or obesity

PICOS: Interventions

Procedure Name (Abbreviation)	FDA-Approved Device (Approval Year)
Surgical procedures	
Adjustable gastric banding (AGB)	Lap-Band (2001)
Biliopancreatic diversion (with or without duodenal switch)	N/A
One-anastomosis gastric bypass (OAGB)	N/A
Roux-en-Y gastric bypass (RYGB)	• Apollo Revise (2022) • Apollo REVISE NXT (2023) • Apollo Revise Sx (2022)
Single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S)	N/A
Sleeve gastrectomy (SG)	N/A
Endoscopic procedures	
Endoscopic sleeve gastroplasty (ESG)	• Apollo ESG (2022) • Apollo ESG NXT (2023) • Apollo ESG Sx (2022)
Intragastric balloon (IGB)	• Obalon (2016) • Orbera (2015; previously BioEnterics Intragastric Balloon [BIB]) • Spatz3 (2021) • TransPyloric Shuttle (TPS; 2019)

Abbreviation. N/A: not applicable.

PICOS: Comparators

- **Nonsurgical weight management treatments** (e.g., antiobesity medications, diet, exercise)
- **Sham procedures** combined with a nonsurgical weight management treatment
- **Head-to-head studies** (for new procedures or any procedure in pediatric populations)

PICOS: Outcomes (1 of 2)

- Efficacy and effectiveness
  - Weight
  - BMI
  - Comorbidity status (e.g., remission of T2DM)
  - Cardiovascular risk (e.g., blood pressure, cholesterol)
  - Health-related quality of life (HRQoL)
  - Patient important outcomes (e.g., mobility, self-esteem)
  - Revision or conversion surgery due to inadequate weight loss or significant weight regain

PICOS: Outcomes (2 of 2)

- Safety
  - Serious adverse events
  - Adverse events of special interest
  - Difficulty swallowing (dysphagia/regurgitation)
  - Micronutrient status (i.e., vitamin B12, vitamin D, or anemia)
  - All-cause mortality (30-day or longer term)
  - Complications related to surgery (e.g., intraoperative organ injury)
  - Any procedure-specific reoperation or reintervention (e.g., leaks)
- Economic outcomes (e.g., health care service use, costs)

PICOS: Study Designs

- **Randomized controlled trials** (RCTs)
  - ≥ 50 participants
- **Comparative nonrandomized studies** (for outcomes where no RCT evidence is available)
  - ≥ 100 participants for adult populations
  - ≥ 50 participants for pediatric populations
- **Registry studies** (for safety-related outcomes only)
  - ≥ 1,000 participants for adult populations
  - ≥ 500 participants for pediatric populations
- **Economic analyses** published within last 5 years

Contextual Questions

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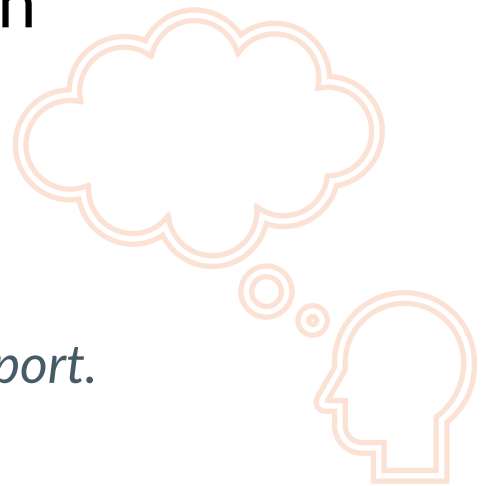
1. Overall **effectiveness profile of nonsurgical weight management** treatments (e.g., anti-obesity medication, diet or exercise programs, psychotherapy)
2. Overall **safety profile of covered bariatric procedures** (i.e., AGB, BPD, RYGB, SG) in adults with overweight or obesity
3. **Accreditation standards** and center of excellence designations for MBS in the US and requirements of each
4. Professional society or guideline **criteria for revision or conversion of MBS**



These results are not covered in this presentation. Please refer to the full report.

Key Questions

1. **Effectiveness of currently covered MBS** (i.e., AGB, BPD, RYGB, SG) **in noncovered populations**
2. **Effectiveness of new MBS not currently covered** (i.e., ESG, IGB, OAGB, SADI-S)
3. **Short-term and long-term safety**
4. **Differential effectiveness and safety** according to patient and clinical factors (e.g., sex, race or ethnicity, baseline BMI)
5. **Costs and cost-effectiveness**

Methods (1 of 2)

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- Searched for:
  - **Peer-reviewed literature** via Ovid MEDLINE and Cochrane CENTRAL through November 8, 2023
  - **Gray literature** (e.g., Agency for Healthcare Research and Quality; Institute for Clinical and Economic Review)
  - **Clinical practice guidelines** (e.g., American Society for Metabolic and Bariatric Surgeons, National Institute for Health and Care Excellence)

Methods (2 of 2)

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- Searched for (continued):
  - **Payer policies** from Medicare, Oregon Medicaid, Aetna, Cigna, and Regence BlueCross BlueShield
  - **Ongoing studies** via ClinicalTrials.gov and ScanMedicine.com
- Conducted **general internet searches** and **checked reference lists** of included studies and relevant systematic reviews and meta-analyses

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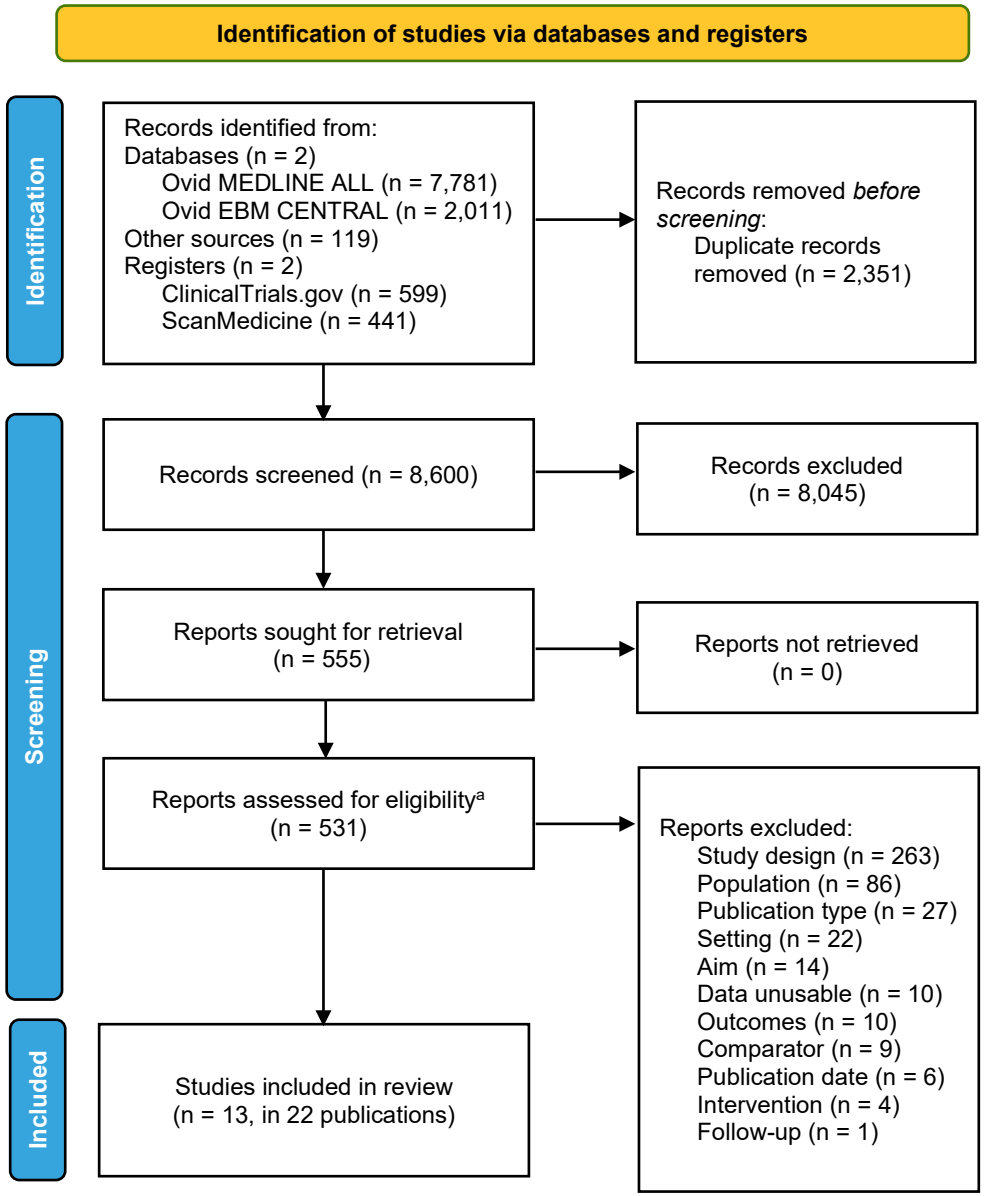
Study Flow


