Clinical Policy: Bariatric Surgery
Reference Number: PA.CP.MP.37
Effective Date: 01/18
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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, but an industry-sponsored prospective study is in progress, and numerous retrospective studies of adolescents have been published with favorable results.

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 BMI (meet criteria in 1 or 2)
      1. Age ≥ 18 years and (a or b):
         a. BMI ≥ 40 kg/m², or;
         b. BMI ≥ 35 and < 40 kg/m² with at least one of the following comorbidities:
            i. Type 2 diabetes mellitus (DM)
            ii. Poorly controlled hypertension
            iii. Dyslipidemia
            iv. Obstructive sleep apnea
            v. Obesity-hypoventilation syndrome/Pickwickian syndrome
            vi. Nonalcoholic fatty liver disease or nonalcoholic steatohepatitis
            vii. Gastroesophageal reflux disease (GERD)
            viii. Asthma
            ix. Venous stasis disease
            x. Severe urinary incontinence
            xi. Osteoarthritis (hip, knees and/or ankles)
            xii. Pseudotumor cerebri
      2. Age < 18 years and (a or b):
         a. BMI ≥ 40 kg/m² with at least one comorbidity listed below that is uncontrolled with lifestyle or pharmacotherapy management:
            i. Hypertension
            ii. Dyslipidemias
            iii. Nonalcoholic steatohepatitis
            iv. Venous stasis disease
            v. Significant impairment of activities of daily living
vi. Intertriginous soft-tissue infections  ix. Weight related arthropathies that impair physical activity
vii. Stress urinary incontinence  x. Obesity related psychosocial distress
viii. GERD

b. BMI $\geq 35$ kg/m$^2$ with at least one severe comorbidity listed below that has significant short-term effects on health that is uncontrolled with lifestyle or pharmacotherapy management:
i. Type 2 DM  iii. Pseudotumor cerebri
ii. Obstructive sleep apnea iv. Severe and progressive steatohepatitis

B. Continued obesity despite previous weight loss attempts unless waiting for attempted weight loss could result in worsening of a health condition.

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 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 congestive heart failure
      c. History of cerebrovascular disease;
      d. Glomerular filtration rate $<30$ mL/min$^1$;
      e. High-grade arrhythmia;
      f. Hemodynamically significant valvular disease.

B. Glycemic control should be optimized as evidenced by one of the following:
   1. HbA1c 6.5 - 7.0%;
   2. Fasting blood glucose level of $\leq$ 110 mg/dL;
   3. 2-hour postprandial blood glucose concentration of $\leq$ 140 mg/dL;
   4. HbA1c of 7 - 8% 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.

C. Pulmonary Evaluation:
   1. Chest x-ray;
   2. Screening for obstructive sleep apnea;
   3. Pulmonary function testing and arterial blood gas analysis for candidates with intrinsic lung disease or disordered sleep patterns;
   4. Polysomnography (PSG) for evaluation of obstructive sleep apnea in members who meet at least one of the following criteria for PSG:
      a. Recurrent witnessed apnea during sleep $>10$ seconds in duration;
b. Excessive or inappropriate daytime sleepiness such as falling asleep while driving or eating;
c. Sleepiness that interferes with daily activities not explained by other conditions, such as poor sleep hygiene, medication, drugs, alcohol, psychiatric or psychological disorders;
d. Having an Epworth Sleepiness Scale score > 10;
e. Persistent or frequent disruptive snoring, choking or gasping episodes associated with awakenings;

5. Specialist should be consulted for interpretation of any abnormal findings.

D. Physical maturity (age < 18 years) - completed 95% of predicted adult stature based on bone age or reaching Tanner stage IV.

Bone age is determined by an x-ray of the wrist and hand that gives an estimate of how mature a child’s bones are in years. Using this bone age and other factors, the child’s predicted adult height may be calculated. The percent of adult height achieved is simply the child’s current height divided by the predicted adult height times 100.

E. Nutritional evaluation, including micronutrient measurements and treatment of insufficiencies/deficiencies prior to surgery.

