Medical Policy
Medical and Surgical Management of Obesity including Anorexiant

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- Policy: Medicare
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Policy Number: 379
BCBSA Reference Number: 7.01.47
NCD/LCD:
- National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity (210.12)
- National Coverage Determination (NCD) for Bariatric Surgery for the Treatment of Morbid Obesity (100.1)

Related Policies
- Gastric Electrical Stimulation, #636
- Surgical and Transesophageal Endoscopic Procedures to Treat Gastroesophageal Reflux Disease, #920

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Surgical Management of Obesity Services Preauthorization Request Form
Providers please complete the form. Click here for the Surgical Management of Obesity Services preauthorization request form (#047).

The following bariatric surgeries may be considered MEDICALLY NECESSARY for obesity that has not responded to conservative measures in patients who meet the “Patient Selection Criteria” described in this policy:

BARIATRIC SURGERY IN ADULTS WITH MORBID OBESITY
The following bariatric surgical procedures may be considered MEDICALLY NECESSARY for the treatment of morbid obesity 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.

Patient Selection Criteria
Adults over the age of 18 or who have documented complete bone growth are eligible for obesity surgery if ALL of the following criteria are met:

• The physician has indicated that the patient:
  o Is a well informed and motivated patient with acceptable operative risks, AND
  o Has a strong desire for substantial weight loss, AND
  o Has failed other non-surgical approaches to long-term weight loss, AND
  o Is enrolled in a program which provides pre-op and post-op multidisciplinary evaluation and care including behavioral health, nutrition, and medical management AND

• The patient is morbidly obese with a BMI > 40kg/m².

OR

• The patient has a BMI >35kg/m² and the physician has indicated that the patient has one or more of the following high risk co-morbid conditions:
  o Sleep apnea
  o Pickwickian syndrome
  o Pseudotumor cerebri
  o Obesity related cardiomyopathy
  o Type II Diabetes
  o At least Stage 1 Hypertension based on JNC-VII (SBP >140 and/or DBP >90) after combination pharmacotherapy
  o Coronary artery disease, or
  o Obesity related pulmonary hypertension.

The following bariatric surgical 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 (i.e., >150 cm)
• Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
• Laparoscopic gastric plication
• Single anastomosis duodenoileal bypass with sleeve gastrectomy
• Jejunooileal bypass¹
• Horizontal gastric partitioning¹
• Gastric wrapping¹
• Gastric Electric Stimulation for the treatment of obesity (Gastric pacemaker), and any bariatric surgery performed as a cure for type 2 diabetes mellitus.¹

The following endoscopic procedures are considered INVESTIGATIONAL as a primary bariatric procedure or as a revision procedure, (ie, to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches):

• Insertion of the StomaphyX™ device
• Endoscopic gastroplasty
• Use of an endoscopically placed duodenojejunal sleeve
• Intragastric balloons
• Aspiration therapy device.

BARIATRIC SURGERY IN PATIENTS WITH A BMI LESS THAN 35 KG/M²
Bariatric surgery is considered **NOT MEDICALLY NECESSARY** for patients with a BMI less than 35 kg/m².

**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. Patients must meet the “Patient Selection Criteria” described in this policy. In addition, any devices used for bariatric surgery must be in accordance with the FDA-approved indications.

**BARIATRIC SURGERY IN PREADOLESCENT CHILDREN**

Bariatric surgery is considered **INVESTIGATIONAL** for the treatment of morbid obesity in preadolescent children.

**CONCOMITANT HIATAL HERNIA REPAIR WITH BARIATRIC SURGERY**

Repair of a hiatal hernia at the time of bariatric surgery may be considered **MEDICALLY NECESSARY** for patients who have a preoperatively-diagnosed hiatal hernia with indications for surgical repair.

The Society of American Gastrointestinal and Endoscopic Surgeons have issued evidence-based guidelines for the management of hiatal hernia. Recommendations for indications for repair are as follows:

- Repair of a type I hernia [sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm] in the absence of reflux disease is not necessary (moderate quality evidence, strong recommendation).
- All symptomatic paraesophageal hiatal hernias should be repaired (high quality evidence, strong recommendation), particularly those with acute obstructive symptoms or which have undergone volvulus.
- Routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient’s age and comorbidities (moderate quality evidence, weak recommendation).

Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair, is considered **INVESTIGATIONAL**.

The physician-directed visits and testing aspects of multi-faceted dietary programs such as Health Management Resources may be considered **MEDICALLY NECESSARY**.

Non-physician directed and food replacement or supplement components of multi-faceted dietary programs such as Health Management Resources are considered **NOT MEDICALLY NECESSARY**.

