

Clinical Policy: Bariatric Surgery

Reference Number: PA.CP.MP.37

Effective Date: 01/18

Revision Date: 02/2023

Coding Implications

Revision Log

Description

There are two categories of bariatric surgery: restrictive procedures and malabsorptive procedures. Gastric restrictive procedures include procedures where a small pouch is created in the stomach to restrict the amount of food that can be eaten, resulting in weight loss. The laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG) are examples of restrictive procedures. Malabsorptive procedures bypass portions of the stomach and intestines causing incomplete digestion and absorption of food. Duodenal switch is an example of a malabsorptive procedure. Roux-en-y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD-DS), and biliopancreatic diversion with gastric reduction duodenal switch (BPD-GRDS) are examples of restrictive and malabsorptive procedures.

LAGB devices are currently not FDA approved for adolescents less than 18 years, and are being used less for adolescents in favor of sleeve gastrectomy (SG).

Policy/Criteria

It is the policy of Pennsylvania Health and Wellness® (PHW) that the bariatric surgery procedures LAGB, LSG, and laparoscopic RYGB for adolescents and adults and laparoscopic BPD-DS/BPD-GRDS for adults are **medically necessary** when meeting the following criteria under **section I and II**:

I. Medical history - *Must meet criteria in A and B OR A and C in section I*

A. Age and body mass index (BMI) (meet criteria in 1 or 2)

1. Age ≥ 18 and: Obesity has continued despite previous weight loss attempts, or waiting for attempted weight loss could result in worsening of a health condition and one of the following (a, b, or c):
 - a. BMI ≥ 40 kg/m², or ≥ 35 /m² for South Asian, Southeast Asian, and East Asian adults; and laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-y gastric bypass (RYGB) or laparoscopic biliopancreatic diversion with duodenal switch (BPD-DS)/biliopancreatic diversion with gastric reduction duodenal switch (BPD-GRDS) is requested;
 - b. BMI ≥ 35 and < 40 kg/m², or ≥ 35 /m² for South Asian, Southeast Asian, and East Asian adults; and LAGB, LSG, laparoscopic RYGB or laparoscopic BPD DS/BPD-GRDS is requested;
 - i. LAGB, LSG, laparoscopic RYGB or BPD-DS/BPD-GRDS is requested;
 - ii. One of the following severe obesity-related complications remediable by weight loss:
 - a) Type 2 diabetes mellitus (DM);
 - b) High risk for type 2 DM (insulin resistance, prediabetes, and/or metabolic syndrome);
 - c) Poorly controlled hypertension;
 - d) Dyslipidemia;

- e) Obstructive sleep apnea;
- f) Obesity-hypoventilation syndrome/Pickwickian syndrome;
- g) Nonalcoholic fatty liver disease or nonalcoholic steatohepatitis;
- h) Coronary artery disease;
- i) Gastroesophageal reflux disease;
- j) Asthma;
- k) Venous stasis disease;
- l) Severe urinary incontinence;
- m) Osteoarthritis (hip, knees and/or ankles);
- n) Idiopathic intracranial hypertension;
- c. BMI ≥ 30 and < 35 kg/m², or ≥ 25 to 29.9 kg/m² for South Asian, Southeast Asian, and East Asian adults, and both of the following:
 - i. Type 2 DM with inadequate glycemic control despite optimal lifestyle and medical therapy;
 - ii. LAGB, LSG or laparoscopic RYGB is requested;
- 2. Age < 18 years, LSG or laparoscopic RYGB is requested, and one of the following (a or b):
 - a. BMI ≥ 40 kg/m² or 140% of the 95th percentile (whichever is lower);
 - b. BMI ≥ 35 kg/m² or 120% of the 95th percentile with ≥ 1 severe comorbidity listed below that has significant short-term effects on health and that is uncontrolled with lifestyle or pharmacotherapy management:
 - i. Type 2 DM
 - ii. Obstructive sleep apnea
 - iii. Idiopathic intracranial hypertension
 - iv. Nonalcoholic steatohepatitis
 - v. Blount's disease
 - vi. Slipped capital femoral epiphysis (SCFE)
 - vii. Gastroesophageal reflux disease
 - viii. Hypertension
 - ix. Hyperlipedemia
 - x. Insulin resistance

II. Preoperative evaluation and medical clearance requirements within 6 months of the scheduled surgery includes *all* of the following:

- A. Cardiac evaluation includes an electrocardiogram and *one* of the following categories (1 or 2):
 - 1. LOW CARDIAC RISK candidates, with *none* of the risk factors listed in Section 2 need cardiac clearance by a PCP or cardiologist. If additional testing is needed, it should be conducted by a cardiologist.
 - 2. HIGH CARDIAC RISK candidates need consultation/evaluation, including electrocardiogram, and cardiac clearance from a cardiologist. High risk candidates include those with *any* of the following:
 - a. History of ischemic heart disease
 - b. History of cognitive heart failure
 - c. History of cerebrovascular disease;
 - d. Glomerular filtration rate < 30 mL/min⁻¹;
 - e. High-grade arrhythmia;
 - f. Hemodynamically significant valvular heart disease.