Identification of studies via databases and registers
Identification
Records identified from:
Databases (n = 2)
Ovid MEDLINE ALL (n = 7,781)
Ovid EBM CENTRAL (n = 2,011)
Other sources (n = 119)
Registers (n = 2)
ClinicalTrials.gov (n = 599)
ScanMedicine (n = 441)
Records removed *before screening*:
Duplicate records removed (n = 2,351)
Screening
Records screened (n = 8,600)
Records excluded (n = 8,045)
Reports sought for retrieval (n = 555)
Reports not retrieved (n = 0)
Reports assessed for eligibility[a] (n = 531)
Reports excluded:
Study design (n = 263)
Population (n = 86)
Publication type (n = 27)
Setting (n = 22)
Aim (n = 14)
Data unusable (n = 10)
Outcomes (n = 10)
Comparator (n = 9)
Publication date (n = 6)
Intervention (n = 4)
Follow-up (n = 1)
Included
Studies included in review (n = 13, in 22 publications)

Findings

Overview

Findings Overview (1 of 3)

Report page 33

Adult populations not eligible for currently covered procedures

- 2 RCTs (total N = 131; mean ages, 41.2 and 53.0 years)
  - 1 comparing AGB with multidisciplinary diabetes care (mean BMI, 29.0 kg/m^2)
  - 1 comparing AGB with a lifestyle intervention plus orlistat (mean BMI, 33.6 kg/m^2)

Any adult population for procedures not currently covered

- 8 RCTs (total N = 1,575; range, 51 to 317; mean age range, 38.6 to 53 years)
  - 3 head-to-head RCTs comparing OAGB with RYGB or SG (mean BMI, 41.6 to 43.8 kg/m^2)
  - 3 comparing ESG, IGB, or OAGB with a lifestyle intervention (mean BMI, 41.5 to 42.6 kg/m^2)
  - 2 comparing 2 IGB devices (Orbera and TransPyloric Shuttle) with sham surgery (mean BMIs, 32.0 and 43.3 kg/m^2)

Findings Overview (2 of 3)

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Children and adolescents

- 3 RCTs (total N = 159; mean age range, 15.7 to 16.6 years)
  - 2 comparing AGB with a lifestyle intervention (mean BMIs, 41.3 and 44.1 kg/m^2)
  - 1 compared RYGB (or SG) with a lifestyle intervention (mean BMI, 42.6 kg/m^2)

Economic studies

- 2 examined ESG, IGB (Orbera), or SG in adults (BMI range, 25 to 44 kg/m^2)
- 1 examined any MBS in children and adolescents aged 10 to 18 (BMI not reported)

Findings Overview (3 of 3)

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Ongoing studies

- Head-to-head
  - 11 RCTs in adults
  - 3 nonrandomized studies: 1 in adults, 1 in adolescents, and 1 includes individuals ≥ 16 years
- MBS vs. lifestyle interventions
  - 6 RCTs in adults
  - 4 nonrandomized studies: 2 in adults and 3 in adolescents

Clinical practice guidelines

- 22 published January 2019 through March 2024
  - 17 exclusively for adult populations
  - 3 include any age
  - 2 exclusively for pediatric populations

Detailed GRADE Tables

GRADE Certainty of Evidence For Adult Populations Not Eligible For Currently Covered Procedures: BMI ≥ 30 to < 35 kg/m^2 (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Weight			
N = 80 1 RCT	At 6 months, AGB associated with significantly greater EWL than intensive medical management (ranging from 79% to 87% EWL in AGB group vs. 22% to 41% in intensive medical management group). Difference maintained at the 10-year timepoint; both surgery and medical management associated with reduced weight from baseline.	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]
Cardiovascular risk factors			
N = 80 1 RCT	AGB associated with significantly lower risk of MetS at 2 years than intensive medical management (2.6% vs. 24.2%; RR, 0.11; 95% CI, 0.01 to 0.80).	●○○○ Very low	Downgraded 3 levels • 3 for imprecision (i.e., small study size, wide CIs, and very small number of events)[a]
N = 80 1 RCT	AGB associated with significantly greater changes in HDL and diastolic blood pressure. Between-group differences not observed for changes in LDL, systolic blood pressure, or triglycerides.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not all risk factors changed)

Note. [a] Inconsistency not assessed as only a single study.
Abbreviations. AGB: adjustable gastric band; CI: confidence interval; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; LDL: low-density lipoprotein cholesterol; MetS: metabolic syndrome; RCT: randomized controlled trial; RR: risk ratio; vs.: versus.

GRADE Certainty of Evidence For Adult Populations Not Eligible For Currently Covered Procedures: BMI ≥ 30 to < 35 kg/m^2 (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Health-related quality of life			
N = 80 1 RCT	All participants had some improvements in SF-36 subdomain scores, but the AGB group saw significantly greater improvements across the 8-domains.	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]
Safety			
N = 80 1 RCT	AEs occurred in both AGB and intensive medical management groups with a higher proportion occurring in the medical group (58% vs. 18%).	●●●○ Moderate	Downgraded 1 level • 1 for imprecision (i.e., small study size)[a]

Note. [a] *Inconsistency not assessed as only a single study.*
Abbreviations. AE: adverse event; AGB: adjustable gastric band; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; RCT: randomized controlled trial; vs.: versus; SF-36: 36-item Short Form Health Survey.

GRADE Certainty of Evidence For Adult Populations Not Eligible For Currently Covered Procedures: BMI ≥ 25 to < 30 kg/m^2 (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
BMI ≥ 25 to < 30 kg/m^2 and T2DM: AGB vs. MDC			
Weight			
N = 48 1 RCT	Participants in the AGB group lost significantly more weight than participants in the MDC group at 2, 5, and 10 years.	●●○○ Low	Downgraded 2 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest
Cardiovascular			
N = 48 1 RCT	AGB was associated with an increased chance of remission from T2DM at 2 years; however, this was not maintained at 5- or 10 years.	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size) [a] • 1 for inconsistency within study (i.e., not maintained at all time points) • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest
N = 48 1 RCT	AGB was associated with significantly greater improvements in diabetes control Between-group differences were not observed for changes in blood pressure or cholesterol, other than triglycerides	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size) [a] • 1 for inconsistency within study (i.e., not all risk factors changed) • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest

Note. [a] *Inconsistency not assessed, as only a single study.*
Abbreviations. AGB: adjustable gastric band; BMI: body mass index; MDC: multidisciplinary diabetes care; RCT: randomized controlled trial; RoB: risk of bias; T2DM: type 2 diabetes mellitus

GRADE Certainty of Evidence For Adult Populations Not Eligible For Currently Covered Procedures: BMI ≥ 25 to < 30 kg/m^2 (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
BMI ≥ 25 to < 30 kg/m^2 and T2DM: AGB vs. MDC			
Health-related quality of life			
N = 48 1 RCT	AGB was associated with a greater improvement in the SF-36 physical health composite score at 2 and 5 years.	●○○○ Very low	Downgraded 3 levels: • 1 for imprecision (i.e., small study size)[a] • 1 for inconsistency within study (i.e., not maintained at all time points) • 1 for high RoB (i.e., serious issue with study design, funding, and investigator conflicts of interest
Safety			
N = 48 1 RCT	AGB was associated with a higher rate of AEs at 2 years. At 5 and 10 years, the number of AEs was similar.	●○○○ Very low	Downgraded 3 levels: • 2 for imprecision (i.e., small study size)[a] • 1 for high RoB (i.e., serious issue with study design, funding and investigator conflicts of interest

Note. [a] Inconsistency not assessed, as only a single study.
Abbreviations. AE: adverse event; AGB: adjustable gastric band; BMI: body mass index; MDC: multidisciplinary diabetes care; RCT: randomized controlled trial; RoB: risk of bias; SF-36: 36-item Short Form Health Survey; T2DM: type 2 diabetes mellitus

GRADE Certainty of Evidence for Procedures Not Currently Covered For Any Adult Population: Noncovered vs. Covered Procedures (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
OAGB vs. RYGB or SG			
Weight			
N = 542 3 RCTs	TWL ranged from 25% to 37% 1 to 3 years post-surgery, regardless of surgical intervention (i.e., OAGB, RYGB, SG). Similarly, EWL ranged from 60% to 66% in the same time periods. One study showed EWL was maintained at years 4 and 5 for OAGB, but not for SG though the changes were small (a decrease of approximately 4% to 5% from year 3).	●●●● High	• Not downgraded.
Cardiovascular risk factors			
N = 542 3 RCTs	Rates of remission of obesity-related comorbidities (e.g., T2DM, hypertension) and changes to other cardiovascular risk factors (e.g., HDL, triglycerides) were similar up to 3 years (and in some cases up to 5 years) regardless of surgical intervention (i.e., OAGB, RYGB, SG).	●●●● High	• Not downgraded.