The following medical and pharmaceutical treatments for obesity are considered **NOT MEDICALLY NECESSARY**:

- Multi-faceted dietary programs such as Optifast, and Medifast
- Orlistat ™ (Xenical ®) because it may be purchased over the counter (alli ™) without a prescription
- Anorexiants.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

Medical necessity criteria and coding guidance can be found through the links below.

[National Coverage Determinations (NCDs)]
National Coverage Determination (NCD) for Intensive Behavioral Therapy for Obesity (210.12)
National Coverage Determination (NCD) for Bariatric Surgery for the Treatment of Morbid Obesity (100.1)

Note: To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient
- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Prior authorization is <strong>required</strong> for surgical services.</td>
<td>Prior authorization is <strong>required</strong> for surgical services.</td>
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<tr>
<td>Prior authorization is <strong>not required</strong> for medical services.</td>
<td>Prior authorization is <strong>required</strong> for surgical services.</td>
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<th>Commercial PPO and Indemnity</th>
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Providers please complete the Preauthorization Request Form. [Click here for the Surgical Management of Obesity Services preauthorization request form (#047)](https://example.com)

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
</tr>
<tr>
<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)</td>
</tr>
<tr>
<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)</td>
</tr>
<tr>
<td>43845</td>
<td>Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenileostomy and ileileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)</td>
</tr>
<tr>
<td>43846</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy</td>
</tr>
</tbody>
</table>
Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

**ICD-10 Procedure Codes**

**ICD-10-PCS procedure codes:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0DB64Z3</td>
<td>Excision of Stomach, Percutaneous Endoscopic Approach, Vertical</td>
</tr>
<tr>
<td>0D160ZA</td>
<td>Bypass Stomach to Jejunum, Open Approach</td>
</tr>
<tr>
<td>0D160ZB</td>
<td>Bypass Stomach to Ileum, Open Approach</td>
</tr>
<tr>
<td>0D164ZA</td>
<td>Bypass Stomach to Jejunum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0D164ZB</td>
<td>Bypass Stomach to Ileum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0D190ZB</td>
<td>Bypass Duodenum to Ileum, Open Approach</td>
</tr>
<tr>
<td>0D194ZB</td>
<td>Bypass Duodenum to Ileum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DB60Z3</td>
<td>Excision of Stomach, Open Approach, Vertical</td>
</tr>
<tr>
<td>0DB60ZZ</td>
<td>Excision of Stomach, Open Approach</td>
</tr>
<tr>
<td>0DB80ZZ</td>
<td>Excision of Small Intestine, Open Approach</td>
</tr>
<tr>
<td>0DB90ZZ</td>
<td>Excision of Duodenum, Open Approach</td>
</tr>
<tr>
<td>0DBB0ZZ</td>
<td>Excision of Ileum, Open Approach</td>
</tr>
<tr>
<td>0DM60ZZ</td>
<td>Reattachment of Stomach, Open Approach</td>
</tr>
<tr>
<td>0DM64ZZ</td>
<td>Reattachment of Stomach, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DM80ZZ</td>
<td>Reattachment of Small Intestine, Open Approach</td>
</tr>
<tr>
<td>0DM84ZZ</td>
<td>Reattachment of Small Intestine, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DM90ZZ</td>
<td>Reattachment of Duodenum, Open Approach</td>
</tr>
<tr>
<td>0DM94ZZ</td>
<td>Reattachment of Duodenum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DMA0ZZ</td>
<td>Reattachment of Jejunum, Open Approach</td>
</tr>
<tr>
<td>0DMA4ZZ</td>
<td>Reattachment of Jejunum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DMB0ZZ</td>
<td>Reattachment of Ileum, Open Approach</td>
</tr>
<tr>
<td>0DMB4ZZ</td>
<td>Reattachment of Ileum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DQ60ZZ</td>
<td>Repair Stomach, Open Approach</td>
</tr>
<tr>
<td>0DQ64ZZ</td>
<td>Repair Stomach, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DQ80ZZ</td>
<td>Repair Small Intestine, Open Approach</td>
</tr>
<tr>
<td>0DQ84ZZ</td>
<td>Repair Small Intestine, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DQ90ZZ</td>
<td>Repair Duodenum, Open Approach</td>
</tr>
<tr>
<td>0DQ94ZZ</td>
<td>Repair Duodenum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DQA0ZZ</td>
<td>Repair Jejunum, Open Approach</td>
</tr>
<tr>
<td>0DQA4ZZ</td>
<td>Repair Jejunum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DQB0ZZ</td>
<td>Repair Ileum, Open Approach</td>
</tr>
<tr>
<td>0DQB4ZZ</td>
<td>Repair Ileum, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td>0DV60CZ</td>
<td>Restriction of Stomach with Extraluminal Device, Open Approach</td>
</tr>
<tr>
<td>0DV64CZ</td>
<td>Restriction of Stomach with Extraluminal Device, Percutaneous Endoscopic Approach</td>
</tr>
</tbody>
</table>