- B. Glycemic control, *one* of the following: (not required if qualifying for surgery based on BMI ≥ 30 kg/m² and < 35 kg/m² with type 2 DM):
1. HbA1c $< 7.0\%$;
 2. HbA1c $\geq 7.0\%$ and $< 8.0\%$ in candidates with advanced microvascular or macrovascular complications, extensive co-morbid conditions, or long-standing diabetes in which the general goal has been difficult to attain despite intensive efforts.

Note: HbA1c $\geq 8.0\%$ requires medical director review of the timing and need for the bariatric procedure.

- C. Pulmonary Evaluation:
1. Screening for obstructive sleep apnea with confirmatory polysomnography if screening tests are positive;
 2. Pulmonary function testing and arterial blood gas analysis for candidates with intrinsic lung disease or disordered sleep patterns;
 3. Specialist consultation for interpretation of any abnormal findings.
- D. Nutritional evaluation, including micronutrient measurements (iron studies, B12, and folic acid, and 25-vitamin D) and treatment of insufficiencies/deficiencies prior to surgery. More extensive testing may be necessary in patients undergoing malabsorptive procedures, based on symptoms and risks.
- E. Nutritional therapy/ counseling
1. Initial comprehensive diet history to include assessment of current pattern of nutrition and exercise and steps to modify problem eating behaviors;
 2. Monthly nutritional counseling until the date of the surgery;
 3. Prescribed exercise program
 4. Must provide documentation that counseling has been conducted regarding the potential for success of weight loss surgery dependent on post-op diet modification (if patient < 18 years of age, consultation must be with adolescent AND parent/guardian).
- F. Age-appropriate psychiatry/psychology consultation including all of the following:
1. An in-person psychological evaluation to assess for major mental health disorders which would contradict surgery and determine ability to comply with post-operative care and guidelines;
 2. If age < 18 years: evaluation must also include assessment of emotional maturity, decisional capacity, family support and family willingness to participate in lifestyle changes.
- G. A serum TSH level if clinical evidence of hypothyroid is present and treatment if found to be hypothyroid.
- H. A fasting lipid panel must be obtained, and treatment initiated for dyslipidemia.

- I. Clinically significant gastrointestinal (GI) symptoms evaluated with upper GI series or endoscopy, if present, and treated prior to bariatric surgery.
- J. Screening for *Helicobacter pylori* with a urea breath test or stool antigen test if signs or symptoms of active peptic ulcer disease are present, with documentation of treatment if positive for *H.pylori*.
- K. Prophylactic treatment for gouty attacks in patients with a history of gout.
- L. If tobacco user, must stop use > 6 weeks prior to surgery.

III. Repeat Surgeries

- A. Repeat bariatric surgery is considered medically necessary for one of the following:
 - 1. To correct complications from a previous bariatric surgery, such as obstruction or strictures (could include conversion surgeries to LSG or RYGB for adults or adolescents; or BPD-DS for adults);
 - 2. Conversion from LAGB to a LSG, RYGB or BPD-DS; or revision of a primary procedure that has failed due to dilation of the gastric pouch when all of the following criteria are met:
 - a. All criteria listed above for the initial bariatric procedure must be met again;
 - b. Previous surgery for morbid obesity was at least 2 years prior to repeat procedure;
 - c. Weight loss from the initial procedure was less than 50% of the member/enrollee's excess body weight at the time of the initial procedure;
 - d. If the conversion is requested due to removal of an eroded laparoscopic adjustable band, at least two months have passed between the band removal and the subsequent bariatric procedure;
 - e. Documented compliance with previously prescribed postoperative nutrition and exercise program;
 - f. Supporting documentation from the provider should also include a clinical explanation of the circumstances as to why the procedure failed.
 - 3. Conversion of SG to RYGB for the treatment of gastro-esophageal reflux disease (GERD) when anti-reflux medical therapy has been tried and failed;
 - 4. Conversion of SG to RYGB or BPD-DS as a bridging procedure for BMI \geq 50 kg/m².

