Priority Health

MEDICAL POLICY No. 91595-R17

SURGICAL TREATMENT OF OBESITY

Effective Date: February 1, 2026

Review Dates: 8/11, 12/11, 2/12, 2/13, 2/14, 11/14, 2/15, 2/16, 2/17, 2/18, 5/18, 5/19, 8/19, 5/20, 5/21, 2/22, 5/22, 8/22, 2/23, 8/23, 11/23, 2/24, 11/24, 11/25

Date Of Origin: August 10, 2011

Status: Current

Summary of Changes

Changes:

- **Endoscopic Sleeve Gastroplasty (ESG)** may be considered medically necessary when specified criteria are met.
- **Transoral Outlet Reduction (TORe)** may be considered medically necessary when specified criteria are met

Clarifications (***in italics***):

- Corrective bariatric surgery: Diagnosis of gastroesophageal reflux disease (GERD) must have been confirmed by one or more of the following:
  - Abnormal 24-hour pH monitoring
  - Endoscopically proven ***LA grade C or D*** esophagitis

Notes:

- ***This medical policy does not apply to Priority Health Medicare members. Medicare claim billing and processing must follow CMS guidelines for coverage.***
- ***This medical policy does not apply to Priority Health Medicaid members. See the Michigan Department of Health and Human Services Medicaid Provider Manual (Practitioner, Section 3 – General Practice, Section 3.25 Weight Reduction)***

I. POLICY/CRITERIA

A. Criteria 1-4 must be met to be considered for Primary Bariatric Surgical (PBS) and Reoperation Bariatric Surgical (RBS) treatment of obesity:

1. Age > 18 years and the surgery must be performed by a surgeon who is a regular member in good standing of the American Society for Metabolic and Bariatric Surgery (ASMBS).

2. Prior approval must be obtained for Bariatric Surgery.

3. A pre-operative care and evaluation must occur in which all of the following must be met:

   a. Complete medical evaluation by PCP or other physician.

b. Evidence that all other alternatives have been discussed with and offered to patient, and that all reasonable non-surgical options have been attempted.
c. Documentation of active participation in and compliance with a medical weight management program, when applicable**, under the direction of the member's primary care physician (PCP) or other managing physician. The medical weight management program must include all of the following:

   i. Documentation of active participation and compliance with a medical weight management program for a minimum duration of 6 months with at least 6 office visits including both a diet and exercise component and in which the obesity and weight-related conditions (i.e., diabetes, hypertension and hyperlipidemia) are being addressed.

   ii. Thorough progress notes and records that include the following regarding the obesity problem:

      a) A provider-measured height and weight and calculated BMI
      b) The patient's history
      c) The physical findings
      d) The physician's assessment
      e) The physician's treatment recommendation(s)/plan(s).

   The medical weight management program must be completed within two years of the request for surgery.

   All documentation in #3 above should be submitted with the request for Bariatric Surgery. The BMI calculated from the height and weight obtained at the initial assessment for bariatric surgery will dictate the applicable BMI criterion used to determine medical necessity for bariatric surgery (see section below).

   Please use the link below to access templates that demonstrate the required documentation. These forms may be used in conjunction with the medical record to document the physician directed weight management program.

   https://www.priorityhealth.com/provider/manual/forms/medical-device-auth-forms

**Criterion 3c for at least 6 months medical management. This does not apply if BMI is ≥ 50.

The Medical Director will review each such case on an individualized basis to determine compliance with this policy section.

Past weight loss attempts without physician supervision through programs such as Weight Watchers, Curves, personal trainers, etc. are insufficient to meet this criterion.

d. A comprehensive psychosocial evaluation* conducted by a licensed behavioral specialist. It is recommended that this evaluator possess knowledge, experience, and training relevant to obesity, eating disorders, and weight loss surgery.

   This evaluation must establish the patient's:

   - Emotional stability
   - Ability to comprehend the risks of surgery and to give informed consent
   - Ability to cope with expected post-surgical lifestyle changes and limitations.

   *Note: Psychosocial evaluation must include presurgical psychosocial domains as recommended by the American Society for Metabolic and Bariatric Surgery and the American Psychiatric Association (for example, Bariatric Presurgical Psychosocial Evaluation Form). Evaluation must include substance use history with required statement as to whether substance use resulted in maladaptive behavior or is considered prohibitive to bariatric surgery.

e. None of the following medical conditions is present:

   i. Pregnancy
   ii. Severe psychopathology.

   Note: For members who have severe psychopathology who are currently under the care of a psychiatrist, or who are on psychotropic medications, preoperative psychiatry clearance is necessary in order to determine informed consent and an ability to comply with pre- and post-operative regimen.

   iii. Medical condition that makes patient a prohibitive risk.

iv. Any disease (e.g., cancer, uremia, liver failure), associated with a likelihood of survival less than 1 year.
v. Substance abuse including alcohol and other drugs of abuse.

Note: For members who have a diagnosed substance use disorder, there must be documented compliance with abstinence, including negative monthly urine drug screens for at least six continuous months.

