

EFFECTIVE DATE: 06|01|2026

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OVERVIEW

Surgery for obesity, termed bariatric surgery, is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous different surgical techniques available. These different techniques have heterogenous mechanisms of action, with varying degrees of gastric restriction that creates a small gastric pouch, malabsorption of nutrients, and metabolic changes that result from gastric and intestinal surgery.

This policy only addresses the following:

- **Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) for Medicare Advantage Plans and Commercial Products, AND,**
- **Services that are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products.**

For all other services not addressed in this policy, please refer to the Prior Authorization of Services, Treatments or Procedures policy listed in the Related Policies section below.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S)

SADI-S may be considered medically necessary for adults ages 18 and older and for adolescents ages 13 to <18 when the following medical criteria, I – X, is met:

- I. Must have ONE of the following:
 - a. Class 3 Obesity (BMI ≥ 40 kg/m²); OR,
 - b. Class 1 Obesity (BMI ≥ 30 to 34.9 kg/m²) OR Class 2 Obesity (BMI ≥ 35 to 39.9 kg/m²) AND Type 2 Diabetes; AND,
- II. Failed weight loss by conservative measures, which includes active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise; AND,
- III. No tobacco use by history or tobacco free ≥ 6 weeks prior to surgery; AND,
- IV. No substance or alcohol use disorder by history or substance and alcohol free period ≥ 1 year; AND,
- V. Psychosocial evaluation and clearance by behavioral health (BH) provider; AND,
- VI. Dietary consultation; AND,
- VII. Patient understands surgical procedure and post procedure adherence; AND,
- VIII. No pregnancy or plans for pregnancy within 18 months after surgery; AND,
- IX. The procedure should be performed in appropriately selected individuals, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery.
*For adolescents, greater consideration should be given to psychosocial and informed consent issues.

Revision surgery to address perioperative or late complications of the SADI-S procedure is considered medically necessary. These include but are not limited to, staple line failure, obstruction, stricture, nonabsorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, and band slippage that cannot be corrected with manipulation or adjustment.

Revision of a primary SADI-S procedure that has failed due to dilation of the gastric pouch (documented by upper gastrointestinal examination or endoscopy) is considered medically necessary if the initial procedure was successful in inducing weight loss prior to pouch dilation, and the individual has been compliant with a prescribed nutrition and exercise program.

Revision of a primary SADI-S procedure to address severe gastroesophageal reflux disease refractory to medical treatment is considered medically necessary.

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and is recommended for Commercial Products for Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S). Refer to the Coding and Related Policies sections for details.

Prior authorization is required for Medicare Advantage Plans and is recommended for Commercial Products for CPT code 43847. Refer to the Related Policies section for details.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S)

The SADI-S procedure is considered medically necessary when the medical criteria above is met.

The SADI-S procedure is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when the medical criteria above is not met.

The SADI-S procedure for preadolescent individuals (<age 13) with Obesity is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare Advantage Plans

The bariatric surgery procedures listed below are considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Open adjustable gastric banding
- Open sleeve gastrectomy
- Open and laparoscopic vertical banding gastroplasty
- Gastric balloon for treatment of obesity
- Intestinal bypass

Note: Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all Medicare Advantage Plans policies. Therefore, Medicare Advantage Plans policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by CMS.

Commercial Products

The bariatric surgery procedures listed below are considered not medically necessary for the treatment of morbid obesity in adults who have failed weight loss by conservative measures as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Vertical-banded gastroplasty
- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., >150 cm)

The following endoscopic procedures are not medically necessary as a primary bariatric procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches), as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Insertion of the StomaphyX™ device
- Endoscopic gastroplasty
- Use of an endoscopically placed duodenojejunal sleeve
- Intra-gastric balloons
- Aspiration therapy device
- Esophagogastroduodenoscopy - flexible, transoral, with volume adjustment of intra-gastric bariatric balloon

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable surgery benefits/coverage or for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Bariatric surgery is performed to treat obesity and obesity-related comorbid conditions. The first treatment of obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few individuals with obesity can reduce and control weight through diet and exercise. Most patients find it difficult to comply with these lifestyle modifications on a long-term basis. When conservative measures fail, some patients may consider surgical approaches.