IV. Contraindications for surgical weight loss procedures include:

- A. Medically correctable causes of obesity;
 - B. Current or planned pregnancy within 12 to 18 months of the procedure;
 - C. Severe coagulopathy;
 - D. Current drug or alcohol abuse.
- V. It is the policy of PHW that the current medical literature is inadequate to determine the safety, efficacy and long-term outcomes for the following bariatric surgery procedures:
- A. Distal gastric bypass (very long limb gastric bypass);
 - B. Loop Gastric Bypass ("Mini-Gastric Bypass");
 - C. Laparoscopic re-sleeve gastrectomy (LRSG) performed after the resulting gastric pouch is primarily too large or dilates after the original LSG;

- D. Fobi pouch;
- E. Laparoscopic greater curvature plication (Gastric Imbrication);
- F. LAP-BAND when BMI is 30 to 35 with or without comorbid conditions;
- G. Stomach aspiration therapy (e.g.: AspireAssist);
- H. Endoscopic Suture Revisions post bariatric surgery;
- I. Single anastomosis duodenoileal bypass (SADI);
- J. Gastric plication/ Endoluminal vertical gastroplasty;
- K. Endoscopic gastrointestinal bypass devices (EGIBD (barrier devices));
- L. One-anastomosis gastric bypass;
- M. Endoscopic sleeve gastroplasty;
- N. Transoral endoscopic surgery;
- O. Vagus Nerve Blocking (e.g., Maestro);
- P. Gastric balloon (e.g., ReShape Duo, Orbera intragastric balloon, Obalon Balloon).

VI. It is the policy of PHW that the following bariatric surgery procedures are considered **not medically necessary**, due to potential complications and a lack of positive outcomes:

- A. Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure);
- B. Jejunioleal bypass (jejuno-colic bypass);
- C. Gastric pacing/gastric electrical stimulation;
- D. Gastric wrapping.
- E. For PA Medicaid products, PHW will consider on a case by case basis:
 - a. Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure), although BPD with duodenal switch will be considered on a case by case basis; and
 - b. Vertical Banded Gastroplasty (VBG), (this will also be considered on a case by case basis).

Background

There is sufficient evidence in peer-reviewed medical literature to support the use of the above mentioned bariatric surgeries for the clinically obese individual. Persons with clinically severe obesity are at risk for increased mortality and multiple co-morbidities. These co-morbidities include hypertension, hypertrophic cardiomyopathy, hyperlipidemia, diabetes, cholelithiasis, obstructive sleep apnea, hypoventilation, degenerative arthritis and psychosocial impairments.

The majority of severely obese patients losing weight through non-operative methods alone regain all the weight lost over the next five years. Surgical treatment is the only proven method of achieving long term weight control for the morbidly obese. Eating behaviors after surgery improve dramatically due to the restricted size of the stomach, allowing only small amounts of food to be taken in at a time.

The type of surgical procedure performed should be based on body mass index (BMI), comorbidity profile, treatment goals, surgeon's expertise, patient preference and risk stratification.³⁹ The most commonly performed bariatric procedure in the United States is laparoscopic sleeve gastrectomy (LSG), followed by laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), and Biliopancreatic diversion with duodenal switch (BPD-DS).³⁹ The sleeve gastrectomy (SG) continues to trend upwards due to

lower rates of complications and nutritional deficiencies while maintaining comparable weight loss and metabolic disease outcomes.³⁹ It was the most commonly performed bariatric procedure in the United States and in the world in 2016, and laparoscopic surgery is the preferred methodology.¹⁶

The success of the bariatric surgery relies on the motivation and dedication to the program of the patient. The patient must be able to participate in the treatment and long-term follow up required after surgery. Studies have shown that about 10% of patients may have unsatisfactory weight loss or regain much of the weight they have lost. This may occur due to frequent snacking on high-calorie foods or lack of exercise. Technical problems that may occur include a stretched pouch due to overeating following surgery. Ensuring patients are motivated to lose weight can help prevent some of these issues.

Maximum weight loss usually occurs between 18 and 24 months postoperatively. The average weight loss at five years ranges from 48 to 74% after gastric bypass and 50 to 60% following gastric banding. Several studies have follow-up from 5-15 years with these patients maintaining weight loss of 50-60% of excess weight.

The Lap Band is a small bracelet-like band placed around the top of the stomach to produce a small pouch about the size of a thumb. The size of the outlet is controlled by a circular balloon inside the band that can be inflated and deflated with saline solution through an access port placed under the skin. The more inflated the balloon, the narrower the opening and slower passage of food to the rest of the stomach.