Abbreviations. EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein cholesterol; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus; TWL: total weight loss.

GRADE Certainty of Evidence for Procedures Not Currently Covered For Any Adult Population: Noncovered vs. Covered Procedures (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
OAGB vs. RYGB or SG			
Health-related quality of life			
N = 126 1 RCT	Improvements in HRQoL, as measured with IWQOL-Lite, were similar in individuals who underwent OAGB or RYGB. Clinically significant increases in the physical and self-esteem domains was observed for both groups (20 and 12 points, respectively).	●●●○ Moderate	Downgraded 1 level: • 1 for imprecision (i.e., small study size)
Safety			
N = 542 3 RCTs	Reported safety outcomes varied across the studies, but most showed no differences (e.g., rates of anemia, vitamin deficiencies, complications related to surgery) between the surgical interventions. One study reported significantly more SAEs in participants who underwent OAGB compared with RYGB.	●●●○ Moderate	Downgraded 1 level: • 1 for inconsistency (i.e., different markers of safety reported across studies)

Abbreviations. GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HRQoL: health-related quality of life; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SAE: serious adverse event; SG: sleeve gastrectomy.

GRADE Certainty of Evidence For Procedures Not Currently Covered for Any Adult Population: Noncovered Procedures vs. Lifestyle Interventions (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Noncovered procedures vs. lifestyle interventions			
Weight			
N = 586 3 RCTs	Participants who underwent a surgical intervention (i.e., ESG, IGB, OAGB) had significantly larger reductions in weight and BMI than those who received lifestyle interventions. Reductions in weight, BMI, EWL, and excess BMI loss were clinically significant.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the largest study [N = 317] had a high RoB)
Cardiovascular risk factors			
N = 60 1 RCT	Larger improvements in blood pressure and triglycerides were seen in those who received OAGB vs. diet alone. Additionally, remission of prediabetes or T2DM were achieved in 100% and 93% in the OAGB group, respectively; there were no remissions of these conditions for those who were treated with diet alone.	●●○○ Low	Downgraded 2 levels: • 1 for imprecision (i.e., single study with small study size) • 1 for indirectness (i.e., study conducted in Kazakhstan)

Abbreviations. BMI: body mass index; ESG: endoscopic sleeve gastroplasty; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; IGB: intragastric balloon; OAGB: one-anastomosis gastric bypass; RCT: randomized controlled trial; RoB: risk of bias; T2DM: type 2 diabetes mellitus.

GRADE Certainty of Evidence For Procedures Not Currently Covered for Any Adult Population: Noncovered Procedures vs. Lifestyle Interventions (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Noncovered procedures vs. lifestyle interventions			
Health-related quality of life			
No studies reported HRQoL.			
Safety			
N = 350 2 RCTs	AEs and SAEs, and the total number of events, were much higher for IGB and ESG than for lifestyle interventions. The most common AEs were nausea, vomiting, and abdominal pain. SAEs (e.g., severe dehydration, surgery-related injuries) were experienced by 10% of those who underwent IGB; 20% had the IGB removed before 6-months.	●●●○ Moderate	Downgraded 1 level: • 1 for inconsistency (i.e., different markers of safety reported across studies)

Abbreviations. AE: adverse event; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HRQoL: health-related quality of life; IGB: intragastric balloon; RCT: randomized controlled trial; SAE: serious adverse event.

GRADE Certainty of Evidence For Procedures Not Currently Covered for Any Adult Population: Noncovered Procedures vs. Sham Surgery (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Noncovered procedures vs. sham surgery			
Weight			
N = 657 2 RCTs	Participants who had an IGB implanted (Obalon or TPS) had statistically significant improvements in BMI at 6 months. They also had significant improvements in EWL, TWL, and the proportion who achieved a clinically meaningful reduction of ≥ 5% TWL.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB)
Cardiovascular			
N = 657 2 RCTs	Some very small statistically significant changes were observed in favor of the IGB devices (Obalon or TPS), but these were not clinically significant.	●●○○ Low	Downgraded 2 levels: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB) • 1 for inconsistency (i.e., conflicting results for CV risk factors)

Abbreviations. BMI: body mass index; CV: cardiovascular; EWL: excess weight loss; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; IGB: intragastric balloon; RCT: randomized controlled trial; RoB: risk of bias; TPS: TransPyloric Shuttle; TWL: total weight loss.

GRADE Certainty of Evidence For Procedures Not Currently Covered for Any Adult Population: Noncovered Procedures vs. Sham Surgery (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Noncovered procedures vs. sham surgery			
Health-related quality of life			
N = 270 1 RCT	Those who had the TPS device implanted had greater improvements in their total IWQOL-Lite score compared with the sham surgery group (+10.5 vs. +7.8 points, respectively). These improvements are considered clinically meaningful.	●●●○ Moderate	Downgraded 1 level: • 1 for imprecision (i.e., single study with small study size)
Safety			
N = 657 2 RCTs	Any AE was common for all procedures (ranging from 94% to 100% in the IGB groups and 70% to 98% in the sham surgery groups), but this difference was significant in 1 study (n = 270; *P* < .001). SAEs were rare (2% to 3% of all participants). However, early removal of the TPS device occurred in 23% of participants.	●●●○ Moderate	Downgraded 1 level: • 1 for RoB (i.e., the larger study [N = 387] had a high RoB and the other had a moderate RoB)

Abbreviations. AE: adverse event; CV: cardiovascular; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; IGB: intragastric balloon; IWQOL-Lite: Impact of Weight on Quality of Life-Lite survey; RCT: randomized controlled trial; RoB: risk of bias; SAE: serious adverse event; TPS: TransPyloric Shuttle.

GRADE Certainty of Evidence For Weight-Related Outcomes in Adolescents (1 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Weight			
N = 149 3 RCTs	Adolescents who underwent a RYGB or SG had significantly larger reductions in weight (mean total weight loss, 20 kg) and BMI (−1.71 kg/m^2) than those in receipt of a lifestyle intervention.	●●●○ Moderate	Downgraded 1 levels • 1 for imprecision (i.e., total N)
Cardiovascular risk factors			
N = 59[a] 3 RCTs	Resolution of high cholesterol was significantly more likely in adolescents who underwent a surgical procedure. No between-group differences in the resolution of metabolic syndrome, T2DM, or hypertension were observed.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., not all comorbidities were resolved)
N = 149 3 RCTs	No between-group differences in triglyceride concentrations were observed for RYGB or SG vs. a lifestyle intervention; a small, but not clinically significant, difference was seen when comparing AGB with a lifestyle intervention. No other between-group differences were observed for blood pressure, HDL or LDL.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., other CV risk factors were inconsistent across studies)

Note. [a] Represents subset of participants with 1 of the comorbidities mentioned; participant may have ≥ 1 comorbidity.
Abbreviations. BMI: body mass index; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; HDL: high-density lipoprotein; LDL: low-density lipoprotein; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy; T2DM: type 2 diabetes mellitus.

GRADE Certainty of Evidence For Weight-Related Outcomes in Adolescents (2 of 2)

Participants Number of RCTs	Findings	Certainty of Evidence	Rationale
Health-related quality of life			
N = 50 1 RCT	No between-group differences were observed for depression, obesity-related problems (i.e., OP-14 scale), or in 6 of 7 subdomains of the RAND-36; only the general health score was significantly improved in those who received RYGB.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., not all comorbidities were resolved)
Safety			
N = 149 3 RCTs	Safety outcomes were minimally reported. In 2 studies, only surgery-related outcomes were reported. In the third study, AEs occurred in similar proportions, but the types of events differed, and approximately half were unrelated to the interventions.	●●○○ Low	Downgraded 2 levels • 1 for imprecision (i.e., total N) • 1 for inconsistency (i.e., small number of events)

Abbreviations. AE: adverse event; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; OP-14: Obesity-related Problems; RAND-36: 36-item Short Form Health Survey; RCT: randomized controlled trial.