Single Anastomosis Duodenoileal Bypass with Sleeve Gastrectomy (SADI-S) (no specific CPT code):

Since 2007, single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) has been proposed as an alternative to Roux-en-Y gastric bypass (RYGB) in the treatment of obesity. Between Nov 8, 2018, and Sept 29, 2021, a total of 381 patients were randomly assigned (intention-to-treat population) and included in the primary analysis (SADI-S: 190, RYGB: 191). Mean age was 44.4 years (SD 10.64), mean BMI was 46.2 kg/m² (6.40), 265 (70%) were female, and 79 (21%) had a primary sleeve gastrectomy. 43 (12%) of 370 participants were lost to follow-up. At 2 years, the mean %EWL was statistically significantly higher in the SADI-S group compared with the RYGB group (-76.0% [SD 26.7] vs -68.1% [28.7]), confirming the superiority of SADI-S (mean difference -6.72% [95% CI -12.64 to -0.80], p=0.026). The primary outcome was missing for 78 (20%) of 381 participants, with 46 (59%) of 78 participants in the SADI-S group and 32 (41%) of 78 in the RYGB group, p=0.09. The number of serious adverse events related to the surgical technique in the safety population, including all operated patients, was 40 in the SADI-S group including three anastomotic leaks and eight severe diarrhea compared with 35 in the RYGB group including five internal hernia and five severe abdominal pain cases of which two required diagnostic laparoscopy. SADI-S showed superior weight loss compared with RYGB at 2 years, with a similar safety profile. The evidence is sufficient to determine the effects of the technology on health outcomes.

Commercial Products Only

Vertical-banded Gastroplasty (VBG)

Vertical-banded gastroplasty (VBG) was formerly one of the most common gastric restrictive procedures performed in the United States but has now been essentially replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. In order to create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

VBG is a purely restrictive procedure that is largely not performed in the U.S. and has been replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50%. Vertical-banded gastroplasty is not included on the list of endorsed procedures by the American Society for Metabolic and Bariatric Surgery. The evidence is insufficient to determine the effects of the technology on health outcomes.

Gastric Bypass Using a Billroth II Type of Anastomosis (mini-gastric bypass):

Recently, a variant of the gastric bypass, called the mini-gastric bypass, has been popularized. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. This unique aspect of this procedure is not based on its laparoscopic approach but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass. The evidence is insufficient to determine the effects of the technology on health outcomes.

Biliopancreatic Diversion without Duodenal Switch

A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without the DS and gastric bypass. However, BPD without DS leads to complications, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine the effects of the technology on health outcomes.

Long-Limb Gastric Bypass (le, >150 cm) (Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption):

Variations of gastric bypass procedures (CPT code 43847) have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, (e.g. resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

Laparoscopic Gastric Plication (CPT code 43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty is commonly used for this procedure)

Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.

There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication with other bariatric surgery procedures. A 2021 systematic review demonstrated that SG is superior to greater curvature gastric plication with regard to providing effective weight loss through 24 months; statistical significance was not reached at 36 months. The difference in the improvement of comorbidities and risk of major complications or mortality did not reach statistical significance between

groups. One RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. Longer-term follow-up and additional comparative studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Endoscopic Procedures

While bariatric surgery revision or correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices also being evaluated for the endoscopic treatment of GERD (see evidence review 2.01.38). The published data on the use of these devices for treatment of regained weight is limited. Published case series have reported results using a number of devices and procedures (including sclerosing injections) as a treatment for this condition. The largest series (2007) found involved 28 patients treated with a sclerosing agent (sodium morrhuate). Reported trials that used 1 of the suturing devices had fewer than 10 patients. For example, Herron et al (2008) reported on a feasibility study in animals. Thompson et al (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who regained weight and had dilated gastrojejunal anastomoses after RYGB. Nocomparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss.

The StomaphyX device, which has been used in this approach, was cleared by FDA through the 510(k) process. It was determined to be equivalent to the EndoCinch system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. Eid et al (2014) reported on results from a single-center RCT that compared the StomaphyX device with a sham procedure for revisions in patients with prior weight loss after RYGB at least 2 years earlier. Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy endpoint in at least 50% of StomaphyX patients. The primary 12-month efficacy endpoint (reduction in pre-RYGB excess weight by $\geq 15\%$, excess BMI loss, and BMI $< 35 \text{ kg/m}^2$) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group ($p < .01$).

A 2009 survey of American Society for Metabolic and Bariatric Surgery members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. The surgeons were “willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures.” The durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven. A 2013 systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by the American Society for Metabolic and Bariatric Surgery concluded: “The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available.” The evidence is insufficient to determine the effects of the technology on health outcomes.

Intragastric Balloon Devices

Evidence includes random controlled trials (RCTs), a case series with long-term follow-up on 1 of the devices, and systematic reviews on various intragastric balloon (IGB) devices. RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or LT alone. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. A large case series with follow-up up to 5 years has suggested that patients regain weight over time. Additional long-term follow-up data are needed. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, 1 warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016 to 2017 following the IGB procedure. In June 2018, the FDA reported that, since 2016, a total of 12 deaths occurred in patients with liquid-filled intragastric balloons worldwide; 7 of these deaths were in patients in the U.S. Health care providers are encouraged to monitor patients receiving IGBs. The evidence is insufficient to determine the effects of the technology on health outcomes.