RYGB creates a small stomach pouch, bypassing most of the stomach, duodenum, and upper intestine. Weight loss occurs through restriction of food intake and by decreasing the absorption of food by re-routing food directly from the pouch into the small intestine. With over 25 years of experience with RYGB in adults, the long-term results are well established for weight loss and improvement in comorbidities, and this surgery now accounts for approximately 20% of bariatric procedures in adolescents.³²

BPD-DS is a complex operation that includes removing a large portion of the stomach to promote smaller meal sizes, re-routing of food away from much of the small intestine to prevent partial absorption of food, and re-routing of bile and other digestive juices that impair digestion. The operation bypasses most of the duodenum but leaves a small portion for food and the absorption of some vitamins and minerals. BPD-DS produces significant weight loss but has a greater risk of long-term complications due to decreased absorption of food, vitamins, and minerals.

There are both early and later complications associated with these operations. Early complications can include bleeding, infections, leaks from suture sites and blood clots. Strictures, hernias, and malnutrition, especially when not taking prescribed vitamins and minerals, are all

late complications that can occur in addition to the above mentioned stretched pouch or separated stitches. A repeat surgery is at times required to repair some of these complications.

In an updated position statement on the role of bariatric surgery in class I obesity (BMI of 30.0–34.9 kg/m²), the American Society for Metabolic and Bariatric Surgery (ASMBS) recommends patients with BMI 30 to 35 kg/m² and obesity-related co-morbidities who do not achieve substantial, durable weight loss and co-morbidity improvement with reasonable nonsurgical methods, bariatric surgery should be offered as an option for suitable individuals. In this population, surgical intervention should be considered after failure of nonsurgical treatments. Particularly given the presence of high-quality data in patients with type 2 diabetes, bariatric and metabolic surgery should be strongly considered for patients with BMI 30 to 35 kg/m² and type 2 diabetes. LAGB, LSG, and RYGB have been shown to be well-tolerated and effective treatments for patients with BMI 30 to 35 kg/m². Safety and efficacy of these procedures in low-BMI patients appear to be similar to results in patients with severe obesity. Currently, the best evidence for bariatric and metabolic surgery for patients with class I obesity and co-morbid conditions exists for patients in the 18 to 65 age group.³³

Bariatric Surgery in Adolescents

Weight loss surgery has been performed in small groups of adolescents since the 1970s. Recent data has shown a significant increase in the rate since 2000.³⁴ It is likely that we will continue to see a rise in the rate of adolescents undergoing weight loss surgery with the current pediatric obesity epidemic. Children and adolescents who are severely obese are at risk for the same mortality and co-morbidities as adults.^{1,11} These co-morbidities include hypertension, hypertrophic cardiomyopathy, hyperlipidemia, diabetes, cholelithiasis, obstructive sleep apnea, depression and impaired quality of life. In addition, children in the BMI category ≥ 35 kg/m² will almost always remain obese, and 65% will have a BMI ≥ 40 as an adult.³²

Changes in diet and physical activity must be attempted prior to weight loss surgery in adolescents. A multi-disciplinary, family-based approach should be undertaken to support a staged weight loss plan.³⁵ However, studies suggest that dietary and behavioral interventions rarely result in significant and sustained weight loss in adolescents. This same multi-disciplinary and family approach must be taken when evaluating and planning for bariatric surgery in an adolescent.^{1,11}

The multi-disciplinary team should include an experienced bariatric surgeon, pediatric obesity specialist, nurse, dietician, and pediatric psychologist or psychiatrist. Additional sub-specialists must be readily available for evaluation of co-morbidities. The success of the bariatric surgery does rely on the motivation and dedication to the program of the patient and their family. The patient and family must be willing and able to participate in the treatment and long-term follow up required after surgery. The adolescent must show evidence of mature decision-making with appropriate understanding of the risks and benefits of surgery.

Current existing retrospective data on adolescent weight loss surgery demonstrate that bypass leads to clinically significant and durable decrease in weight loss and BMI. Studies have investigated LABG for the treatment of adolescent obesity, but it has fallen out of favor due to modest weight loss and high rates of revision and weight recidivism. Obesity-related diseases

also improve or resolve after surgically induced weight loss in adolescents. There have not been enough studies to indicate what the long-term weight loss sustainability is in adolescents. Specific predictors of weight regain after bariatric surgery are still unknown.