GRADE Certainty of Evidence For Costs and Cost-Effectiveness of MBS

Number of Studies	Findings	Certainty of Evidence	Rationale
MBS in adults			
IGB vs. commercially available nonsurgical weight-loss interventions			
1 CE analysis	• IGB were not CE for adults with overweight or obesity (BMI ≥ 25 kg/m^2) when compared with other nonsurgical options at any WTP threshold • Other interventions were less costly and more effective	●●○○ Low	Downgraded 2 levels for: • 2 for risk of bias (i.e., very limited reporting of methods)[a]
ESG and SG vs. semaglutide and lifestyle intervention			
1 CE analysis	• ESG was CE, with an ICER of $4,105 per QALY gained for adults aged 40 with a BMI of 33 kg/m^2 • SG was CE, with an ICER of $5,883 per QALY gained for adults aged 40 with a BMI of 37 kg/m^2 • SG was CE, with an ICER of $7,821 per QALY gained for adults aged 40 with a BMI of 44 kg/m^2 • Both procedures were CE when compared individually with lifestyle intervention • Semaglutide was less effective and more costly (i.e., dominated) than another intervention	●○○○ Very low	Downgraded 3 levels • 1 for imprecision (i.e., model sensitivity to the cost of the procedure)[a] • 1 for indirectness (i.e., only adults aged 40) • 1 for risk of bias
MBS in children and adolescents			
No eligible CE analyses comparing MBS with other interventions were identified in the populations of interest			
Comparison of MBS procedures in adults and children			
No eligible CE analyses comparing different MBS procedures were identified in the populations of interest			

Note. [a] *Inconsistency not assessable due to only 1 study.*
Abbreviations. BMI: body mass index; CE: cost-effectiveness; ESG: endoscopic sleeve gastroplasty; GRADE: Grading of Recommendations, Assessment, Development, and Evaluation; ICER: incremental cost-effectiveness ratio; IGB: intragastric balloon; MBS: metabolic and bariatric surgery; QALY: quality-adjusted life year; SG: sleeve gastrectomy; WTP: willingness-to-pay.

MBSAQIP Accreditation Designations

MBSAQIP Accreditation Designation Descriptions: Inpatient Designations (1 of 2)

Designation Type[a]	Bariatric Procedures	Populations	Annual Volume Requirements	Available in WA?
Inpatient designations				
Comprehensive Center	• ASMBS-endorsed procedures[b]	• Adults	• ≥ 50 bariatric stapling procedures	Yes
Comprehensive Center with Adolescent Qualifications	• ASMBS-endorsed procedures[b]	• Adults and adolescents	• ≥ 50 bariatric stapling procedures	Yes[c]
Comprehensive Center with Obesity Medicine Qualifications	• ASMBS-endorsed procedures[b]	• Adults	• ≥ 50 bariatric stapling procedures	Yes
Comprehensive Center with Adolescent and Obesity Management Qualifications	• ASMBS-endorsed procedures[b]	• Adults and adolescents	• ≥ 50 bariatric stapling procedures	Yes

Notes. [a] Regardless of designation, all centers must demonstrate compliance with MBSAQIP standards, successfully complete site visits, and enter data into the MBSAQIP registry. [b] MBSAQIP-accredited centers must receive approval from an Institutional Review Board to perform primary procedures not endorsed by the ASMBS. [c] This designation does not exist on its own in WA, but there is 1 comprehensive center with both adolescent and obesity medicine qualifications
Source. American College of Surgeons,
Abbreviations. AGB: adjustable gastric banding; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; CVD: cardiovascular disease; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; WA: Washington State.

MBSAQIP Accreditation Designation Descriptions: Inpatient Designations (2 of 2)

Designation Type[a]	Bariatric Procedures	Populations	Annual Volume Requirements	Available in WA?
Inpatient designations				
Low Acuity Center	• ASMBS-endorsed primary procedures[b] • AGB replacement, positioning, or removal • Port revision or removal • Emergent revisional procedures[d]	• Adults aged 18 to 65 • BMI < 55 for males and < 60 for females • No history of organ failure or current CVD	≥ 25 bariatric procedures	Yes
Adolescent Center	ASMBS-endorsed procedures[b]	Adolescents	≥ 15 bariatric stapling procedures	No

Notes. [a] Regardless of designation, all centers must demonstrate compliance with MBSAQIP standards, successfully complete site visits, and enter data into the MBSAQIP registry. [b] MBSAQIP-accredited centers must receive approval from an Institutional Review Board to perform primary procedures not endorsed by the ASMBS. [d] An emergent case is usually performed shortly after patient diagnosis or the onset of related preoperative symptomatology. Patient well-being and outcome is potentially threatened by unnecessary delay and the patient status could deteriorate unpredictably or rapidly.
Source. American College of Surgeons, 2022.
Abbreviations. AGB: adjustable gastric banding; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; CVD: cardiovascular disease; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; WA: Washington State.

MBSAQIP Accreditation Designation Descriptions: Outpatient Designations

Designation Type[a]	Bariatric Procedures	Populations	Annual Volume Requirements	Available in WA?
Outpatient designations				
Ambulatory Surgery Center	• ASMBS-endorsed primary procedures[b] • AGB replacement, positioning, or removal • Port revision or removal • Emergent revisional procedures[d]	• Adults aged 18 to 65 • BMI < 55 for males and < 60 for females • No history of organ failure or current CVD	≥ 25 bariatric procedures	Yes

Notes. [a] Regardless of designation, all centers must demonstrate compliance with MBSAQIP standards, successfully complete site visits, and enter data into the MBSAQIP registry. [b] MBSAQIP-accredited centers must receive approval from an Institutional Review Board to perform primary procedures not endorsed by the ASMBS. [d] An emergent case is usually performed shortly after patient diagnosis or the onset of related preoperative symptomatology. Patient well-being and outcome is potentially threatened by unnecessary delay and the patient status could deteriorate unpredictably or rapidly.
Source. American College of Surgeons, 2022.
Abbreviations. AGB: adjustable gastric banding; ASMBS: American Society for Metabolic and Bariatric Surgery; BMI: body mass index; CVD: cardiovascular disease; MBSAQIP: Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; WA: Washington State.

HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

Based on Legislative mandate: RCW 70.14.100(2).

The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the

task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
All-cause mortality, adults		
Reoperations, adults		
Readmissions, adults		
ED visits, adults		
Mortality, adolescents		
Reoperations, adolescents		
Readmissions, adolescents		
ED visits, adolescents		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Weight		
HRQOL		
Cardiovascular		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	**Less** Less cost effective	**Equivocal**	**More** More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is *insufficient* to make a conclusion about whether the health technology is *safe, efficacious, and cost-effective*;
- Evidence is *sufficient* to conclude that the health technology is *unsafe, ineffectual, or not cost-effective*
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for all indicated conditions*;
- Evidence is *sufficient* to conclude that the health technology is *safe, efficacious, and cost-effective for some conditions or in some situations*

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	**Covered unconditionally**	**Covered with conditions**

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

The report "identified no Medicare national coverage determination on the use of SBRT or any local coverage determinations that apply to the state of Washington."

Medicare Coverage

[see page 31 of final report]

- **Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**

  In 2006, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) limiting Medicare coverage to accredited centers[154]; subsequently, by 2010 almost 90% of MBS procedures were performed in accredited centers.[150,153] Although CMS ultimately reversed the facility accreditation requirement in 2013, citing inconsistent outcomes at bariatric centers of excellence and concern regarding access limitations, participation in national accreditation has remained high.[150,153,155-157]

Clinical Practice Guidelines
[see page 206 – 217 of final report]

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
US guidelines										
• American Association of Clinical Endocrinology[218] • American Association for the Study of Liver Diseases	2022	Fair	NR	NR	NR	✓[b]	✓[b]	≥ 32.5[b]	✓	≥ 27.5[b]
• American Academy of Sleep Medicine[219]	2021	Good	✓[c]	X	NR	✓[c]	X	NR	NR	NR
• American Gastroenterological Association[51]	2021	Good	NR							
• Department of Defense[50] • Veterans Affairs	2020	Good	✓	X	NR	✓	X	NR	✓	NR
• American Association of Clinical Endocrinology[72] • American College of Endocrinology • American Society of Anesthesiologists • American Society for Metabolic and Bariatric Surgery (ASMBS) • Obesity Medicine Association • The Obesity Society	2020	Fair	✓	X	≥ 35	✓	X	≥ 30	✓	≥ 27.5
• American Society for Metabolic and Bariatric Surgery (ASMBS)[36] • International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	2023	Poor	✓	✓	≥ 30	✓	✓	≥ 27.5	✓	≥ 27.5

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
• American Society for Metabolic and Bariatric Surgery (ASMBS)[224] [for SADI-S]	2020	Poor	NR							
International guidelines										
• Korean Society for the Study of Obesity[220]	2023	Poor	NR	NR	≥ 35	NR	NR	≥ 30	NR	≥ 27.5
• International Federation for Surgery of Obesity and Metabolic Disorders (IFSO)[225] [for OAGB]	2021	Poor	NR							
• International Federation for Surgery of Obesity and Metabolic Disorders[54] [for SADI-S]	2021	Poor	NR							
• Japanese Society for Treatment of Obesity[221] • Japan Diabetes Society • Japan Society for the Study of Obesity	2022	Poor	NR	NR	NR	NR	NR	NR	NR	≥ 32[d]
• Ministry of Public Health Qatar[222]	2021	Good	✓	X	NR	✓	X	NR	✓	≥ 27.5
• European Association for Endoscopic Surgery[35]	2020	Good	✓	X	NR	✓	X	NR	✓	NR
• National Institute for Health and Care Excellence (NICE)[53] [for overweight and obesity]	*Expected 2024*	Good	✓	X	≥ 37.5	✓	X	≥ 32.5	✓	≥ 27.5
• National Institute for Health and Care Excellence (NICE)[228] [for ESG]	2024	Fair	✓	X	✓	✓	NR	✓	NR	≥ 27.5