F. 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).

G. 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 history is positive for alcohol or drug abuse, meets both of the following:
      a. Must provide documentation of alcohol and drug abstinence for ≥ 1 year prior to surgery;
      b. Negative urine drug screen within 3 months of request;
   3. If age < 18 years: evaluation must also include assessment of emotional maturity, decisional capacity, family support and family willingness to participate in lifestyle changes.

H. Members at risk for primary hypothyroidism are screened with a TSH level and treated if found to be hypothyroid.
I. A fasting lipid panel must be obtained and treatment initiated for dyslipidemia.

J. Screening for *Helicobacter pylori* 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;
   2. Conversion from LAGB to a 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 3 years prior to repeat procedure;
      c. Weight loss from the initial procedure was less than 50% of the member's excess body weight at the time of the initial procedure;
      d. Documented compliance with previously prescribed postoperative nutrition and exercise program. If non-compliant with postoperative regimen, member will be required to take part in an established multidisciplinary bariatric program to meet all of the initial surgery criteria listed above;
      e. Supporting documentation from the provider should also include a clinical explanation of the circumstances as to why the procedure failed and if initial procedure failure was related to non-compliance with diet then why the requesting provider feels member will be compliant with diet after repeat surgery.

### IV. Contraindications for surgical weight loss procedures include:

A. Medically correctable causes of obesity;
B. An ongoing substance abuse problem within the preceding year;
C. Untreated major depression or psychosis;
D. Uncontrolled and untreated eating disorders (eg, bulimia);
E. A medical, psychiatric, psychosocial, or cognitive condition that prevents adherence to post-operative dietary and medication regimens or impairs decisional capacity;
F. Current or planned pregnancy within 12 to 18 months of the procedure;
G. Severe cardiac disease with prohibitive anesthetic risks;
H. Severe coagulopathy;
I. Inability on the part of the patient or parent (if adolescent) to comprehend the risks and benefits of the surgical procedure.

### V. It is the policy of PHW that the following bariatric surgery procedures are considered investigational, because the medical literature indicates that studies have been inadequate to determine their efficacy and long-term outcomes:

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. AspireAssist;
H. Endoscopic Suture Revisions post bariatric surgery.

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. Jejunoileal bypass (jejuno-colic bypass);
B. Gastric balloon;
C. Gastric pacing;
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 success of the bariatric surgery does rely 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.

Roux-en-Y gastric bypass (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.

Biliopancreatic diversion with duodenal switch (BPD-DS) is a complex operation that includes 1) removing a large portion of the stomach to promote smaller meal sizes, 2) re-routing of food away from much of the small intestine to partially prevent absorption of food, and 3) re-routing of bile and other digestive juices which 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.

*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. 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. 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.

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. 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.
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 both bypass and banding lead to clinically significant and durable decrease in weight loss and BMI. 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.

**Investigational Procedures**

Long-limb or Distal Gastric Bypass for Superobesity: An RCT has recently been 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): 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. The authors report a feasibility study including 13 patients undergoing a redo LSG for either progressive weight regain after initial weight loss of insufficient weight loss. 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. They conclude that larger and longer follow-up studies are needed to verify results.

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 two 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. Thompson et al. (2017) performed a 1-year RCT 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, Noren et al. (2016) conducted a prospective observational study on 25 patients. 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.

Endoscopic Suture Revisions Post Bariatric Surgery: To enhance weight loss, endoscopic procedures to promote restriction of the pouch or stoma include 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 suture revisions post RYGB.

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 jejunoileal 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 jejunoileal 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.
Jejunoileal Bypass or Jejunoileal Intestinal Bypass (JIB): The jejunoileal 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. As this surgery is very new and not widely offered. There is a paucity of peer-reviewed scientific literature on this procedure.

**Coding Implications**
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<th>Description</th>
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<td>CPT® Codes</td>
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<td>R26-R26.9</td>
<td>Abnormalities of gait and mobility</td>
</tr>
<tr>
<td>T85.59-T85.598</td>
<td>Other mechanical complication of gastrointestinal prosthetic devices, implants and grafts</td>
</tr>
<tr>
<td>T81-T81.9</td>
<td>Complications of procedures, not elsewhere classified</td>
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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 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.

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