Recently updated guidelines from the ASMBS on pediatric metabolic and bariatric surgery conclude that metabolic and bariatric surgery (MBS) is a proven, effective treatment for severe obesity disease in adolescents and should be considered standard of care. Treatment of severe obesity in adolescents clearly requires a multidisciplinary approach where MBS should not be consigned to the treatment of last resort. Rather, when considered appropriate and within the clinical best practice guidelines, MBS should be readily offered to adolescents with obesity to effectively reverse co-morbidities and achieve overall wellness. Prior weight loss attempts, Tanner stage, and bone age should not be barriers to definitive treatment.³⁴

Investigational Procedures

Long-limb or Distal Gastric Bypass for Superobesity: A randomized controlled trial (RCT) was completed by Svanevik et al., but only perioperative outcomes have been reported thus far. Svanevik et al. found that in superobese patients with BMI between 50 and 60 kg/m², distal gastric bypass was associated with longer operating time and more severe complications resulting in reoperation than proximal gastric bypass. There is increased risk of adverse nutritional outcomes with longer limb gastric bypass. At this time the long-limb or distal gastric bypass for superobesity is considered investigational, until more long-term studies can be done which reflect better outcomes than existing procedures.

Loop Gastric Bypass (Mini Gastric Bypass, one-anastomosis gastric bypass): The mini gastric bypass has not been universally accepted due to higher rates of alkaline bile reflux and limited long-term research. More long-term research is needed to solidify mini gastric bypass surgery's position as a viable bariatric surgery option.

Re-Sleeve Gastrectomy for Failed Laparoscopic Sleeve Gastrectomy: Iannelli et al. (2012) noted that laparoscopic sleeve gastrectomy (LSG) was rapidly accepted as a valuable bariatric procedure before its effectiveness on weight loss in the long-term is clearly demonstrated.¹³ The authors report a feasibility study including 13 patients undergoing a redo LSG for either progressive weight regain after initial weight loss or insufficient weight loss.¹³ AlSabah et al. describe 24 patients who underwent re-sleeve laparoscopic gastrectomy after an initial LSG. Compared to 12 patients that initially had LSG, which was converted to LRYGB, results were similar, with no significant differences in percent of excess weight loss at one year.² They conclude that larger and longer follow-up studies are needed to verify results.²

Fobi Pouch or Silastic® Ring: The Fobi Pouch bariatric operation for obesity is a combination of stomach reduction and gastric bypass. The Silastic ring is placed around the vertically constructed gastric pouch above the anastomosis between the pouch and the intestinal Roux limb. Possible long term nutritional deficiencies involve fat soluble vitamin deficiencies of Calcium, Iron, B12, and Folic Acid. Patients are placed on nutritional supplements for the rest of their lives, and yearly monitoring is needed. The Fobi Pouch gastric bypass takes about double

the time that a vertical banded gastroplasty operation takes. There is limited research on the outcomes of the Fobi pouch versus other bariatric surgery procedures.

Gastric Imbrication: Fried et al. (2011) completed a 3-year RCT on the safety and efficacy of laparoscopic adjustable gastric banding with and without imbrication sutures. The results of the RCT have demonstrated that SAGB combined with a conservative approach to band adjustments and limited retrogastric dissection is effective and safe with and without imbrication sutures. Not using imbrication sutures results in significant benefits in operative speed with comparable clinical weight loss and intermediate term safety. Sharma et al. conducted a randomized, double blinded trial comparing LSG and laparoscopic gastric imbrication (LGI). They found no differences in weight, age, or BMI preoperatively at 6 months or 3 years between the 2 groups.

The AspireAssist System (AspireAssist) was FDA approved in 2016. It is a weight loss device comprised of an endoscopically placed percutaneous gastrostomy tube and an external device to facilitate drainage of about 30% of each meal consumed. It is meant to be used in conjunction with diet and exercise. In 2017 a 1-year RCT was performed comparing results of 207 patients treated with AspireAssist. The treatment group (n=137) received AspireAssist and lifestyle counseling, and the control group (n=70) received lifestyle counseling alone. Compared to the control group, those who received the AspireAssist and counseling lost more weight. 58.6% of participants in the AspireAssist group, and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight (P<0.001). Additionally, a prospective observational study was conducted on 25 patients, and by the end of the 2-year observation period, only 15 patients were still in the study. They concluded that AspireAssist is an efficient and safe treatment for obesity. There is no research on AspireAssist versus other bariatric surgery procedures.

To enhance weight loss, the following endoscopic procedures have been attempted to promote restriction of the pouch or stoma. These revisions have included: sclerotherapy of the site using 6 to 30 mL of sodium morrhuate injected circumferentially; tissue plication systems to reduce the size of the gastrojejunostomy and the gastric pouch; revisional surgery using a tissue plication device known as StomaPhyX to reduce the pouch size; and application of the endoclip to reduce the size of the gastrojejunal anastomosis. There is a lack of long-term outcomes for endoscopic revisions post RYGB.