Institution(s) Issuing Guideline or Consensus Statement	Year Issued	Methodological Quality	With or Without Comorbidities			With ≥ 1 Severe Obesity-Related Comorbidity[a]			With Poorly Controlled T2DM	
			BMI ≥ 40	BMI ≥ 35 to < 40	Patients of Asian Descent, BMI	BMI ≥ 35	BMI ≥ 30 to < 35	Patients of Asian Descent, BMI	BMI ≥ 30	Patients of Asian Descent, BMI
• European Society for Clinical Nutrition and Metabolism[223] • United European Gastroenterology	2022	Fair	✓[e]	X	NR	✓[e]	X	NR	NR	NR
• BARIA-MAT (France)[226]	2019	Poor	NR							
• Obesity Canada[37] • The Canadian Association of Bariatric Physicians and Surgeons	2020	Good	✓	X	NR	✓	✓[f]	NR	✓	NR
• Diabetes Canada[229]	2022	Fair	NR	NR	NR	✓[d]	X	NR	X	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
US guidelines			
American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (2022)[218]	ESG, IGB	"Endoscopic [MBS] therapies and orally ingested devices should not be recommended in persons with NAFLD due to insufficient evidence"	Grade C; Intermediate/ Weak strength of evidence; BEL 2
	Eligibility criteria	"Clinicians should consider [MBS] as an option to treat NAFLD (Grade B; Intermediate/Weak Strength of Evidence; BEL 2) and improve cardiometabolic health (Grade A; High/Intermediate Strength of Evidence; BEL 2; upgraded based on the cardiometabolic and all-cause mortality benefits in all persons with or without NAFLD) in persons with NAFLD and a BMI ≥ 35 kg/m^2 (≥ 32.5 kg/m^2 in Asian populations), particularly if T2DM is present"	As stated at left
	Eligibility criteria	"[MBS] should also be considered an option in those with a BMI of ≥ 30 to 34.9 kg/m^2 (≥ 27.5 to 32.4 kg/m^2 in Asian populations)"	Grade B; Intermediate/ Weak Strength of Evidence; BEL 2

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)[219]	Eligibility criteria	"We recommend that clinicians discuss referral to a bariatric surgeon with adults with OSA and obesity (class 2/3, BMI ≥ 35) who are intolerant or unaccepting of [positive airway pressure] as part of a patient-oriented discussion of alternative treatment options"	Strong
American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)[51]	IGB	"In individuals with obesity seeking a weight-loss intervention who have failed a trial of conventional weight-loss strategies, AGA suggests the use of IGB therapy with lifestyle modification over lifestyle modification alone"	Conditional recommendation, moderate certainty
VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)[50]	Eligibility criteria	"We suggest offering the option of [MBS], in conjunction with a comprehensive lifestyle intervention, to patients with a body mass index of ≥ 30 kg/m^2 and T2DM"	Weak; We suggest offering this option.
	Eligibility criteria	"We suggest offering the option of [MBS], in conjunction with a comprehensive lifestyle intervention, for long-term weight loss/maintenance and/or to improve obesity-associated condition(s) in adult patients with a BMI ≥ 40 kg/m^2 or those with BMI ≥ 35 kg/m^2 with obesity-associated condition(s)"	Weak; We suggest offering this option.
	IGB	"We suggest offering [IGB] in conjunction with a comprehensive lifestyle intervention to patients with obesity (BMI ≥ 30 kg/m^2) who prioritize short-term (up to 6 months) weight loss"	Weak; We suggest offering this option.
	IGB	"There is insufficient evidence to recommend for or against [IGBs] for long-term weight loss to support chronic weight management or maintenance"	Neither for nor against
Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/ American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists (2020)[72]	Eligibility criteria	"Patients with a BMI ≥ 40 kg/m^2 without coexisting medical problems and for whom [MBS] would not be associated with excessive risk are eligible for [MBS]"	Grade A; BEL 1
	Eligibility criteria	"Patients with a BMI ≥ 35 kg/m^2 and 1 or more severe ORCs remediable by weight loss, including T2DM, high risk for T2DM (insulin resistance, prediabetes, and/or MetS), poorly controlled HTN, NAFLD or NASH, OSA, osteoarthritis of the knee or hip, and urinary stress incontinence, should be considered for a bariatric procedure. Patients with the following comorbidities and BMI ≥ 35 kg/m^2 may also be considered for [MBS], though the strength of evidence is more variable: obesity-hypoventilation syndrome and	Grade C; BEL 3

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		Pickwickian syndrome after a careful evaluation of operative risk; idiopathic intracranial HTN; GERD; severe venous stasis disease; impaired mobility due to obesity; and considerably impaired QoL"	
	Eligibility criteria	"Patients with BMI ≥ 30 to 34.9 kg/m^2 and T2DM with inadequate glycemic control despite optimal lifestyle and medical therapy should be considered for [MBS]; current evidence is insufficient to support recommending [MBS] in the absence of obesity"	Grade B; BEL 2
	Eligibility criteria	"The BMI criterion for [MBS] should be adjusted for ethnicity (e.g., ≥ 18.5 to 22.9 kg/m^2 is normal range, ≥ 23 to 24.9 kg/m^2 is overweight, and ≥ 25 kg/m^2 obesity for Asians)"	Grade D
	Eligibility criteria	"[MBS] should be considered to achieve optimal outcomes regarding health and QoL when the amount of weight loss needed to prevent or treat clinically significant ORCs cannot be obtained using only structured lifestyle change with medical therapy"	Grade B; BEL 2
	AGB, BPD, RYGB, SG	"Laparoscopic AGB, laparoscopic SG, laparoscopic RYGB, and laparoscopic BPD, or related procedures should be considered as primary [MBS] procedures performed in patients requiring weight loss and/or amelioration of ORCs"	Grade A; BEL 1
	BPD	"Physicians must exercise caution when recommending BPD, BPD, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine"	Grade A; BEL 1
	ESG, IGB	"Newer nonsurgical bariatric procedures may be considered for selected patients who are expected to benefit from short-term (i.e., about 6 months) intervention with ongoing and durable structured lifestyle with/without medical therapy"	Grade C; BEL 3
2022 American Society for Metabolic and Bariatric Surgery and International Federation for the Surgery of Obesity and Metabolic Disorders Indications for Metabolic and Bariatric Surgery (2023)[36]	Eligibility criteria	"MBS is recommended for individuals with BMI > 35 kg/m^2, regardless of presence, absence, or severity of co-morbidities."	NR
	Eligibility criteria	"MBS is recommended in patients with T2DM and BMI > 30 kg/m^2." "MBS should be considered in individuals with BMI of 30 to 34.9 kg/m^2 who do not achieve substantial or	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		durable weight loss or co-morbidity improvement using nonsurgical methods."	
	Eligibility criteria	"Clinical obesity in the Asian population is recognized in individuals with BMI > 25 kg/m^2. Access to MBS should not be denied solely based on traditional BMI risk zones"	NR
American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)[224]	SADI-S	SADI-S is "endorsed by ASMBS as an appropriate [MBS] procedure"	NR
American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass (2024)[231]	OAGB	"The ASMBS endorses OAGB as a metabolic and bariatric procedure."	NR
International guidelines			
Evaluation and Treatment of Obesity and Its Comorbidities: 2022 Update of Clinical Practice Guidelines for Obesity by the Korean Society for the Study of Obesity (2023)[220]	Eligibility criteria	"[MBS] should be considered in Korean adults with a BMI ≥ 35 kg/m^2, or a BMI ≥ 30 kg/m^2 or more with obesity-related comorbidities, who have failed to lose weight with nonsurgical treatment"	Grade IIa, level of evidence B
	Eligibility criteria	"[MBS] should be considered in individuals with T2DM with a BMI ≥ 27.5 kg/m^2 and a blood sugar level that is not properly controlled with nonsurgical treatment"	Grade IIa, level of evidence B
	AGB, BPD, RYGB, SG	"It is recommended to choose from among standard procedures that have been proven to be effective and safe, such as SG, RYGB, AGB, and BPD, taking into account the individual's status"	Grade I, level of evidence A
Metabolic Surgery in Treatment of Obese Japanese Patients with Type 2 Diabetes: A Joint Consensus Statement from the Japanese Society for Treatment of Obesity, the Japan Diabetes Society, and the Japan Society for the Study of Obesity (2022)[221]	SG	"SG is recommended for obese patients with T2DM with a short duration of diabetes and a well-retained insulin secretory capacity"	Recommendation
	Eligibility criteria	"[MBS] is recommended as a treatment option regardless of glycemic control if the patient has T2DM with BMI ≥ 35 kg/m^2 at the time of consultation and the BMI ≥ 35 kg/m^2 persists despite treatments by a diabetologist or obesity specialist for≥ 6 months."	Recommendation
	Eligibility criteria	"[MBS] should be considered a treatment option if the patient has T2DM with BMI ≥ 32 kg/m^2 at the time of consultation and has not achieved≥ 5% weight loss or has achieved it but	Consideration