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or ICD Procedure Codes above if medical necessity criteria are met:

**ICD-10 Diagnosis Codes**

**ICD-10-CM Diagnosis codes:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E66.01</td>
<td>Morbid (severe) obesity due to excess calories</td>
</tr>
<tr>
<td>Z68.35</td>
<td>Body mass index (BMI) 35.0-35.9, adult</td>
</tr>
</tbody>
</table>
The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty</td>
</tr>
<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty</td>
</tr>
<tr>
<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption</td>
</tr>
</tbody>
</table>

Description

Bariatric Surgery

Bariatric surgery is performed to treat 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, rectal, prostate; for women: breast, uterine, ovarian), and a shortened lifespan. A morbidly obese man at age 20 can expect to live 13 fewer years 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. Most 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 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.”

Resolution (cure) or improvement of type 2 diabetes 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 the treatment of type 2 diabetes. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, eg, glucagon-like peptide-1, glucose-dependent insulinotropic peptide, and peptide YY, are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-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. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide YY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

**Types of Bariatric Surgery Procedures**
The following summarizes the most common bariatric surgery procedures.

**Open Gastric Bypass**
The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure (CPT code 43846) involves both a restrictive and a malabsorptive component, with the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (ie, a gastrojejunal 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." Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 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.

Note: In 2005, CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared with the previous 100 cm. This change reflects the common practice in which the alimentary (ie, 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.

**Laparoscopic Gastric Bypass**
CPT code 43644 was introduced in 2005 and described the same procedure as open gastric bypass (CPT code 43846) but performed laparoscopically.

**Adjustable Gastric Banding**
Adjustable gastric banding (CPT code 43770) involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir 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. Two banding devices are approved by the Food and Drug Administration (FDA) for marketing in the United States. The first to receive the FDA approval was the LAP-BAND (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). 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 lb 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."
In 2011, the FDA-labeled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m\(^2\) with at least 1 obesity-related comorbid condition. The second adjustable gastric banding device approved by the FDA through the premarket approval process is the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are:

“Th[e REALIZE] device is indicated for weight reduction for morbidly obese patients and is indicated for individuals with a Body Mass Index of at least 40 kg/m\(^2\), or a BMI of at least 35 kg/m\(^2\) 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.”

**Sleeve Gastrectomy**

A sleeve gastrectomy (SG; CPT code 43775) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] 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 the stomach into intestines) 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 SG as the first in a 2-stage procedure for very high-risk patients. Weight loss following SG may improve a patient’s overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (eg, BPD).

**Biliopancreatic Diversion**

The BPD procedure (also known as the Scopinaro procedure; CPT code 43847), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD 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 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, creating 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 BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. Also, several case reports have noted liver failure resulting in death or liver transplant.

**BPD With Duodenal Switch**

CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a SG 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 BPD, 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 duodeno-ileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The SG 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 BPD, ie, producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

**Vertical-Banded Gastroplasty**
Vertical-banded gastroplasty (VBG; CPT code 43842) was formerly one of the most common gastric restrictive procedures performed in the United States but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. In order to create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of the 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 2 requiring reoperation. Dilation of the stoma is a common reason for weight regain. VBG may be performed using an open or laparoscopic approach.

**Long-Limb Gastric Bypass (ie, >150 cm)**
Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures (CPT code 43847), 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 (eg, resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is 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 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

**Laparoscopic Malabsorptive Procedure**
CPT code 43645 was introduced in 2005, to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.

**Weight Loss Outcomes**
There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are the percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. EBW is defined as actual weight minus “ideal weight” and “ideal weight” and is based on 1983 Metropolitan Life Insurance height-weight tables for “medium frame.”

These 2 reporting methods are generally preferred over the absolute amount of weight loss because they reflect the ultimate goal of surgery: to reduce weight to a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 1 summarizes the variations in reporting weight loss outcomes.