The single anastomosis duodenoileal bypass (SADI), also known as single-anastomosis duodenal switch (SADS) and most descriptively, single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), combines restrictive, malabsorptive, and probably hormonal mechanisms for weight loss. The sleeve is created first, and the duodenum is divided after the pylorus. SADI creates an anastomosis between the side of the distal ileum and the end of the sleeve-like gastric pouch/duodenum.¹⁶

The ASMBS endorses SADI-S as an appropriate primary metabolic bariatric procedure.¹⁶ Per the ASMBS, the SADI-S procedure is fundamentally a variant of the duodenal switch (DS) operation, in which the transected duodenum is anastomosed to a loop of ileum, as opposed to the classic DS in which a Roux-en-Y configuration is used. However, the ASMBS- notes the publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged,

particularly with published details on SG size and common channel length. There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for DS patients.^{16,38}

The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) considers SADI-S safe and effective based on short-term data from studies but recommends that long-term follow up be continued and that randomized controlled trials be performed in the near future.³⁸ In a 2021 updated statement, IFSO emphasized that SADI-S can result in maintaining significant weight loss for the obese individual, but nutritional deficiencies are a long-term safety concern, and patients need to be aware of this and encouraged to remain in long-term multidisciplinary care.³⁸

Additionally, the National Institute for Health and Care and Excellence (NICE) encourages further research into SADI-S with a focus on long-term outcomes.³⁹ NICE recommendations also state that there are well-recognized complications when treating morbid obesity with SADI-S, including the possibility of serious metabolic complications.³⁹ NICE states, “this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”³⁹(p2)

Endoluminal vertical gastroplasty/gastric plication is an endoscopic approach for suturing the stomach that offers the potential to perform gastric-restrictive procedures endoluminally. The anterior and posterior walls of the stomach are suctioned together, then held in place by either a stapler or T-fastener device to create a tube of stomach similar to the sleeve gastrectomy.

Endoscopic gastrointestinal bypass devices (EGIBD) are barrier devices deployed to prevent luminal contents from being absorbed in the proximal small intestine (e.g., ValenTX, EndoBarrier). Data are still lacking about the longevity of these endobarriers and their outcomes once the barrier is removed.

Not Medically Necessary Procedures

Biliopancreatic Diversion (BPD) Procedure (Scopinaro procedure): The biliopancreatic diversion (BPD) is a malabsorptive procedure that was introduced as a solution to the high rates of liver failure resulting from bowel exclusion in the jejunioleal bypass. The procedure consists of a partial gastrectomy and gastroileostomy with a long segment of Roux limb and a short common channel, resulting in fat and starch malabsorption. BPD also has a restrictive component. The BPD/DS procedure differs from the BPD in the portion of the stomach that is removed, as well as preservation of the pylorus. This allows more forward flow of the contents of the biliopancreatic limb and avoids the complications of stasis that plagued the jejunioleal bypass (JIB). It is associated with fewer complications than BPD alone. BPD/DS is a complex procedure that is only performed at a few centers in the U.S.

Jejunioleal Bypass or Jejunioleal Intestinal Bypass (JIB): The jejunioleal bypass (also called the intestinal bypass) is performed by dividing the jejunum close to the ligament of Treitz and connecting it a short distance proximal to the ileocecal valve, thereby diverting a long segment of

small bowel, resulting in malabsorption. This procedure is no longer performed due to the high complication rate and frequent need for revisional surgery. Per the American Society for Metabolic & Bariatric Surgery, the JIB is no longer a recommended bariatric surgical procedure. The lessons learned from the JIB include the crucial importance of long-term follow-up and the dangers of a permanent, severe and global malabsorption.

Vertical Banded Gastroplasty (VBG): VBG has fallen out of favor as a restrictive procedure for severe obesity, due largely to the advantages of adjustable gastric banding. VBG requires division of the stomach or intestinal resection, while LAGB does not. In addition, the staples used in VBG may break down and cause weight regain, and VBG requires the use of prosthetic mesh that may increase the incidence of stomach stenosis. Thus, CMS says in their National Coverage Determination for Bariatric Treatment for Morbid Obesity that “VBG procedures are essentially no longer performed.”

Gastric Balloon: Previous endoscopic technologies used to treat obesity endoscopically, such as the gastric balloon, had limited exposure in the U.S. and were removed from the market because of associated complications, such as balloon deflation with migration and resultant small intestinal obstruction.

Gastric Pacing: A number of procedures have been investigated for weight loss surgery but have not been totally accepted by the surgical community. Gastric pacing has been performed in several trials but has not been shown to have any long-term effect and has been abandoned.

Gastric Wrapping: A gastric wrap is minimally invasive surgery and involves folding the stomach in on itself and then the edges are stitched to turn the stomach into a narrow tube, therefore restricting the amount of food that can be consumed. This surgery is new and not widely offered, and there is a paucity of peer-reviewed scientific literature on this procedure.