Aspiration Therapy Device

The evidence consists of an RCT with 4 years of follow-up and a small case series with up to 2 years of follow-up. The RCT found significantly greater weight loss (measured several ways) with AT compared with LT at 1 year. Forty of 58 patients (69%) achieved at least 10% TWL at 4 years or at time of study withdrawal; however, only 15/111 initial AT patients completed the study through 4 years. In addition to a high degree of missing data, the PATHWAY study noted a potentially high degree of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on AT remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, safety, and nutrition. The evidence is insufficient to determine the effects of the technology on health outcomes.

Esophagogastroduodenoscopy with Bariatric Surgery

Esophagogastroduodenoscopy (EGD) is useful for detecting conditions that may contraindicate bariatric surgery, such as malignancies. It assists in planning the appropriate bariatric procedure by identifying other gastrointestinal conditions like large hiatus hernia and peptic ulcer, which could impact surgery. EGD also detects conditions needing preoperative treatment, such as *Helicobacter pylori* infection. Moreover, endoscopy provides an anatomical assessment of the distal stomach, which becomes inaccessible after specific bariatric procedures.

For individuals with obesity undergoing bariatric surgery who receive esophagogastroduodenoscopy (EGD), the evidence includes systematic reviews of observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Current research has focused on pre-operative utility of EGD. The evidence evaluating the scope of EGD in both intraoperative and postoperative settings is lacking in comparison. Systematic reviews have found that only one-fifth of patients had findings from EGD that either altered their operative management or postponed their bariatric surgery. There is a need for direct comparative homogenous studies assessing whether EGD should be routine before bariatric surgery, and whether it is judicious to expose many patients to an invasive procedure that has potential risk and insufficient evidence of effectiveness. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Bariatric Surgery in Patients with a BMI less than 35 kg/m²:

Limited evidence is available on bariatric surgery in patients with a BMI of less than 35 kg/m². Case series report a high rate of remission of diabetes in undergoing gastric bypass surgery, and this indication was judged to meet the TEC criteria in 2012. However, bariatric surgery for diabetes in patients with a BMI less than 35 is not currently considered standard of care and is not supported in current specialty society guidelines. For patients without diabetes, there is limited evidence on outcomes of surgery and no evidence that health outcomes are improved. As a result, bariatric surgery for patients with a BMI less than 35 is investigational.

Bariatric Surgery for Preadolescent Children

For individuals who are preadolescent children with morbid obesity and receive bariatric surgery, the evidence includes no studies focused solely on this population. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. No studies have been identified that specifically focus on bariatric surgery in preadolescent children. However, a recent prospective noncomparative cohort study has shown significant, long-term (follow-up of 10 years) weight loss and resolution of comorbidities without safety concerns following LSG in children as young as 5 years old. Additionally, a recent analysis of surgical outcomes in preteens versus teens, using data from the American College of Surgeons-Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program database, demonstrated that bariatric surgery in preteens is both safe and effective when performed at specialized centers. Nonetheless, further comparative studies are required to draw definitive conclusions about the net health benefits of bariatric surgery in preadolescent children with obesity. The evidence is insufficient to determine the effects of the technology on health outcomes.

Other Types of Bariatric Surgery Procedures

The evidence on other types of bariatric surgery procedures is insufficient to form conclusions on the impact on health outcomes. For biliopancreatic bypass, the weight loss is similar or greater than gastric bypass but the complications rates, especially for nutritional complications, may also be higher. The evidence base for other types of procedures is insufficient to form conclusions.

Medicare Advantage Plans Only

Based on the Centers for Medicare and Medicaid Services National or Local Coverage Determinations (NCDs or LCDs), the following procedures are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Open adjustable gastric banding
- Open sleeve gastrectomy
- Open and laparoscopic vertical banding gastroplasty
- Gastric balloon for treatment of obesity
- Intestinal bypass

CODING

Medicare Advantage Plans and Commercial Products

Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)

There is no specific code for the SADI-S procedure. Therefore, one of the following CPT codes should be used:

- 43659** Unlisted laparoscopy procedure, stomach
- 43999** Unlisted procedure, stomach
- 44799** Unlisted procedure, small intestine
- 44238** Unlisted laparoscopy procedure, intestine (except rectum)
- 43848** Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure) *Code can be filed for revision only.

The following CPT code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 43290** Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
- 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
- 0813T** Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon (New code 1/01/2024)

There are no specific CPT code(s) for the not covered/not medically necessary indications listed in this policy. Claims should be filed using the unlisted CPT code(s):

- 43659** Unlisted laparoscopy procedure, stomach
- 43999** Unlisted procedure, stomach

The following HCPCS code(s) is not separately reimbursed:

- S2083** Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Commercial Products

When utilized for long-limb gastric bypass procedure (i.e., >150 cm), the following CPT code is not medically necessary for Commercial Products

- 43847** Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption

*When CPT code 43847 is utilized for Roux-en-Y, refer to the Related Policies section.

RELATED POLICIES

PUBLISHED

Provider Update, April 2026
Provider Update, April 2025
Provider Update, June 2024
Provider Update, April 2023
Provider Update, May 2022

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