The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required.* Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

**Description**

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.

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.)

Resolution (cure) or improvement of type 2 diabetes mellitus after bariatric surgery and observations that glycemic control may improve immediately after surgery, before a significant amount of weight is lost, have promoted interest in a surgical approach to treatment of type 2 diabetes. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional anti-diabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (1GLP-1), glucose -dependent insulinnotropic peptide (GIP), and peptide YY (PYY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP
acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

The following summarizes the different types of bariatric surgery procedures.

1. **Vertical-Banded Gastroplasty**

   Vertical-banded gastroplasty was formerly one of the most common gastric restrictive procedures performed in this country but has more recently declined in popularity. 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.

2. **Adjustable Gastric Banding**

   Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple. Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe; currently, one such device is approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S., Lap-Band (BioEnterics, Carpinteria, CA). The labeled indications for this device are as follows:

   “The Lap-Band system is indicated for use in weight reduction for severely obese patients with a body mass index (BMI) of at least 40 or a BMI of at least 35 with one or more severe comorbid conditions, or those who are 100 lbs or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives.”

   A second adjustable gastric banding device was approved by the FDA through the Premarket Approval (PMA) process in September 2007, the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are as listed below:

   “The [REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m2, or a BMI of at least 35 kg/m2 with one or more comorbid conditions. The band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.”

3. **Open Gastric Bypass**

   The original gastric bypass surgeries were based on the observation that post-gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunostomy anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load
delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications compared to other gastric restrictive procedures, including iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

Common practice in that the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

4. **Laparoscopic Gastric Bypass**

Same procedure as No. 3, but performed laparoscopically.

5. **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.

6. **Sleeve gastrectomy**

A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a two-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient’s overall medical status, and thus reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

7. **Endoluminal (also called endosurgical, endoscopic, or natural orifice) bariatric procedures**

With these procedures access to the relevant anatomical structures is gained through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce the risks associated with open and laparoscopic interventions. Examples of endoluminal bariatric procedures studies include gastroplasty using a transoral endoscopically guided stapler and placement of devices such as a duodenal-jejunal sleeve and gastric balloon.

8. **Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure)**

Biliopancreatic bypass (BPB) procedure, developed and used extensively in Italy, 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. A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.

B. A 200-cm long “alimentary tract” consists of 200 cm of ileum connecting the stomach to a common distal segment.

C. A 300- to 400-cm “biliary tract” connects the duodenum, jejunum, and remaining ileum to the common distal segment.

D. 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.

E. 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.

9. Biliopancreatic Bypass with Duodenal Switch

The duodenal switch procedure is essentially a variant of the biliopancreatic bypass described above. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the biliopancreatic bypass, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

10. Long-Limb Gastric Bypass (i.e., > 150 cm)

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 permits 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 explicitly describes a short limb (< 150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

11. Laparoscopic Malabsorptive Procedure
Protocol

Bariatric Surgery

Last Review Date: 09/12

Related Protocol:
Gastric Electrical Stimulation

Corporate Medical Guideline

1. Bariatric Surgery in Adults with Morbid Obesity

The following bariatric surgery procedures may be considered medically necessary for the treatment of morbid obesity (see Policy Guidelines for patient selection criteria) in adults who have failed weight loss by conservative measures. Bariatric surgery should be performed in appropriately selected patients, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up post-surgery.

- Open gastric bypass using a Roux-en-Y anastomosis
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis
- Laparoscopic adjustable gastric banding
- Sleeve gastrectomy
- Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro procedure) with duodenal switch

The following bariatric surgery procedures are considered investigational for the treatment of morbid obesity in adults who have failed weight loss by conservative measures:

- 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).

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

Bariatric surgery is considered investigational for patients with a BMI less than 35 kg/m2.

3. Revision Bariatric Surgery

Revision surgery to address perioperative or late complications of a bariatric procedure is considered medically necessary. These include, but are not limited to, staple-line failure, obstruction, stricture, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight.

Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch (documented by upper gastrointestinal examination or endoscopy) is considered medically necessary if the initial procedure was successful in inducing weight loss prior to pouch dilation and the patient has been compliant with a prescribed nutrition and exercise program and the patient still meets criteria (BMI) for bariatric surgery.

4. Bariatric Surgery in Adolescents

Bariatric surgery in adolescents may be considered medically necessary according to the same weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent
issues (see Policy Guidelines). In addition, any devices used for bariatric surgery must be in accordance with the FDA-approved indications for use.