4. Body Mass Index (BMI) criteria – Member **must** meet "a" or "b" or "c":

   a. BMI ≥ 35: Participation in medical weight management program, and the presence of at least one of the following life-endangering obesity-related co-morbidities:

      i. Obstructive sleep apnea significant enough to require medical treatment (e.g., prescription oral appliance, positive air pressure therapy)
      ii. Significant atherosclerotic cardiovascular disease (e.g. myocardial infarction, stroke, coronary stenting)
      iii. Hypertension requiring treatment with at least one medication.
      iv. Type 2 diabetes mellitus,
      v. Heart failure

   Note: Hyperlipidemia, gastroesophageal reflux disease (GERD), and degenerative joint disease do NOT qualify as they are NOT considered life endangering.

   b. BMI ≥ 40: Participation in a medical weight management program is required (presence of a co-morbidity is NOT required).

   c. BMI ≥ 50: Neither participation in a medical weight management program, nor presence of a co-morbidity, is required.

B. Limitations

1. The following bariatric procedures are covered when the surgical criteria above have been met:

   a. Roux-en-Y gastrojejunostomy
   b. Laparoscopically Adjustable Banding with FDA approved device
   c. Biliopancreatic Diversion with Duodenal Switch (BPD/DS)
   d. Sleeve gastrectomy

e. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) (i.e. single anastomosis duodenal switch (SADS), loop duodenal switch, stomach intestinal pylorus sparing surgery (SIPS)

2. **Endoscopic Sleeve Gastroplasty (ESG)** may be considered medically necessary in class II obesity when all of the following criteria are met:

   a. surgical criteria (see I. A. above) are met, and
   b. one or more comorbidities (see I. A. 4. a. above)) are present, and
   c. the procedure is performed by a fellowship trained specialist with experience in advanced endoscopic procedures.

3. **Transoral Outlet Reduction (TORe)** may be considered medically necessary when all of the following criteria are met (**please consult benefit documents for coverage of second bariatric procedures**):

   a) 18-65 years old
   b) BMI between 30-50 kg/m^2
   c) At least 6 months post-Roux-en-Y gastric bypass (RYGB) with evidence of inadequate weight loss (failure to achieve 50% or more excess weight loss after surgery) or significant weight regain (gain of more than 5% excess weight loss from nadir)

5. Coverage for medical and surgical programs is limited by applicable copays, coinsurance and deductibles.

6. Other bariatric procedures, including but not limited to the following, are not covered:

   a. Gastric banding with devices that are not FDA approved
   b. Gastric balloon and space occupying devices (e.g. Orbera, Reshape Duo)
   c. Other intestinal bypass procedures
   d. Mini-gastric bypass
   e. Endoscopic revision of bariatric surgery other than TORe, including the ROSE™ (Revision Obesity Surgery, Endoscopic) and Stomaphyx™ procedures.
   f. Vagal Blocking for Obesity Control (e.g. VBLOC, Maestro Rechargeable System)
   g. AspireAssist device
   h. Silastic ring vertical gastric bypass (including: Fobi Pouch; RYGB combined with simultaneous gastric banding)
   i. Magnetic Duodeno-ileostomy (Mag-DI)

7. Coverage for Medicaid/Healthy Michigan Plan members is limited to one bariatric surgery per lifetime. Unless Medically/Clinically Necessary (see Corrective Revisional Bariatric Surgery - Section I, C, 2, a-c below), a second bariatric surgery is **not** Covered, even if the initial bariatric surgery occurred prior to Coverage under this plan.

8. The adjustable silicone gastric banding (LAP-Band) was reviewed by Priority Health's Technology Assessment Committee (TAC) in September 2003, December 2003, March 2005 and June 2005 and this policy reflects recommendations of the TAC. Biliopancreatic Diversion with Duodenal Switch was reviewed by Priority Health's Technology Assessment Committee in March 2006 and this policy reflects recommendation of the TAC. Endoscopic revision of bariatric surgery was reviewed by Priority Health's Technology Assessment Committee in December 2007 and this policy reflects the recommendation of TAC.

C. Reoperation Bariatric Surgery (RBS):

Reoperation Bariatric Surgery (RBS) includes Conversion BS (PBS to second procedure), or Corrective BS (to treat complications of PBS).

1. Conversion Bariatric Surgery:

a. In members whose primary bariatric surgery (PBS) was Roux-en-Y gastric bypass (RYGB), vertical sleeve gastrectomy (VSG), or biliopancreatic diversion with duodenal switch (BPD-DS) or without duodenal switch (BPD), conversion bariatric surgery is medically necessary in patients who continue to meet medical necessity criteria for PBS (as in I.A. above), and who meet all of the following medical necessity criteria:

   i. For members who have not had adequate success (defined as loss of more than 50% of excess body weight) 2 years following the primary bariatric surgery (PBS) procedure, conversion to any of the following are considered medically necessary:
      1. Sleeve gastrectomy
      2. RYGB
      3. BPD/DS
   ii. The member has demonstrated compliance with a prescribed nutrition and exercise program following the procedure, as evidenced by:
      1. Clinical documentation

2. Nutrition counseling to verify report of inability to eat appropriate foods and calorie due to persistent symptoms (pain, nausea, emesis).

b. In members whose primary bariatric surgery (PBS) was an adjustable gastric band (AGB), Conversion Bariatric Surgery is medically necessary for members who continue to meet medical necessity criteria for PBS (as in I.A. above), and who meet all of the following medical necessity criteria:

i. For members who have not had adequate success (defined as loss of more than 50% of excess body weight) 2 years following the primary bariatric surgery (PBS) procedure, conversion to any of the following is considered medically necessary:
   1. Sleeve gastrectomy
   2. RYGB
   3. BPD/DS

ii. The member has demonstrated compliance with a prescribed nutrition and exercise program following the procedure, as evidenced by:
   1. Clinical documentation
   2. Nutrition counseling to verify report of inability to eat appropriate foods and calories due to persistent symptoms (pain, nausea, emesis).

iii. There are complications that cannot be corrected with band manipulation, adjustments or removal.