Coding Implications

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CPT codes that support medical necessity

CPT®* Codes	Description
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

CPT®* Codes	Description
43770*	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
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 restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
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

*Some codes may be used for both medically necessary and not medically necessary indications.

CPT codes that do not support medical necessity

CPT®*	Description
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

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
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed

HCPCS codes that support medical necessity

HCPCS Codes	Description
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

+ Indicates a code requiring an additional character

ICD-10 Codes	Description
E10.10-E13.9	Diabetes Mellitus
E66.01-E66.9	Overweight and obesity
E74.00-E74.9	Other disorders of carbohydrate metabolism
E78.00-E78.9	Disorders of lipoprotein metabolism
G47.00-G47.9	Sleep disorder
G93.2	Benign intracranial hypertension
I10-I15.9	Hypertensive diseases
I20.0-I20.9	Angina pectoris
I25.10-I25.9	Chronic ischemic heart disease
I27.0-I27.9	Other pulmonary heart disease
I42.0-I42.9	Cardiomyopathy
I50.1-I50.9	Heart failure
I67.0-I67.9	Other cerebrovascular diseases
I83.001-I83.93	Varicose veins of lower extremities
K21.00-K21.9	Gastro-esophageal reflux disease
K31.1	Adult hypertrophic pyloric stenosis

ICD-10 Codes	Description
K31.6	Fistula of stomach and duodenum
K56.50-K56.52	Intestinal adhesions [bands] with obstruction (post-procedural) (post-infection)
K68.11- K68.9	Disorders of retroperitoneum
K91.0-K91.89	Intraoperative and postprocedural complications and disorders, not elsewhere classified
M16.0-M16.9	Osteoarthritis of hip
M17.0-M17.9	Osteoarthritis of knee
M19.171- M19.179	Post-traumatic osteoarthritis, ankle and foot
M19.271- M19.279	Secondary osteoarthritis, ankle and foot
M24.00-M24.9	Other specific joint derangements
M25.80 - M25.879	Other specified joint disorders
M50.00-M50.93	Cervical disc disorders
M51.04-M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders
M53.0-M53.9	Other and unspecified dorsopathies, not elsewhere classified
M54.00 - M54.9	Dorsalgia
R06.00-R06.9	Dyspnea
R09.01-R09.89	Other symptoms and signs involving the circulatory and respiratory systems
R26.0-R26.9	Abnormalities of gait and mobility
T81.10X+- T81.9XX+	Complications of procedures, not elsewhere classified
T85.590+- T85.598+	Other mechanical complication of gastrointestinal prosthetic devices, implants and grafts

Reviews, Revisions, and Approvals	Date of Last Revision	Approval Date
Policy Developed	11/17	01/18
Modified Sections I.B. and I.C. requiring a 6 month trial of an exercise/weight loss program, or a medical condition that would supercede the need for such a program, and instead required “previous attempts at weight loss” per the American Society for Metabolic and Bariatric Surgery updated position statement on insurance mandated preoperative weight loss requirements (2016). Removed requirement in II.F. for 6 months of nutritional counseling, while still requiring monthly nutritional counseling until date of surgery. Removed requirement for documented compliance with exercise program in section II.G. Modified II.A.2 removing requirement for specific cardiac testing (stress test, echocardiogram) for high cardiac risk candidates and revised to state they require consultation/evaluation and cardiac clearance from a cardiologist. Replaced cardiac risk qualifiers with that from the reconstructed RCRI, in addition to significant	09/18	

