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)?

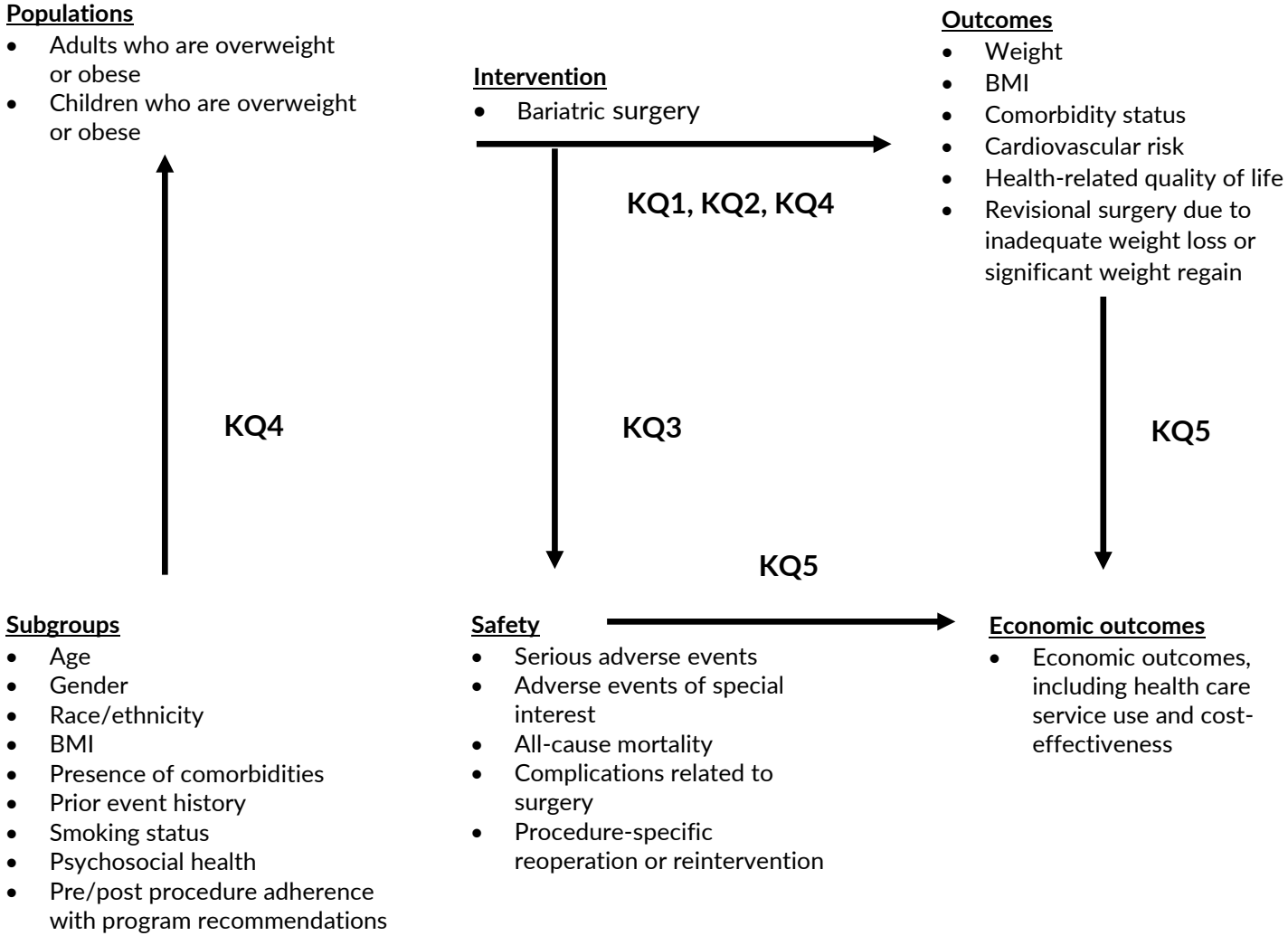
CQ2. What is the overall safety profile of covered bariatric procedures (Roux-en-Y gastric bypass, adjustable gastric banding, vertical sleeve gastrectomy, and biliopancreatic diversion [with or without duodenal switch]) in adults who are overweight or obese?

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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