Medical Coverage Policy | Bariatric Surgery-Not medically necessary procedures

EFFECTIVE DATE: 11|04|14
POLICY LAST UPDATED: 08|03|2015

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 documents the procedures that are considered not medically necessary.

Note: For covered bariatric surgery, please refer to the policy noted in the related policy section.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products
Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Blue CHiP for Medicare
The bariatric surgery procedures listed below are considered not medically necessary because there is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate its effectiveness.

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

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

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 because there is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate its effectiveness.

- 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)

- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Endoscopic procedures (e.g., insertion of the StomaphyX™ device) 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)
- Laparoscopic gastric plicataion

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Bariatric surgery is performed for the treatment of morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m2 or a BMI greater than 35 kg/m2 with associated complications including, but not limited to, diabetes, hypertension, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management. Morbid obesity results in a very high risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectum, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. The majority of 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. A 1991 National Institutes of Health (NIH) Consensus Conference defined surgical candidates as those patients with a BMI* of greater than 40 kg/m2, or greater than 35 kg/m2 in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes. (*See Policy Guidelines on how to calculate BMI.)

Intragastric balloon is unproven as a treatment for obesity. Further studies are needed to determine the safety and efficacy of intragastric balloon as a treatment option for obesity. Adverse effects associated with the intragastric balloon include gastric erosion, reflux, and obstruction (Fernandes, 2007). Currently, the available evidence in the published, peer-reviewed scientific literature is insufficient to establish the safety and efficacy of this procedure.

Vertical-banded gastroplasty 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. 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.

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.

Biliopancreatic bypass (BPB) without duodenal switch:
Biliopancreatic bypass procedure (also known as the Scopinaro procedure) (CPT code 43847- gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

Developed and used extensively in Italy, BPB was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPB consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:

- A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the ear1y postoperative period, both of which limit food intake.
- A 200-cm long "alimentary tract" consists of 200 em of ileum connecting the stomach to a common distal segment.
- A 300- to 400-cm "biliary tract" connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- A 50- to 100-cm "common tract" is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.
- Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to biliopancreatic bypass, including most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, there have been several case reports of liver failure resulting in death or liver transplant.

Long-Limb Gastric Bypass (le, >150 em) (CPT code 43847 - Gastrlc restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption):
Recently, variations of gastric bypass procedures 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 pennits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially 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 ern) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

Two-stage procedure:

The evidence on the comparative efficacy of different bariatric surgery approaches consists largely of low-quality evidence, with a lack of long-term, high-quality RCTs. Compared with gastric bypass, the evidence is sufficient to conclude that laparoscopic adjustable gastric banding is associated with lower short-term complications and lower medium- to long-term weight loss. The evidence is also sufficient to conclude that sleeve gastrectomy has similar or lower short-term complications, with medium- to long-term weight loss that is somewhat less than for gastric bypass. 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.

Laparoscopic Gastric Plication (no specific CPT code):
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.

Endoscopic procedures (e.g., insertion of the StomaphyX™ device) 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):
Some of these procedures use devices that are also being evaluated for endoscopic treatment of gastroesophageal reflux (GERD) (policy No. 2.01.38). The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate). (60) Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron et al. reported on a feasibility study in animals. (61) Thompson et al. reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who had weight regain and dilated gastrojejunal anastomoses after RYGB. (62) No comparative 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 the FDA through the 510(k) process. It was determined be equivalent to the EndoCinch™ system, which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal tract surgery. In summary, the published scientific literature on use of these devices in patients who regain weight after bariatric surgery is very limited. No comparative studies were identified. These endoscopic procedures are considered investigational.

Bariatric Surgery in Patients with a BMI less than 35 kg/m:
Limited evidence is available on bariatric surgery in patients with a body mass index (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.

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.

CODING

BlueCHiP for Medicare and Commercial Products

There are no specific CPT codes for the not medically necessary indications listed in this policy. Claims should be filed using the unlisted CPT code
43659
43999

The code listed below is not medically necessary:
43842
The following code is not separately reimbursed:
S2083: Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

RELATED POLICIES
Preauthorization via Web-Based Tool for Procedures

PUBLISHED
Provider Update, October 2015
Provider Update, January 2015

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