Reviews, Revisions, and Approvals	Date of Last Revision	Approval Date
<p>arrhythmias and valvular heart disease. Reworded hypothyroidism screening criteria to require testing if signs/symptoms of hypothyroidism other than obesity. For H. Pylori testing, removed requirement for screening in high prevalence areas, and required treatment if positive. Modified Section VI.A adding that for Biliopancreatic diversion (BPD) procedure (also known as the Scopinaro procedure), BPD with duodenal switch will be considered on a case by case basis. In Section VI.C added that Vertical Banded Gastroplasty (VBG), will also be considered on a case-by-case basis.</p>		
<p>Revised and reorganized section I.A.1 by BMI and type of procedures considered medically necessary. I.A.1.c, added medically necessary BMI category of > 30- < 35 when criteria is met. Revised I.A.2, a and b, clarifying weight parameters to reflect current terminology. I.A.2.a, removed requirement for comorbidities. I.A.2.c, added comorbidities to this section. Removed II.D, requirement that Tanner stage, or bone age should be completed. III.V, added single anastomosis duodenoileal bypass (SADI); gastric plication/ endoluminal vertical gastroplasty; and endoscopic gastrointestinal bypass devices (barrier devices) as investigational. Updated background. Coding updates</p> <p>In section IV, removed contraindications that are addressed elsewhere in the policy for clarity.</p> <p>Restructured criteria in section I. Medical History. Moved codes 43842 and 43847 to table of codes that do not support medical necessity. Added the following codes to the table that does not support medical necessity: 43647, 43881, 64590.</p> <p>In glycemic control section, changed HbA1C requirement to <7% instead of 6.5-7%. Noted that glycemic control requirement doesn't apply to those who qualify for surgery based on BMI between 30 and 35 with type 2 DM.</p> <p>Changes to section III. Repeat surgeries: Clarified in III.A.1. that repair of complications could include revisions to LSG or RYGB for adults or adolescents, or to BPD-DS for adults. Added to III.A.2 that LSG was an acceptable revision procedure. Edited III.A.2.b. to say that previous surgery was 2 years prior, instead of 3. Added criteria to III.A.2.d. that if the conversion is requested due to removal of an eroded laparoscopic adjustable band, at least two months have passed between the band removal and the subsequent bariatric procedure. Added indication in III.A.3 for conversion of sleeve gastrectomy to Roux-en-Y gastric bypass for the treatment of gastro-esophageal reflux disease (GERD) when anti-reflux medical therapy has been tried</p>	12/2020	2/9/2021

Reviews, Revisions, and Approvals	Date of Last Revision	Approval Date
<p>and failed. Updated description and background information regarding gastric banding in adolescents.</p>		
<p>Added Coronary artery disease as a comorbidity under A.1.b.ii. Edits made to ICD-10 codes; M54-M54.9 now M54.00-M54.9; T81.1X+-T81.9X now T81.10X+ - T81.9XX+; and T85.59 – T85.59 now T85.590+ - T85.598+. References reviewed and updated. Specified that H. Pylori screening should be conducted using a urea breath test or stool antigen test. Added the following ICD-10 code ranges: M17.0-M17.9, M19.171-M19.179 and M19.271-M19.279. 10/1/20 ICD 10 updates: Replaced category K21.0-K21.9 with K21.00- K21.9. Removed “member” from II.C.4. and II.G. Reworded II.G with no impact on criteria. Replaced “member” with “member/ enrollee” in all other instances. Section I: Added BMI criteria for Asian ethnicity to IA.1.a, I.A.1.b and I.A.1.c. Added high risk of T2D to list of severe obesity related complications; added “inadequate glycemic control...” to I.A.1.c.i. Section II: Removed criteria for ECG during cardiac clearance except for high risk; in II.B, removed criteria options of Fasting blood glucose level of ≤ 110 mg/dL and 2-hour postprandial blood glucose concentration of ≤ 140 mg/dL; added note about medical director review if A1C ≥8; removed requirement of chest x-ray and specific criteria for PSG, noting that PSG is warranted if OSA screening is positive in II.C. Pulmonary Evaluation; added examples of nutritional tests to be conducted, and that malabsorptive procedures may require further testing to section II. D; removed requirement of 1 year abstinence of drug & alcohol use and urine drug screen if history of abuse in II.F; added “current drug and alcohol abuse” to list of contraindications; added clinically significant GI symptoms should be evaluated & treated prior to surgery in II.I. In III.A.2.e, removed option for non-compliance with post-operative regimen if completing a multidisciplinary bariatric program. In III.A.2.f., removed option for non-compliance. Reworded V, replacing “investigational” with “current medical literature is inadequate to determine the safety, efficacy and long-term outcomes” and added one-anastomosis gastric bypass; endoscopic sleeve gastropasty; transoral endoscopic surgery; vagus nerve blocking (e.g., Maestro) and gastric balloon (e.g., ReShape Duo, Orbera intragastric balloon, Obalon Balloon) to this list. Updated background. Added the following CPT codes as not supporting medical necessity: 43648, 43882, 64595, 0312T, 0313T, 0314T, 0315T, 0316T and 0317T. References reviewed, updated and reformatted. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.”</p>	<p>12/13/2021</p>	

Reviews, Revisions, and Approvals	Date of Last Revision	Approval Date
<p>Annual review. Description updated with no impact on criteria. Criteria I.A. procedures listed with abbreviations with no impact on criteria. Background updated with no impact on criteria. Corrected ICD10 code I10.0 to I10. Section III: updated abbreviations in III.3 with no clinical significance; added indication for SG to RYGB or BPD-DS DS as a bridging procedure for BMI ≥ 50 kg/m² in III.4. References reviewed and updated.</p>	02/2023	

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