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		continues to have poor glycemic control (HbA1c > 8.0%) despite treatments by a diabetologist or obesity specialist for≥ 6 months"	
	RYGB	"Because the remission rate of diabetes is higher in the cases with a surgery that add the malabsorptive procedure such as gastrointestinal bypass, it is advisable to consider carrying out the gastrointestinal bypass surgery for patients with reduced insulin secretory capacity."	Consideration
European Guideline on Obesity Care in Patients with Gastrointestinal and Liver Diseases - Joint European Society for Clinical Nutrition and Metabolism / United European Gastroenterology Guideline (2022)[223]	Eligibility criteria	"In patients with [irritable bowel disease] and BMI > 40 kg/m^2 or > 35 kg/m^2 with obesity-related comorbidities and previous failed nonsurgical weight-loss attempts can be offered [MBS], preferably considering non-malabsorptive procedures not involving the small bowel"	Grade of recommendation 0 - Strong consensus
	Eligibility criteria	"Patients with [irritable bowel syndrome] and BMI > 40 kg/m^2 or > 35 kg/m^2 with obesity-related comorbidities can be offered [MBS] provided that serious attempts to lose weight with nonsurgical methods have been made"	Grade of recommendation: GPP (Good practice points/expert consensus); Strong consensus
	Eligibility criteria	"Patients with [chronic liver disease] (NAFLD or NASH) with BMI > 35 kg/m^2 unresponsive to multimodality treatment should be considered for [MBS]"	Grade of recommendation B; Strong consensus
	Eligibility criteria; RYGB	"In patients with GERD and BMI ≥ 40 kg/m^2 or ≥ 35 kg/m^2 with obesity-related comorbidities, [MBS] can be considered to achieve weight reduction if nonsurgical interventions failed to achieve the goals. The preferred procedure is RYGB"	Grade of recommendation 0; Strong consensus
	RYGB, SG	"RYGB or laparoscopic SG should be preferred as [MBS] procedures in patients with obesity and NAFLD"	Grade of recommendation B; Strong consensus
IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (2021)[225]	OAGB	"The outcomes from OAGB are promising…and appear at least equivalent to other [MBS] procedures"	NR
Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One	SADI-S	"Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure"	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020 (2021)[54]	SADI-S	"IFSO supports the SADI-S/OADS as a recognized [MBS], but highly encourages RCTs in the near future"	NR
Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020 Endorsed by IFSO-EC, EASO and ESPCOP[35]	Eligibility criteria	"Laparoscopic [MBS] should be considered for patients with BMI ≥ 40 kg/m^2 and for patients with BMI ≥ 35 to < 40 kg/m^2 with associated comorbidities that are expected to improve with weight loss"	Strong recommendation
	Eligibility criteria	"Laparoscopic [MBS] should be considered for patients with ≥ BMI ≥ 30 to 35 kg/m^2 and T2DM and/or arterial hypertension with poor control despite optimal medical therapy"	Strong recommendation
	AGB	"AGB surgeries are associated with a high rate of reoperations for complications or conversion to another bariatric procedure for insufficient weight loss in the long term"	Position statement
	AGB, SG	"SG may be preferred over adjustable gastric banding for weight loss and control/resolution of metabolic comorbidities"	Conditional recommendation
	AGB, RYGB	"RYGB should be preferred over [AGB]"	Strong recommendation
	BPD, SG	"No recommendation for either BPD or SG can be made on the basis of available comparative evidence"	Conditional recommendation
	BPD, RYGB	"With regard to mid-term weight loss there is no difference between BPD and RYGB. BPD is superior to RYGB for control/ remission of T2DM. Long-term comparative data are, however, lacking"	Position statement
	OAGB	"OAGB may offer greater short-term weight loss compared to RYGB, gastric plication, AGB and SG. Long-term comparative data are, however, lacking. The effect on nutritional deficiencies remains controversial."	Position statement
	SADI-S	"No recommendation on SADI-S compared with OAGB, BPD, RYGB or SG can be made on the basis of available evidence"	Conditional recommendation
Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-	Eligibility criteria	"A minimal interval of 12 months between BS [bariatric surgery] and pregnancy is recommended to allow the weight of the patient to stabilize."	Grade C

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
partum Management After Bariatric Surgery (2019)[226]	SG	"Available data on pregnancy after sleeve gastrectomy are insufficient to recommend this intervention over others."	Grade C
	BPD, OAGB, SADI-S	BPD, OAGB, and SADI-S "should be considered with caution" for women of a childbearing age "given the nutritional deficiencies and cases of undernutrition associated with these procedures"	Grade C
	AGB	"AGB deflation is associated with higher maternal weight gain, and thus systematic deflation is not recommended during pregnancy"	Grade C
	AGB	"AGB inflation is not recommended either throughout pregnancy and rapid deflation is indicated if digestive symptoms appear"	Grade C
Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)[37]	Eligibility criteria	"[MBS] can be considered for people with BMI ≥ 40 kg/m^2, or BMI ≥ 35 kg/m^2 with at least one adiposity-related disease"	Level 4, Grade D, Consensus
	Eligibility criteria	"[MBS] should be considered in patients with poorly controlled T2DM and Class 1 obesity (BMI ≥ 30 to < 35 kg/m^2) despite optimal medical management"	Level 1a; Grade A
	Eligibility criteria	"[MBS] may be considered for weight loss and/or to control adiposity-related diseases in persons with Class 1 obesity, in whom optimal medical and behavioral management have been insufficient to produce significant weight loss"	Level 2a, Grade B
	BPD, RYGB, SG	"We suggest the choice of [MBS] (SG, gastric bypass or duodenal switch) be decided according to the patient's need, in collaboration with an experienced interprofessional team"	Level 4, Grade D, Consensus
	OAGB	"We suggest that [OAGB] not be routinely offered, due to long-term complications in comparison with standard RYGB"	Level 4, Grade D,
	AGB	"We suggest that AGB not be offered due to unacceptable complications and long-term failure"	Level 4, Grade D
Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)[229]	Eligibility criteria	"[MBS] should be recommended to nonpregnant adults with T2DM and a BMI ≥ 35 kg/m^2 as an option to potentially induce T2DM remission"	Grade A, Level 1A
	Eligibility criteria	"[MBS] for diabetes remission cannot be recommended at this time in those with preoperative BMI ≥ 30 to < 35 kg/m^2 because of limitations of current evidence on the relative remission rates with different types of [MBS] procedures and	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
		the balance of potential risks and long-term effects of [MBS] in individuals with T2DM with nonsevere obesity"	
Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)[222]	IGB	"Endoscopic [MBSs] are indicated in the following patients: BMI ≥ 27 kg/m^2 with obesity-related complications; BMI ≥ 30 kg/m^2 without obesity-related complications; BMI ≥ 40 kg/m^2. When the patient prefers nonsurgical management, there is a contraindication to surgery. Preoperative weight loss as a 'bridge therapy' to safe surgery is required"	Recommended best practice on the basis of the clinical experience of the Guideline Development Group members
	Eligibility criteria	"[MBS] is indicated in the following patients: • BMI ≥ 30 to 34.9 kg/m^2 with uncontrollable T2DM: The patient should be assessed, and their comorbidity management optimized, prior to surgery. Consider surgery at a lower BMI (≥ 27.5 kg/m^2) after MDT assessment for people of South Asian family origin, who have diabetes. • BMI ≥ 35 to 39.9 kg/m^2 with obesity-related complications. • BMI ≥ 40 kg/m^2 without obesity-related complications. • Special populations, e.g.: Waiting for organ transplantation with a BMI ≥ 30 kg/m^2 and demonstrated lack of response to specialist medical weight management. • Post-renal transplant with a BMI ≥ 30 kg/m^2 and an uncontrollable obesity complication"	Recommended best practice on the basis of the clinical experience of the Guideline Development Group members
NICE Guideline: Overweight and Obesity Management: Draft for Consultation (*Expected 2024*)[53]	Eligibility criteria	"Offer adults a referral for a comprehensive assessment by specialist overweight and obesity management services providing multidisciplinary management of obesity, to see whether [MBS] is suitable for them if they: have a BMI ≥ 40 kg/m^2, BMI ≥ 35 kg/m^2 to 39.9 kg/m^2 with a significant health condition that could be improved if they lost weight and agree to the necessary long-term follow up after surgery (for example, lifelong annual reviews)"	NR
	Eligibility criteria	"Offer an expedited assessment for [MBS] to people: with a BMI ≥ 35 kg/m^2 who have recent-onset (diagnosed within the past 10 years) T2DM and as long as they are also receiving, or will receive, assessment in a specialist overweight and obesity management service"	NR

