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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 heterogeneous 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

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 CMS (Centers for Medicare and Medicaid Services), 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 as Medicare offers.

Commercial

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).

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, or obstructive sleep apnea. 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 (VBG). VBG is one of the early types of bariatric surgery developed in the 1980s. This is a purely restrictive procedure that has been largely replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there is a high rate of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. The overall rates of revisions and reoperations at up to 10 years may be as high as 50%. Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the U.S.

Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass): The mini-gastric bypass has primarily been advocated by one surgeon. In 2001, Rutledge published his experience with 1,274 patients who underwent the mini-gastric bypass procedure. (23) The mean operating time was 36 minutes, and the mean hospital stay was 1.5 days. Mean excess weight loss was 51% at 6 months, 68% at 12 months, and 77% at 2 years. The overall complication rate reported was 5.2%. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices away from the stomach.

Biliopancreatic Bypass without duodenal switch: The bulk of the experience with biliopancreatic bypass appears to be in Europe, particularly Italy, with fewer case series reported in the U.S. According to Murr and colleagues, (40) BPB has not been widely accepted in the U.S. due to unacceptable serious long-term morbidities. For example, BPB has largely been abandoned at the Mayo Clinic due to the occurrence of steatorrhea, diarrhea, foul-smelling stools, severe bone pain, and the need for a life-long commitment to supplemental vitamins and minerals. In addition, there have been scattered case reports of liver damage,

resulting either in death or liver transplant. (40-42) In addition, Murr et al. hypothesized that the incidence of protein malnutrition may be higher in the U.S. compared to Scopinaro's Italian series, since the North American diet has a higher percentage of fat and lower amounts of carbohydrates.

Gastric Bypass with Long Limb (>150 cm). As discussed in the Description section, the degree of malabsorption associated with long-limb gastric bypass will vary with the length of the alimentary and biliary limbs. These modifications have been developed in an effort to decrease the metabolic side effects associated with BPB. However, there has been limited published evidence on outcomes from this procedure and a large degree of variability in the technical aspects of the procedure among the published literature. Murr et al. reported on 26 patients who underwent a "very very long-limb Roux-en-Y gastric bypass." (39) In comparison to a case series of 11 patients who underwent BPB, the authors reported similar weight loss but decreased metabolic or nutritional abnormalities, attributed in part to the increased length of the common segment, 100 cm compared to 50 cm used in BPB. Sugerman et al. also attribute increasing the length of the common segment to decreasing metabolic morbidities.

The majority of comparisons of weight loss do not reveal significant differences between short- and long-limb gastric bypass. The strongest evidence in this category is from 2 RCTs. (48, 49) In both of these trials, there were no significant differences in weight loss between groups. Brolin et al. (50) compared 3 limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at 1 year, while the other two groups had similar decrease in BMI. MacLean et al. (51) examined morbidly obese and super-obese patients separately and reported a significant difference in favor of the long-limb gastric bypass group. However, this analysis compared the final BMI of the two groups and did not report the actual change in BMI or the initial BMI for each group.

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.

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 to 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

There are no specific CPT codes for some of 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

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