2. Corrective Bariatric Surgery:

a. In members whose primary bariatric surgery (PBS) was Roux-en-Y gastric bypass (RYGB), vertical sleeve gastrectomy (VSG), or biliopancreatic diversion with duodenal switch (BPD-DS) or without duodenal switch (BPD), corrective bariatric surgery is considered medically necessary to correct acute or chronic mechanical and or anatomic complications including:
   i. Fistula
   ii. Obstruction
   iii. Stricture
   iv. Marginal ulcer, if causing abdominal pain
   v. Inability to eat or drink
   vi. Persistent vomiting of prescribed meals

b. In members whose primary bariatric surgery (PBS) was an adjustable gastric band (AGB), corrective bariatric surgery including

manipulation, adjustments, repair or removal is considered medically necessary if there are complications (e.g., port leakage, slippage, erosion) resulting in inability to eat appropriate foods due to persistent symptoms.

c. In members whose primary bariatric surgery (PBS) was vertical sleeve gastrectomy (VSG), or biliopancreatic diversion with duodenal switch (BPD-DS) or without duodenal switch (BPD), or adjustable gastric band (AGB), corrective bariatric surgery with Roux-en-Y gastric bypass (RYGB) or BDP-DS, is considered medically necessary for persistent gastroesophageal reflux disease unresponsive to medical therapy for members who continue individual compliance with postoperative nutrition and exercise recommendations.

   Diagnosis of gastroesophageal reflux disease (GERD) must have been confirmed by one or more of the following:

   - Abnormal 24-hour pH monitoring
   - Endoscopically proven LA grade C or D esophagitis

   Additionally, GERD must have been refractory/unresponsive to maximum medical treatment, including both over-the-counter and prescribed anti-reflux medications (including maximum proton pump inhibitor (PPI) therapy) ≥ 8 weeks.

D. Not Medically Necessary:

1. Poor response to Primary Bariatric Surgery due to patient post-operative behavior (not following dietary restriction, large portion meals, lack of documented exercise) does not constitute a surgical complication and the revision of this condition is considered **not medically necessary.**
2. PBS and RBS will frequently ameliorate symptoms of co-morbidities such as diabetes, gastroesophageal reflux disease and obstructive sleep apnea. However, the purpose of bariatric surgery in obese persons is to achieve weight loss. Therefore, coverage would not exist for bariatric surgery to treat co-morbidities caused or exacerbated by obesity unless in accordance with the limitations and language as above.

E. SPECIAL NOTES

Specific group benefit plans may require coverage for the medical or surgical treatment of obesity beyond the coverage set forth in this policy.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals. For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
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NCD 100.1	Bariatric Surgery for Treatment of Morbid Obesity
Local Coverage Determinations (LCDs)	
None identified.	

III. BACKGROUND

Surgical treatment for obesity may be a covered benefit for the indications described above. The treatment of co-morbidities (e.g. diabetes mellitus, hypertension) associated with obesity is a covered benefit in accordance with the limitations and language in the coverage documents. It is Priority Health's position that co-morbidities that are related to an obesity diagnosis should be treated medically, and if such co-morbidities can be controlled by less invasive means than bariatric surgery, bariatric surgery is not the preferred treatment.

All surgical services for weight management require prior authorization.

The Aspire Assist (Aspire Bariatrics) device: To place the device, surgeons insert a tube in the stomach with an endoscope via a small incision in the abdomen. A disk-shaped port valve that lies outside the body, flush against the skin of the

abdomen, is connected to the tube and remains in place. Approximately 20 to 30 minutes after meal consumption, the patient attaches the device's external connector and tubing to the port valve, opens the valve and drains the contents. Once opened, it takes approximately five to 10 minutes to drain food matter through the tube and into the toilet. The device removes approximately 30 percent of the calories consumed. In a clinical trial of 111 patients treated with Aspire Assist and appropriate lifestyle therapy, and 60 control patients who received only the lifestyle therapy, patients using Aspire Assist lost an average of 12.1 percent of their total body weight compared to 3.6 percent for the control patients after one year.

Transoral Outlet Reduction (TORe)

Weight regain after bariatric surgery can be attributed to several mechanisms, most commonly lack of compliance with diet and exercise. Enlargement of the gastric pouch or dilation of the gastrojejunal anastomosis (stoma) may contribute to weight regain after RYGB surgery by allowing more liberal food intake. Endoscopic techniques for reducing enlarged stomas or pouches include endoscopic mechanical devices (eg, suturing or plication devices, over-the-scope metal clips) and thermal therapy (eg, argon plasma coagulation). Selecting a technique is individualized and is informed by equipment availability, endoscopist preference, and stoma/pouch size. **Endoscopic transoral outlet reduction (TORe)** combines thermal therapy using argon plasma coagulation (APC) with full-thickness suturing to cause scarring of the anastomosis and mechanically reduce the stomal diameter.