Policy Guideline

*Patient Selection Criteria

Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m² or a BMI greater than 35 kg/m² with at least one clinically significant obesity-related disease such as diabetes mellitus, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

While there is limited evidence on which to assess the long-term impacts of bariatric surgery for patients under the age of 18 years, very severely obese (BMI > 40 kg/m²) adolescents with serious obesity-related comorbidities that are poorly controlled or who have a BMI of 50 kg/m² or greater with less severe comorbidities may be considered for bariatric surgery. The U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND System indicates it is for use only in severely obese adult patients.

To determine whether or not patients have responded to conservative measures for weight reduction, patients must have been active participants in non-surgical weight reduction programs that include frequent, e.g., monthly, documentation of weight, dietary regimen, and exercise. In general, patients must have participated in these programs for at least six months. These conservative attempts must be reviewed by the practitioner seeking approval for the surgical procedure.

Patients with BMI greater than or equal to 50 kg/m² need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m². Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

BMI is calculated by dividing a patient’s weight (in kilograms) by height (in meters) squared.

- To convert pounds to kilograms, multiply pounds by 0.45.
- To convert inches to meters, multiply inches by 0.0254.

Bariatric surgery in children and adolescents

The evidence for bariatric surgery in patients younger than age 18 years consists primarily of studies of adolescents, with a lack of evidence for younger children. Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 with comorbidities to a BMI of 50. The majority of guidelines use weight-based criteria that parallel those for adult patients.

In addition to the weight-based criteria, there is greater emphasis on issues of developmental maturity, psychosocial status, and informed consent for adolescent patients. All guidelines mention these issues, but recommendations are not uniform for addressing them. The following are examples from U.S. guidelines published since 2005 that address issues of maturity and psychosocial status:

The Endocrine Society (1):

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.
Institute for Clinical Systems Improvement (2):

- Recommendations for adolescents apply to “mature adolescents”, which is defined as having reached skeletal maturity.
- Bariatric surgery in the adolescent patient is controversial and should be undertaken on a case-by-case basis in a high-volume bariatric surgery center.

The choice of procedure in adolescents may also differ from adults, but there is a lack of consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (3):

- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices that used for laparoscopic adjustable gastric banding do not have FDA-approval in the U.S. for individuals younger than age 18 years.
- Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions in adolescents because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that biliopancreatic diversion not be done in adolescents.

Medicare Advantage

Individuals who may be considered medically necessary as candidates for gastrointestinal surgery include those with a body mass index (BMI) above 35 who suffer from Type II diabetes or life-threatening cardiopulmonary problems such as severe sleep apnea or obesity-related heart disease and have previously been unsuccessful with medical treatment for obesity.

They should also not have Psychological contraindication and should have a history of failed medical weight loss.

The following procedures are medically necessary when the above criteria have been met:

- Laparoscopic Adjustable Gastric Banding,
- Gastric Bypass Surgery (open and laparoscopic Roux-en-Y),
- Open and laparoscopic Biliopancreatic Diversion with Duodenal Switch, and
- Stand-alone laparoscopic sleeve gastrectomy (LSG).

The operation must be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of management, assessment and follow-up.

The above procedures are covered only when performed at facilities that are:

- Certified by the American College of Surgeons as Level 1 Bariatric Surgery Center, OR
- Certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence.

A list of approved facilities and their approval dates are listed and maintained on the CMS Coverage website at: [http://www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://www.cms.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage).

The following are investigational for Medicare Advantage:

- Open vertical banded gastroplasty,
- Laparoscopic vertical banded gastroplasty,
- Open sleeve gastrectomy,
- Laparoscopic sleeve gastrectomy, not as a stand-alone service,
- Open adjustable gastric banding,
- Gastric balloon, and
• Intestinal bypass.

Revisional surgeries for patients who have had previous surgical treatment for morbid obesity may be **medically necessary** if the patient had previously met the medical necessity indications at the time of the initial surgery.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

“**conservative**” or “**conservative measures**” hyper link wording:

Conservative measures are defined as non-surgical treatment including dietary counseling and some amount of exercise under the supervision of a physician. (If, in the opinion of the physician, the patient’s condition precludes the ability to exercise, this will be taken into consideration under individual medical director review on a case by case basis.) Conservative measures need to be documented as refractory for at least six months. There should be a failure to sustain a 5-10% or more reduction in body weight prior to consultation for bariatric surgery. The patient should be screened carefully by the appropriate mental health professional with regard to their ability to follow up with post op requirements. There should be no evidence of alcohol or drug abuse and it is strongly recommended that the bariatric surgeon urge the patient to remain nicotine free for six weeks prior to surgery.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


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