

Health Technology Clinical Committee DRAFT Findings and Decision

Topic:Bariatric surgeryMeeting date:May 17, 2024Final adoption:Pending

Number and coverage topic:

20240517B - Bariatric surgery

HTCC coverage determination:

Bariatric surgery is a covered benefit with conditions.

HTCC reimbursement determination:

Limitations of coverage:

- Adults
 - Adults with body mass index (BMI) ≥35 (non-Asian descent) OR BMI ≥32.5 (Asian descent),

OR

Adults with type 2 diabetes mellitus (T2DM) AND BMI ≥30 (non-Asian descent) OR BMI ≥27.5 (Asian descent)

AND

- Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- Adolescents
 - Adolescents (13+) with bone maturity AND BMI ≥40 OR BMI ≥35 with one obesityrelated complication

<mark>AND</mark>

Procedure is sleeve gastrectomy or Roux-en-Y gastric bypass

AND

 Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

• Approved procedures include:

- Adjustable gastric banding
- Sleeve gastrectomy
- Endoscopic sleeve gastroplasty
- Roux-en-Y gastric bypass
- o Biliopancreatic diversion with or without duodenal switch
- o Single-anastomosis duodenal ileostomy with sleeve gastrectomy (SADI-S)
- One-anastomosis gastric bypass (OAGB)

Non-covered indicators:

• Intragastric balloons are not a covered benefit

Related documents:

- Final key questions
- Final evidence report

Draft

Meeting materials and transcript

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. The committee decided that the current evidence on adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal ileostomy with sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal satter decided that the current evidence on adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults, and sleeve gastrectomy and Roux-en-Y gastric bypass in adolescents is sufficient to determine coverage with conditions. The committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for use in adults and sleeve gastrectomy and Roux-en-Y gastric bypass in adolescents. Separately, the committee voted not to cover intragastric balloons for adults or adolescents.

	Not covered	Covered under certain conditions	Covered unconditionally
Adjustable gastric bands, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass in adults	0	9	0
Sleeve gastrectomy and Roux-en-Y gastric bypass			
in adolescents	0	9	0

Discussion

The committee reviewed and discussed the available studies for use of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and adolescents. Conditions for

Draft

coverage were discussed, drafted, and voted on. All committee members present supported the conditions of coverage of adjustable gastric banding, sleeve gastrectomy, endoscopic sleeve gastroplasty, Roux-en-Y gastric bypass, biliopancreatic diversion with or without duodenal switch, single-anastomosis duodenal ileostomy with sleeve gastrectomy, and one-anastomosis gastric bypass for adults and sleeve gastrectomy and Roux-en-Y gastric bypass for adolescents. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

Bariatric surgery is covered with conditions for the following:

- Approved procedures include:
 - Adjustable gastric banding
 - o Sleeve gastrectomy
 - Endoscopic sleeve gastroplasty
 - o Roux-en-Y gastric bypass
 - o Biliopancreatic diversion with or without duodenal switch
 - o Single-anastomosis duodenal ileostomy with sleeve gastrectomy
 - One-anastomosis gastric bypass
 - Adults
 - Adults with body mass index (BMI) ≥35 (non-Asian descent) OR BMI ≥32.5 (Asian descent),

OR

Adults with type 2 diabetes mellitus (T2DM) AND BMI ≥30 (non-Asian descent) OR BMI ≥27.5 (Asian descent)

AND

- Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation
- Adolescents
 - \circ Adolescents (13+) with bone maturity AND BMI ≥40, OR ≥35 with one obesity-related complication

<mark>AND</mark>

Procedure is sleeve gastrectomy or Roux-en-Y gastric bypass¹

AND

 Performed by a center with Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accreditation

Bariatric surgery is not a covered benefit for the use of intragastric balloons in adults or adolescents.

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is an NCD for bariatric surgery:

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

¹ Highlighted portions amended to include HTCC's original draft language during May 17, 2024 meeting.

In 2006, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) limiting Medicare coverage to accredited centers¹⁵⁴; 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}

The committee discussed clinical guidelines identified from the following organizations:

- 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)
- Referral of Adults with Obstructive Sleep Apnea for Surgical Consultation: An American Academy of Sleep Medicine Clinical Practice Guideline (2021)
- American Gastroenterological Association (AGA) Clinical Practice Guidelines on Intragastric Balloons in the Management of Obesity (2021)
- VA/DoD Clinical Practice Guideline for the Management of Adult Overweight and Obesity (2020)
- 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)
- 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)
- American Society for Metabolic and Bariatric Surgery Updated Statement on Single-Anastomosis Duodenal Switch (2020)
- American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass (2024)
- 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)
- 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)
- 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)
- IFSO Update Position Statement on One Anastomosis Gastric Bypass (OAGB) (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. Endorsed by IFSO-EC, EASO and ESPCOP

Draft

- Clinical Practice Guidelines for Childbearing Female Candidates for Bariatric Surgery, Pregnancy, and Post-partum Management After Bariatric Surgery (2019)
- Obesity Canada and the Canadian Association of Bariatric Physicians and Surgeons Clinical Practice Guidelines: Bariatric Surgery: Surgical Options and Outcomes (2020)
- Remission of Type 2 Diabetes: Diabetes Canada Clinical Practice Guidelines Expert Working Group (2022)
- Ministry of Public Health Qatar National Clinical Guideline: Bariatric & Metabolic Surgery in Adults (2021)
- NICE Guideline: Overweight and Obesity Management: Draft for Consultation (*Expected 2024*)
- NICE Interventional Procedures Guidance: Endoscopic Sleeve Gastroplasty for Obesity (2024)
- European Association for Endoscopic Surgery Rapid Guideline: Systematic Review, Network Meta-Analysis, CINeMA and GRADE assessment, and European Consensus on Bariatric Surgery-Extension 2022

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on use of bariatric surgery for public comment to be followed by consideration for final approval at the next committee meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company that takes public input at all stages.

Pursuant to RCW 70.14.110, a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.