Relevant joint guidelines from the American Society for Gastrointestinal Endoscopy (ASGE), the Society of Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Metabolic and Bariatric Surgery (ASMBS), The Role of Endoscopy in the Bariatric Patient, were published in 2015. From these guidelines: *"Endoscopic suturing devices have also been developed to reduce stoma size and gastric pouch volumes, but have not been widely adopted. Quality data regarding endoluminal approaches to stomal reduction and its resultant impact on weight management remain sparse, and these approaches cannot be recommended for widespread application at this time"* (p. 1069).

In a randomized controlled multicenter trial by Thompson and colleagues (2013), patients with weight regain or inadequate loss after RYGB and GJ diameter greater than 2 cm were assigned randomly to groups that underwent TORe (n = 50) or a sham procedure (controls, n = 27). Intraoperative performance, safety, weight loss, and clinical outcomes were assessed. Subjects who received TORe had a significantly greater mean percentage weight loss from baseline (3.5%; 95%

confidence interval, 1.8%-5.3%) than controls (0.4%; 95% confidence interval, 2.3% weight gain to 3.0% weight loss) (P = .021), using a last observation carried forward intent-to-treat analysis. As-treated analysis also showed greater mean percentage weight loss in the TORe group than controls (3.9% and 0.2%, respectively; P = .014). Weight loss or stabilization was achieved in 96% of subjects receiving TORe and 78% of controls (P = .019). The TORe group had reduced systolic and diastolic blood pressure (P < .001) and a trend toward improved metabolic indices. In addition, 85% of the TORe group reported compliance with the healthy lifestyle eating program, compared with 53.8% of controls; 83% of TORe subjects said they would undergo the procedure again, and 78% said they would recommend the procedure to a friend. The groups had similar frequencies of adverse events.

A publication by Jirapinyo et al. (2020) evaluated the five-year outcomes of TORe. The primary outcome was efficacy of TORe at 1, 3, and 5 years. Three hundred thirty-one RYGB patients underwent 342 TORe procedures and met inclusion criteria. Of these, 331, 258, and 123 patients were eligible for 1-, 3- and 5-year follow-ups, respectively. Mean body mass index was 40 ± 9 kg/m^2. Pre-TORe gastrojejunal anastomosis (GJA) size was 23.4 ± 6.0 mm, which decreased to 8.4 ± 1.6 mm after TORe. Patients experienced 8.5% ± 8.5%, 6.9% ± 10.1%, and 8.8% ± 12.5% total weight loss (TWL) at 1, 3, and 5 years with follow-up rates of 83.3%, 81.8%, and 82.9%, respectively. Of 342 TORe procedures, 76%, 17.5%, 4.4%, and 2.1% were performed using single purse-string, interrupted, double purse-string, and running suture patterns, respectively, with an average of 9 ± 4 stitches per GJA. Pouch reinforcement suturing was performed in 57.3%, with an average of 3 ± 2 stitches per pouch. There were no severe adverse events. Some patients (39.3%) had additional weight loss therapy (pharmacotherapy or procedure), with 3.6% getting repeat TORe. Amount of weight loss at 1 year (β = .43, P = .01) and an additional endoscopic weight loss procedure (β = 8.52, P = .01) were predictors of the percentage of TWL at 5 years.

A systematic review and meta-analysis by Dhindsa and colleagues (2020) assessed technical success, absolute weight loss (AWL), and percent of total weight loss (%TWL) at 3, 6, and 12 months after TORe. Thirteen studies on 850 patients were included. The pooled rate of technical success was 99.89 %. The absolute weight loss (kg) at 3, 6, and 12 months was 6.14, 10.15, and 7.14, respectively. The percent TWL at 3, 6, and 12 months was 6.69, 11.34, and 8.55, respectively. The pooled rate of adverse events was 11.4 % with abdominal pain being the most common adverse event. The correlation coefficient (r) was -0.11 between post TORe GJA size and weight loss at 12 months.

Endoscopic Sleeve Gastroplasty (ESG)

Endoscopic sleeve gastroplasty (ESG) is a reversible, endoluminal organ-sparing bariatric procedure that is done with use of a commercially available, full-thickness endoscopic suturing device (Overstitch System; Apollo Endosurgery, Austin, TX, USA). It imbricates the majority of the stomach by serial interrupted sutures placed from the incisura to the cardia. The influence of ESG over obesity pathophysiology has been shown to go beyond mechanical restriction, to affect satiation and metabolic dysregulation pathways. (Abu Dayyeh et al., 2022)