Title (Year Issued)	Focus	Recommendations	Strength of Recommendation
	Eligibility criteria	"Consider an expedited assessment for [MBS] for people: with a BMI of ≥ 30 to 34.9 kg/m^2 who have recent-onset (diagnosed within the past 10 years) T2DM and who are also receiving, or will receive, assessment in a specialist overweight and obesity management service"	NR
	Eligibility criteria	"Consider an expedited assessment for [MBS] for people of South Asian, Chinese, other Asian, Middle Eastern, Black African, or African–Caribbean background using a lower BMI threshold (reduced by 2.5 kg/m^2) than in [the previous recommendations], to account for the fact that these groups are prone to central adiposity and their cardiometabolic risk occurs at lower BMI"	NR
NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)[228]	ESG	"ESG for obesity may be used if standard arrangements are in place for clinical governance, consent and audit"	NR
European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022[70]	SG; RYGB; AGB; BPD	"We suggest SG or laparoscopic RYGB over AGB, BPD with duodenal switch, and gastric plication for the management of severe obesity and associated metabolic diseases"	NR
	OAGB; SADI-S	"OAGB and SADI-S are suggested as alternatives, although evidence on benefits and harms, and specific selection criteria is limited compared to SG and RYGB"	NR

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no or unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

Washington State Health Care Authority

Final Key Questions and Background

Bariatric Surgery

Background

Technology of Interest

Bariatric surgery is an umbrella term for procedures that aid the reduction of excess weight by making changes to the digestive system, when conventional treatments (e.g., diet and exercise, medication) have not worked.[1] The American Society of Metabolic and Bariatric Surgery (ASMBS) currently endorses 7 bariatric procedures, including revision procedures and devices approved by the US Food and Drug Administration (FDA)[2]:

- Roux-en-Y gastric bypass
- Adjustable gastric banding
- Vertical sleeve gastrectomy
- Biliopancreatic diversion (with or without duodenal switch)
- Single anastomosis duodeno-ileostomy with sleeve
- Intragastric balloon
- One anastomosis gastric bypass

All procedures decrease stomach volume to limit how much food and drink can be consumed at one time.[1] However, other procedures (e.g., Roux-en-Y gastric bypass) also make changes to the small intestine to reduce absorption of calories and alter gut hormones to help reset hunger and satiety.[1] Adjustable gastric bands and intragastric balloons are reversible procedures that may be used prior to another type of bariatric surgery to reduce weight to a level that is suitable for surgery.[3,4] Intragastric balloons are usually placed for up to 6 months, but some can be placed for a maximum of 12 months.[3]

Clinical Need and Target Populations

The prevalence of overweight and obesity in US adults and children has continued to rise. Between 2017 and March 2020, the national prevalence of adult obesity (defined as a body mass index [BMI] greater than or equal to 30 kg/m^2 [27.5 kg/m^2 in Asian populations]) reached 42%.[5] During the same period, the prevalence of obesity in US children and adolescents was approximately 13% for those aged 2 to 5 years and 21% in those aged 6 to 19 years.[5] The US prevalence of overweight and obesity, including severe obesity, reached 73.8% in 2018, a nearly 30% increase since 1960 (estimated 45%).[5] Data from the 2022 Behavioral Risk Factor Surveillance System, which includes data collected between 2020 and 2022, indicates the prevalence of adult obesity in Washington is 30% to 35%; individuals identifying as Non-Hispanic American Indian or Alaska Native have an obesity prevalence of 40% to 45%.[6]

Policy Context

As the prevalence of overweight and obesity continue to rise in the US so does the number of bariatric surgery procedures performed annually. Estimates show that that 256,000 procedures were performed in 2019, increasing about 3% to nearly 263,000 in 2021.[7] The number of procedures performed is expected to continue rising, particularly in light of recently published guidelines from the ASMBS,

International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), and the American Academy of Pediatrics (AAP).

In October 2022 the ASMBS/IFSO published a joint update to the 1991 National Institutes of Health indications for metabolic and bariatric surgery.[8] Major changes to the 1991 guidance include[8]:

- Recommending metabolic and bariatric surgeries (MBS) for individuals with a BMI ≥ 35 kg/m^2, regardless of the presence, absence, or severity of comorbidities
- Considering MBS for individuals with metabolic disease and a BMI of 30 to 34.9 kg/m^2
- Adjusting BMI thresholds in the Asian population (also recently re-endorsed by the American Diabetes Association[9])
  - A BMI ≥ 25 kg/m^2 suggests clinical obesity in this population
  - Individuals from this population with a BMI ≥ 27.5 kg/m^2 should be offered MBS
- Considering MBS for appropriately selected children and adolescents

Relatedly, in February 2023 the AAP published updated clinical practice guidelines and recommendations for the evaluation and treatment of children and adolescents with overweight and obesity.[10] The AAP recommend offering a referral for an evaluation for MBS to appropriate surgery centers for adolescents aged 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex).[10]

In 2015, the Health Technology Clinical Committee made the following coverage determination[11]:

- Bariatric surgery is a covered benefit for adults (≥ 18 years of age) for the following conditions:
  - BMI ≥ 40
  - BMI 35 to < 40 and at least 1 obesity-related comorbidity
  - BMI 30 to < 35 and type II diabetes mellitus
- When covered, individuals must abide by all other agency surgery program criteria (e.g., specified centers or practitioners; preoperative psychological evaluation; participating in preoperative and postoperative multidisciplinary care programs).
- Bariatric surgery is not covered for the following groups:
  - Children (individuals < 18 years of age)
  - Adults with a BMI < 30
  - Adults with a BMI 30 to < 35 without type II diabetes mellitus

In 2023, this topic was selected for rereview based on medium concerns about safety and high concerns about effectiveness and cost.[12] The objective of the health technology assessment is to evaluate the effectiveness, safety, and cost-effectiveness of bariatric surgery in adults and children who are overweight or obese. This evidence review will help inform Washington's independent Health Technology Clinical Committee as it determines coverage regarding the use of bariatric surgery in adults and children.

Key Questions

KQ1. What is the comparative clinical effectiveness of bariatric surgery procedures currently covered (Roux-en-Y gastric bypass, adjustable gastric banding, vertical sleeve gastrectomy, and biliopancreatic diversion [with or without duodenal switch]) versus conventional weight-loss management in:

a. Adults (aged 18 years and older) who are not currently covered (i.e., adults with a BMI of 35 to less than 40 who do not have an obesity-related condition; adults with a BMI of 30 to less than 35 who do not have type 2 diabetes; adults with a BMI of lower than 30)?

b. Children (aged 17 or younger) who are overweight or obese, on an overall basis and by specific age groups (e.g., 13 to 17, 12 or younger)?

KQ2. What is the comparative clinical effectiveness of bariatric surgery procedures not currently covered (single anastomosis duodeno-ileostomy with sleeve, intragastric balloon, one anastomosis gastric bypass) versus conventional weight-loss management, with or without obesity-related comorbid conditions in:

a. Adults (aged 18 years and older) who are overweight or obese?

b. Children (aged 17 or younger) who are overweight or obese, on an overall basis and by specific age groups (e.g., 13 to 17, 12 or younger)?

KQ3. What is the potential short-term and long-term safety of bariatric surgery procedures, including rates of procedure-specific complications (including those requiring revision surgery), longer-term morbidity, and mortality in the populations specified in KQ1 and KQ2?

KQ4. What is the differential effectiveness and safety of bariatric surgery procedures according to patient and clinical factors, such as:

a. Age (chronological, physiologic, skeletal)

b. Gender

c. Race and ethnicity

d. BMI (assessed as both continuous and categorical variable)

e. Presence of comorbidities (e.g., hypertension, type 2 diabetes)

f. Prior medical event history (e.g., myocardial infarction, stroke)

g. Smoking status

h. Psychosocial health

i. Pre- and post-procedure adherence with program recommendations

KQ5. What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?

Contextual Questions

Contextual questions will not be systematically reviewed and are not shown in the analytic framework. To address contextual questions, we will rely on recent systematic reviews or a subset of the largest, most relevant recent primary research articles identified through our search.

CQ1. What is the overall effectiveness profile of nonsurgical weight management treatments (including prescription medication, dietary supplements, diet-control programs, exercise, psychotherapy, and nutritional counseling)?