In a randomized, controlled multicenter trial, 209 patients were enrolled and randomly assigned (1:1·5; with stratified permuted blocks) to ESG with lifestyle modifications (ESG group) or lifestyle modifications alone (control group), with potential retightening or crossover to ESG, respectively, at 52 weeks. Lifestyle modifications included a low-calorie diet and physical activity. Participants in the primary ESG group were followed up for 104 weeks. The primary endpoint at 52 weeks was the percentage of excess weight loss (EWL), with excess weight being that over the ideal weight for a BMI of 25 kg/m². Secondary endpoints included change in metabolic comorbidities between the groups. Multiple imputed intention-to-treat analyses with mixed effects models were used. Analyses were done on a per-protocol basis and a modified intention-to-treat basis. The safety population was defined as all participants who underwent ESG (both primary and crossover ESG) up to 52 weeks. 85 participants were randomly assigned to ESG and 124 were assigned to the control group. At 52 weeks, the primary endpoint of mean percentage of EWL was 49.2% (SD 32.0) for the ESG group and 3.2% (18.6) for the control group ($p<0.0001$). Mean percentage of total bodyweight loss was 13.6% (8.0) for the ESG group and 0.8% (5.0) for the control group ($p<0.0001$), and 59 (77%) of 77 participants in the ESG group reached 25% or more of EWL at 52 weeks compared with 13 (12%) of 110 in the control group ($p<0.0001$). At 52 weeks, 41 (80%) of 51 participants in the ESG group had an improvement in one or more metabolic comorbidities, whereas six (12%) worsened, compared with the control group in which 28 (45%) of 62 participants had similar improvement, whereas 31 (50%) worsened. At 104 weeks, 41 (68%) of 60 participants in the ESG group maintained 25% or more of EWL. ESG-related serious adverse events occurred in three (2%) of 131 participants, without mortality or need for intensive care or surgery. (Abu Dayyeh et al., 2022)

In a systematic review and meta-analysis by Hedjoudje and colleagues, data from 8 original studies, published from 2016 through 2019, which included a total of 1772 patients, were included in an analysis of efficacy and safety of ESG. At 6 months, mean TBWL was 15.1% (95% CI, 14.3-16.0), mean decrease in body mass index was 5.65 kg/m2 (95% CI, 5.07-6.22), and mean excess weight loss was 57.7% (95% CI, 52.0-63.4). Weight loss was sustained at 12 months and 18-24 months with a TBWL of 16.5% (95% CI, 15.2-17.8) and 17.2% (95% CI, 14.6-19.7), respectively. The pooled post-ESG rate of severe adverse events was

2.2% (95% CI, 1.6%-3.1%), including pain or nausea requiring hospitalization (n = 18, 1.08%), upper gastrointestinal bleeding (n=9, 0.56%), and peri-gastric leak or fluid collection (n = 8, 0.48%). (Hedjoudje et al., 2019)

Another systematic review and meta analysis aimed to determine the short- and medium-term weight loss outcomes and comorbidity resolution following endoscopic sleeve gastroplasty. 35 relevant studies including data from 7,525 patients was included. Overall, pooled short-term (12 months) total weight loss (TWL) was 16.2% (95% CI 13.1-19.4%) in 23 studies (n = 5659). Pooled medium-term TWL was 15.4% (95% CI 13.7-17.2%) in 10 studies (n = 4040). Diabetes resolution was 55.4% (95% CI 46-64%), hypertension resolution was 62.8% (95% CI 43-82%), dyslipidemia resolution was 56.3% (95% CI 49-63%), and obstructive sleep apnea resolution was 51.7% (95% CI 16.2-87.3%) in four studies (n = 480). (Fehervari et al., 2023)

Guidelines/Position Statements:

National Institute for Health and Care Excellence (NICE, 2024): Endoscopic Sleeve Gastroplasty for Obesity (IPG783)

- "1.1 Use endoscopic sleeve gastroplasty as an option to treat obesity in adults with standard arrangements in place for clinical governance, consent and audit" (p. 2).
- "3.6 The committee considered that this procedure may particularly benefit people:
- "with class 3 obesity for whom invasive bariatric surgery would be considered high risk
- "who decline bariatric surgery because of the associated risks and complications
- "who have class 1 or class 2 obesity, for whom the procedure may prevent progression of obesity and associated comorbidities" (pp. 5-6).

ASGE and ESGE (Jirapinyo et al., 2024): American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy Guideline on Primary Endoscopic Bariatric and Metabolic Therapies for Adults With Obesity

- "In adults with overweight or obesity, the ASGE–ESGE suggests the use of endoscopic bariatric and metabolic therapies plus LM over LM alone for patients with a BMI ≥30 kg/m^2 with or without an obesity-related comorbidity or a BMI of 27 to 29.9 kg/m^2 with at least 1 obesity-related comorbidity. [Conditional strength of recommendation, very low quality of evidence]" (p. 868).

- "In adults with obesity, the ASGE–ESGE suggests treatment with EGR plus LM over LM alone. [Conditional strength of recommendation, moderate quality of evidence]" (p. 874).
- NOTE: EGR includes both ESG using Apollo and primary obesity surgery endoluminal.
- "EGR may be performed using the Overstitch Endoscopic Suturing System (Apollo Endosurgery), Incisionless Operating Platform (IOP; USGI Medical), or Endomina System (Endo Tools Therapeutics) … Evidence is insufficient to specifically recommend 1 device over another. The choice of device is based on clinical context, patient values, availability, and operator experience" (p. 875).

EAES (Di Lorenzo et al., 2020): Clinical Practice Guidelines of the European Association for Endoscopic Surgery (EAES) on Bariatric Surgery: Update 2020 Endorsed by IFSO-EC, EASO and ESPCOP

- "Endoluminal suturing procedures may have a role in the treatment of obese patients with BMI below 40 kg/m^2" (p. 2350).
- "Five observational studies have addressed the use of OverStitch™ … The procedure may be considered safe, well tolerated and effective with a mean [excessive weight loss (EWL)] of 50% at 1 year. Evidence suggests durability of plications and progressive weight loss up to 2 years" (p. 2350).

IFSO (Salminen et al., 2024): IFSO Consensus on Definitions and Clinical Practice Guidelines for Obesity Management—an International Delphi Study

- "ESG combined with lifestyle intervention is preferable to lifestyle interventions alone, for the management of adults with class II obesity" (p. 36).
- "ESG combined with lifestyle intervention is an acceptable management option for adults with class III obesity who either do not qualify (given medical or psychological comorbidities) or do not wish to pursue [metabolic bariatric surgery]" (p. 36).
- "ESG combined with lifestyle intervention is preferable to lifestyle interventions alone, for the management of adults with class I obesity" (p. 36).

World Gastroenterology Association and IFSO (2023): World Gastroenterology Organisation and International Federation for the Surgery of Obesity and Metabolic Diseases (IFSO) Guidelines

- "With endoscopic gastric suturing procedures, adjunctive weight loss medications or repeat procedures may be necessary" (p. 171).
- "Endoscopic gastric suturing procedures should be considered for patients who are in the overweight category and have obesity-related comorbidities" (p. 171).
- "Endoscopic gastric suturing procedures should be considered in patients with Class 3 obesity when they are not good surgical candidates or have declined surgery" (p. 171).

Magnetic Duodeno-Ileostomy (Mag-DI)

Compression anastomosis (CA) has been a minimally invasive strategy used intermittently with variable efficacy since the methodology using sutureless metal rings was introduced in the 18th century. A modification, magnetic CA (MCA), was initiated in the 20th century and used in distal colon resection. In the 21st century, MCA is utilized in vascular, esophageal, biliary, and colorectal surgery. In the metabolic/bariatric surgery setting, MCA has been explored in clinical studies of self-assembling magnet technology, particularly the linear magnetic anastomosis system (LMAS). (Gagner et al., 2024)

Magnetic Duodeno-Ileostomy (Mag-DI) is a novel, minimally invasive surgical technique designed to create a side-to-side anastomosis between the duodenum and ileum using self-aligning magnetic compression anastomosis devices. This procedure facilitates direct intestinal continuity while bypassing a portion of the small intestine, and is primarily investigated as a metabolic intervention for obesity and type 2 diabetes mellitus. The Mag-DI technique involves the endoscopic or laparoscopic placement of paired magnetic rings—one in the duodenum and one in the ileum—which attract and compress the intervening tissue. This compression leads to localized ischemia and necrosis, ultimately forming a stable anastomosis without the need for sutures or staples. The approach aims to reduce surgical complexity, minimize operative time, and lower the risk of complications compared to traditional anastomotic methods.

In a prospective single-center study, the feasibility, safety, and efficacy of the novel linear magnetic anastomosis system (LMAS [3 cm]) in performing a side-to-side duodeno-ileostomy (MagDI) bipartition to revise clinically suboptimal primary sleeve gastrectomy (SG) was evaluated. Patients with severe obesity with/without type 2 diabetes (T2D) with suboptimal weight loss, regain, and/or T2D recurrence post SG underwent revisional MagDI. A distal and proximal magnet were delivered endoscopically to the ileum and duodenum and aligned via laparoscopic assistance. Gradual magnet fusion formed a DI bipartition. Technical feasibility and safety (Clavien-Dindo [CD] severe adverse event classification)

were reported at 1 year. 24 patients (95.8% female, mean age 44.9 ± 1.5 years, and body mass index [BMI] 39.4 ± 1.3 kg/m^2) underwent MagDI. Feasibility was attained via correct magnet placement (mean operative time 63.5 ± 3.3 min), patent anastomoses created, and magnet passage per anus in 100.0% of patients. There were 4 CD-III mild or moderate severe AEs, 0.0% associated with the LMAS or MagDI: 0.0% anastomotic leakage, obstruction, bleeding, infection, reintervention, or death. Mean BMI reduction was 2.1 kg/m^2 ($p < 0.05$); total weight loss 5.3%, excess weight loss 16.4%; and the patient with T2D improved. (Gagner et al., 2024)

Silastic Ring Vertical Gastric Bypass for Bariatric Surgery

Roux-en-Y gastric bypass (RYGB) is a restrictive and malabsorptive procedure in which a small gastric pouch is formed and connected to the small intestine. This procedure can be performed as an open surgery, laparoscopically, or robotically. Silastic ring vertical gastric bypass is a variation of gastric bypass surgery, in which a silastic ring is placed around the pouch formed during RYGB to increase the restriction.

Fobi pouch, a method for silastic ring gastric bypass, involves use of a small (< 25 mL) transected silastic ring vertical gastric bypass with an interposed Roux-en-Y limb, and an externally supported soma.