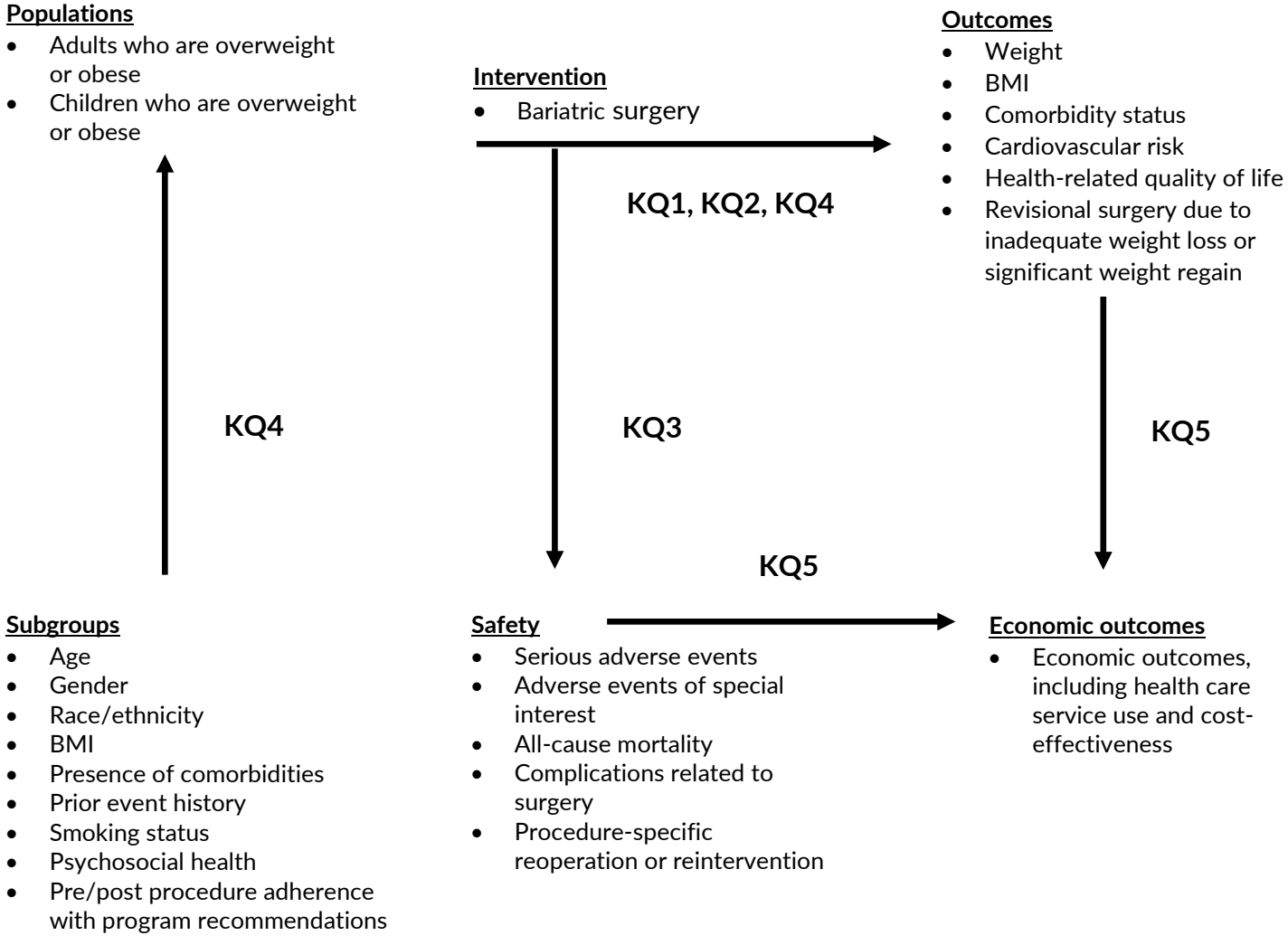
CQ2. What is the overall safety profile of covered bariatric procedures (Roux-en-Y gastric bypass, adjustable gastric banding, vertical sleeve gastrectomy, and biliopancreatic diversion [with or without duodenal switch]) in adults who are overweight or obese?

CQ3. What accreditation standards and center of excellence designations exist for bariatric surgery in the US and what are the requirements of each?

CQ4. What are professional society or guideline criteria for revision or conversion of bariatric surgeries?

Analytic Framework

Figure 1. Analytic Framework



Abbreviations. BMI: body mass index; KQ: key question.

Detailed Inclusion and Exclusion Criteria

Table 1. Detailed Inclusion and Exclusion Criteria for Studies of Bariatric Surgery

Inclusion Criteria	Exclusion Criteria
Populations	
KQ1 • Adults with a BMI of 35 to < 40 without an obesity-related condition • Adults with a BMI of 30 to < 35 without type 2 diabetes • Adults with a BMI < 30 • Children and adolescents who are overweight or obese KQ2 • Adults who are overweight or obese • Children and adolescents who are overweight or obese	• Populations who are overweight or obese due to obesogenic factors (e.g., pregnancy, substance misuse, medication)
Interventions	
KQ1 • Bariatric surgery procedures and FDA-approved devices[13] currently endorsed by the ASMBS[2], alone or in combination with nonsurgical treatments ○ Roux-en-Y gastric bypass ○ Adjustable gastric banding ○ Vertical sleeve gastrectomy ○ Biliopancreatic diversion (with or without duodenal switch) KQ2 • Bariatric surgery procedures and FDA-approved devices[13] currently endorsed by the ASMBS[2], alone or in combination with nonsurgical treatments ○ Single anastomosis duodeno-ileostomy with sleeve ○ Intragastric balloon ○ One anastomosis gastric bypass	• Non-ASMBS–endorsed procedures • Non-FDA–approved devices • Procedures or devices that are outdated and rarely practiced
Comparators	
• Nonsurgical weight management treatments (including prescription medication, dietary supplements, diet-control programs, exercise, psychotherapy, and nutritional counseling), alone or in combination • Sham procedures combined with a nonsurgical weight management treatment	• Treatments not available in the US (including outdated procedures [e.g., jejunoileal bypass] and devices [e.g., Garren-Edwards gastric bubble]) • Comparators other than those stated (e.g., comparison of different surgical techniques for the same procedure)
Outcomes[a]	
Efficacy and effectiveness • Weight • BMI • Comorbidity status (e.g., remission of type 2 diabetes)	• Studies not reporting outcomes of interest • Outcomes with less than 12 months post-intervention data (unless otherwise noted) • Economic outcomes from studies performed in non-US countries

Inclusion Criteria	Exclusion Criteria
• Cardiovascular risk (e.g., blood pressure) • Health-related quality of life ○ Patient important outcomes (e.g., self-esteem, mobility, depression) using specific measurement tools as defined in 2022[14] • Revision or conversion surgery due to inadequate weight loss or significant weight regain <u>Safety</u> • Serious adverse events • Adverse events of special interest (i.e., difficulty swallowing, micronutrient status) • All-cause mortality (30-day or longer term) • Complications related to surgery (e.g., intraoperative organ injury, hernia) • Any procedure-specific reoperation or reintervention and classification of severity (e.g., strictures, leaks) <u>Economic outcomes</u> • Health care service use • Costs • Cost-effectiveness	• Economic outcomes from studies performed in the US that were published more than 5 years ago • Other outcomes not listed
Timing	
• Any point in the treatment pathway[b]	• None stated
Setting	
Any nonemergency clinical setting in: • Countries categorized as very high on the 2021-22 UN HDI[15] • Canada, Mexico, Central America, and the Caribbean • Top 10 countries with the highest number of immigrants to the US (e.g., Mexico, China, India)[16]	• Nonclinical settings (e.g., animal models of disease) • Countries categorized as high, medium or low on the UN HDI, unless otherwise noted
Study design	
<u>For KQ1 to KQ4</u> • RCTs (≥ 50 participants) • Prospective nonrandomized comparative studies for interventions where RCTs are not available (≥ 100 participants) • Large registry studies (≥ 1,000 individuals) for safety outcomes only <u>For KQ5</u> • Comparative studies and economic evaluations • Cost-effectiveness analyses • Economic simulation modeling studies	• Abstracts, conference proceedings, posters, editorials, letters • Studies without a comparator • Placebo-controlled studies • Proof-of-principle studies (e.g., procedure development or technique modification) • Studies without extractable data • Uncontrolled studies • Retrospective studies unless otherwise noted
Sample size	
Minimum sample size of: • 50 participants for RCTs • 100 participants for nonrandomized comparative study designs • 1,000 participants for registry studies	• Studies that do not meet the minimum sample size

Inclusion Criteria	Exclusion Criteria
Publication	
• Peer-reviewed publications • Published in the English-language • Published from January 1, 2000 to present	• Studies reported only as abstracts that do not allow study characteristics to be determined • Studies that cannot be found • Duplicate publications of the same study that do not report different outcomes or follow-up times, or single-site reports from published multicenter studies • Studies published in languages other than English • Studies that have not been formally peer reviewed (i.e., preprint publications)

Notes. [a] Published core outcome sets and multiperspective consensus statements were reviewed for clinical and patient-important outcomes.[14,17] [b] The aim is to include studies regardless of any prior obesity-related treatments since presurgical requirements can vary across individual characteristics (e.g., age, severity of comorbidities), time periods, and geographical regions.
Abbreviations. ASMBS: American Society of Metabolic and Bariatric Surgery; BMI: body mass index; FDA: US Food and Drug Administration; KQ: key question; RCT: randomized controlled trial; UN HDI: UN Human Development Index.

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