Multiple silastic bands are available for use in gastric bypass. These devices have FDA approval for marketing in the United States under product code LTI.

No systematic reviews have been published. No position statements or guidelines have been published, suggesting either no or unclear support for silastic ring vertical gastric bypass for bariatric surgery. Therefore, this procedure is considered experimental, investigational, or unproven.

Psychosocial optimization

A **preoperative psychosocial evaluation/assessment**, conducted by a qualified behavioral health clinician with relevant specialized knowledge, is recommended by professional societies and is required by many third-party payors. While these evaluations may identify clear contraindications for surgery, the psychosocial evaluation is best conceptualized as a way to identify strengths and vulnerabilities and develop recommendations to enhance surgical outcome. Because long-term outcome is substantially influenced by patient behaviors, it follows that preoperative psychosocial optimization is important for all patients, not solely those with a history of psychopathology.

The American Society for Metabolic and Bariatric Surgery (ASMBS) recommends that the **presurgical psychosocial evaluation** of bariatric surgery patients address the following domains:

- Weight history
- Eating disorder symptoms (including maladaptive eating patterns)
- Psychosocial history, including:
    - Psychiatric history and psychosocial functioning
    - Developmental and family history
    - Current and past mental health treatment
    - Cognitive functioning
    - Personality traits and temperament
- Current stressors
- Social support
- Quality of life
- Health-related behaviors, including:
    - Substance use
    - Smoking
    - Adherence
    - Physical activity
- Patient motivation and knowledge, including:
    - Weight loss expectations
    - Motivation
    - Knowledge of surgical procedures, risks, and benefits

While ***drug abuse*** is no longer a current medical diagnosis in either of the most used diagnostic tools in the world (the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM), and the World Health Organization's International Classification of Diseases (ICD)), the National Cancer Institute defines ***drug abuse*** as follows: *The use of illegal drugs or the use of prescription or over-the-counter drugs for purposes other than those for which they are meant to be used, or in excessive amounts. Drug abuse may lead to social, physical, emotional, and job-related problems.* The more appropriate, currently accepted term is ***substance use disorder (SUD)***.

A ***substance use disorder (SUD)*** is a medical condition that is defined by the inability to control the use of a particular substance (or substances) despite harmful consequences. In other words, SUDs occur when an individual compulsively misuses drugs or alcohol and continues abusing the substance despite knowing the negative impact it has on the individual's life.

The **American Psychiatric Association (APA)** has developed 11 criteria for SUD diagnosis in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5):

- Taking the substance for long periods of time or in larger amounts than intended.
- Being unable to cut down or stop substance use.
- Spending a lot of time obtaining, using, and recovering from the effects of the substance.
- Experiencing cravings, or intense desires or urges for the substance.
- Failing to fulfill obligations at home, work, or school due to substance use.
- Continuing substance use despite having interpersonal or social problems that are caused or worsened by substance use.
- Giving up social, recreational, or occupational activities due to substance use.
- Using the substance in risky or dangerous situations.
- Continuing substance use despite having a physical or mental problem that is probably due to substance use.
- Tolerance, or needing more of the substance to achieve previous effects.
- Withdrawal, meaning that unpleasant symptoms occur when once stops using one's substance of choice.

SUDs may range from mild to severe, with severity depending on the number of symptoms/diagnostic criteria a person meets:

- **Mild**: displays 2-3 symptoms/criteria,
- **Moderate**: displays 4-5 symptoms/criteria, and
- **Severe**: displays 6 or more symptoms/criteria.

Esophagitis: Los Angeles Classification

Grade A	One (or more) mucosal break no longer than 5 mm that does not extend between the tops of two mucosal folds
Grade B	One (or more) mucosal break more than 5 mm long that does not extend between the tops of two mucosal folds
Grade C	One (or more) mucosal break that is continuous between the tops of two or more mucosal folds but which involve less than 75% of the circumference
Grade D	One (or more) mucosal break which involves at least 75% of the esophageal circumference

IV. GUIDELINES/POSITION STATEMENTS

Medical/Professional Society	Guideline
National Institute for Health and Care Excellence (NICE)	Endoscopic sleeve gastroplasty for obesity (2024)
American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy	Guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity (2024)
European Association for Endoscopic Surgery (EAES) on bariatric surgery	Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP (2020)
International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	Consensus on Definitions and Clinical Practice Guidelines for Obesity Management (2023)
World Gastroenterology Association and IFSO	World Gastroenterology Organisation and International Federation for the Surgery of Obesity and Metabolic Diseases (IFSO) Guidelines (2023)
American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO)	Indications for Metabolic and Bariatric Surgery (2022)
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)	Guidelines for Clinical Application of Laparoscopic Bariatric Surgery (2008)
Obesity Medicine Association	Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures (2020)
National Institute for Health and Care Excellence (NICE)	Overweight and obesity management (2025)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
MagDI System (GT Metabolic Solutions)	DEN240013	7/2/2024
OverStitch NXT Endoscopic Suturing System (Boston Scientific)	K231553	6/29/2023
AspireAssist® (Aspire Bariatrics)	P150024	6/14/2016
Orbera Intragastric Balloon (Boston Scientific)	P140008	8/6/2015
ReShape Duo™ Integrated Dual Balloon System (ReShape Medical)	P140012	7/28/2015
Lap-Band Adjustable Gastric Banding System (BioEnterics)	P000008	6/5/2001

VI. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

See also Bariatric surgery services

VII. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***

VIII. CODING INFORMATION

ICD-10 Codes that *may* support medical necessity:

E66.01 Morbid (severe) obesity due to excess calories
E66.09 Other obesity due to excess calories
E66.1 Drug-induced obesity
E66.2 Morbid (severe) obesity with alveolar hypoventilation
E66.8 Other obesity
E66.9 Obesity, unspecified

The following codes should be reported as secondary Dx only

Z68.35 Body mass index (BMI) 35.0-35.9, adult
Z68.36 Body mass index (BMI) 36.0-36.9, adult
Z68.37 Body mass index (BMI) 37.0-37.9, adult
Z68.38 Body mass index (BMI) 38.0-38.9, adult
Z68.39 Body mass index (BMI) 39.0-39.9, adult
Z68.41 Body mass index (BMI) 40.0-44.9, adult
Z68.42 Body mass index (BMI) 45.0-49.9, adult
Z68.43 Body mass index (BMI) 50-59.9, adult
Z68.44 Body mass index (BMI) 60.0-69.9, adult
Z68.45 Body mass index (BMI) 70 or greater, adult

CPT/HCPCS Codes:

43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption

43659 Unlisted laparoscopy procedure, stomach (when billed for SADI-S)
43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only
43772 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only
43773 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only
43774 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components
43775 Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43845 Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846 Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43848 Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)

43886 Gastric restrictive procedure, open; revision of subcutaneous port component only
43887 Gastric restrictive procedure, open; removal of subcutaneous port component only
43888 Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43889 Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed *(Effective 1/1/2026)*
43999 Unlisted procedure, stomach *(Explanatory notes must accompany claim)*
Use this code for billing: Open sleeve gastrectomy
C9785 Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
S2083 Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Not covered for indications in this policy:
43647 Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648 Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43842 Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43847 Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43881 Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882 Revision or removal of gastric neurostimulator electrodes, antrum, open

43290 Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291 Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)

0813T Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon

The unlisted codes below are not covered when billed for the following conditions:
Balloon Gastroplasty
Endoscopic revision of bariatric surgery
Open gastric band
Laparoscopic vertical banded gastroplasty
Open sleeve gastrectomy *(Not covered for Priority Health Medicare)*

Silastic ring vertical gastric bypass
(Explanatory notes must accompany claims billed with unlisted codes.)
43659 Unlisted laparoscopy procedure, stomach
43999 Unlisted procedure, stomach

BODY MASS INDEX (BMI) CHART

Height Weight	4'8"	4'10"	5'0"	5'2"	5'4"	5'6"	5'8"	5'10"	6'0"	6'2"	6'4"
150	34	31	29	27	26	24	23	22	20	19	18
160	36	33	31	29	27	26	24	23	22	21	19
170	38	36	33	31	29	27	26	24	23	22	21
180	40	38	35	33	31	29	27	26	24	23	22
190	43	40	37	35	33	31	29	27	26	24	23
200	45	42	39	37	34	32	30	29	27	26	24
210	47	44	41	38	36	34	32	30	28	27	26
220	49	46	43	40	38	36	33	32	30	28	27
230	52	48	45	42	39	37	35	33	31	30	28
240	54	50	47	44	41	39	36	34	33	31	29
250	56	52	49	46	43	40	38	36	34	32	30
260	58	54	51	48	45	42	40	37	35	33	32
270	61	56	53	49	46	44	41	39	37	35	33
280	63	59	55	51	48	45	43	40	38	36	34
290	65	61	57	53	50	47	44	42	39	37	35
300	67	63	59	55	51	48	46	43	41	39	37
310	69	65	61	57	53	50	47	44	42	40	38

320	72	67	62	59	55	52	49	46	43	41	39
330	74	69	64	60	57	53	50	47	45	42	40
340	76	71	66	62	58	55	52	49	46	44	41
350	78	73	68	64	60	56	53	50	47	45	43
360	81	75	70	66	62	58	55	52	49	46	44
370	83	77	72	68	64	60	56	53	50	48	45
380	85	79	74	69	65	61	58	55	52	49	46
390	87	82	76	71	67	63	59	56	53	50	47
400	90	84	78	73	69	65	61	57	54	51	49

	Normal	**Overweight**	**Obesity (Class I)**	**Obesity (Class II)**	**Obesity (Class III)**
BMI	**19-24**	**25-29**	**30-34**	**35-39**	**40-45**

BMI, a weight and height ratio, is often used to diagnose obesity by approximating body fat level. The National Institutes of Health and the World Health Organization have determined that a healthy BMI is between 18.6 and 24.9. BMI between 25.0 and 29.9 indicates an individual is overweight and a BMI greater than 30 indicates obesity.

Among children and adolescents, the Centers for Disease Control and Prevention (CDC) use the term "overweight" if the child is ≥ 85th percentile of BMI and "obese" as the group ≥ 95th percentile of BMI.

To calculate BMI: BMI = Weight (kilogram) divided by Height (meter) squared [(w/h^2) or (kg/m^2)]

Note: To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to meters, multiply inches by 0.0254.

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