<table>
<thead>
<tr>
<th>Table 1. Weight Loss Outcomes</th>
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<td><strong>Outcome Measure</strong></td>
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9
**Decrease in weight**

<table>
<thead>
<tr>
<th>Decrease in weight</th>
<th>Absolute difference in weight pre- and posttreatment</th>
<th>Unclear relation to outcomes, especially in morbidly obese</th>
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**Decrease in BMI**

<table>
<thead>
<tr>
<th>Decrease in BMI</th>
<th>Absolute difference in BMI pre- and posttreatment</th>
<th>May be clinically significant if change in BMI clearly leads to change in risk category</th>
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**Percent EBW loss**

<table>
<thead>
<tr>
<th>Percent EBW loss</th>
<th>Amount of weight loss divided by EBW</th>
<th>Has anchor to help frame clinical significance; unclear threshold for clinical significance</th>
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</table>

**Percent patients losing >50% of EBW**

<table>
<thead>
<tr>
<th>Percent patients losing &gt;50% of EBW</th>
<th>No. patients losing &gt;50% EBW divided by total patients</th>
<th>Additional advantage of framing on per patient basis. Threshold for significance (&gt;50%) arbitrary.</th>
</tr>
</thead>
</table>

**Percent ideal body weight**

<table>
<thead>
<tr>
<th>Percent ideal body weight</th>
<th>Final weight divided by ideal body weight</th>
<th>Has anchor to help frame clinical significance; unclear threshold for clinical significance</th>
</tr>
</thead>
</table>

BMI: body mass index; EBW: excess body weight.

**Durability of Weight Loss**

Weight change (ie, gain or loss) at yearly intervals is often reported. Weight loss at 1 year is considered the minimum length of time for evaluating these procedures; weight loss at 3 to 5 years is considered an intermediate time period for evaluating weight loss; and weight loss at 5 to 10 years or more is considered to represent long-term weight loss following bariatric surgery.

**Short-Term Complications (Operative and Perioperative Complications <30 Days)**

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (eg, pneumonia, myocardial infarction).

**Reoperation Rate**

Reoperation may be required to “take down” or revise the original procedure. Reoperation may be particularly common in VBG due to pouch dilation.

**Long-Term Complications (Metabolic Adverse Events, Nutritional Deficiencies)**

Metabolic adverse events are of particular concern in malabsorptive procedures. Other long-term complications include anastomotic ulcers, esophagitis, and procedure-specific complications such as band erosion or migration for gastric banding surgeries.

**Improved Health Outcomes in Terms of Weight-Related Comorbidities**

Aside from psychosocial concerns, which may be considerable, 1 motivation for bariatric surgery is to decrease the incidence of complications of obesity, such as diabetes, cardiovascular risk factors (ie, increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

**Summary**

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these techniques have heterogeneous mechanisms of action, the result is a smaller gastric pouch that leads to restricted eating. However, these surgeries may lead to malabsorption of nutrients or eventually to metabolic changes.

**Adults with Morbid Obesity**

For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes. A TEC Assessment found similar weight loss with open and
laparoscopic gastric bypass. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass. There is less weight loss with LAGB than with gastric bypass, but LAGB is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies (evaluating SG alone and comparing SG with gastric bypass), as well as systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG compared with gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive biliopancreatic diversion (BPD) with duodenal switch (DS), the evidence includes nonrandomized comparative studies, observational studies, and a systematic review. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Nonrandomized comparative studies have found significantly higher weight loss after BPD with DS compared with gastric bypass at 1 year. A large case series found sustained weight loss after 7 years. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive BPD without DS, the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG, and these studies found that weight loss was similar after BPD without a DS or gastric bypass. However, concerns have been raised about complications associated with BPD without DS, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG, and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes a small RCT and observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months postsurgery. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes 2 RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2014 systematic review only identified a small nonrandomized comparative study comparing laparoscopic gastric plication with other bariatric surgery procedures. Since the systematic review, 2 RCTs have been published, 1 comparing laparoscopic gastric plication with a sham procedure and another comparing laparoscopic gastric plication with SG. Laparoscopic gastric plication was more effective than sham at 1-year follow-up and equally effective as SG at 2-year follow-up. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive single anastomosis duodeno-ileal bypass with SG (SADI-S), the evidence includes observational studies. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. No controlled trials have evaluated SADI-S. There are a few case series, the largest of which had fewer than 100 patients. A retrospective chart review of patients receiving gastric bypass, BPD, and SADI-S, reported that among patients without diabetes, SADI-S was more effective in weight loss and cholesterol outcomes than gastric bypass. Among patients with diabetes, SADI-S and BDP had higher remission rates than gastric bypass. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of SADI-S. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive duodenojejunal sleeve, the evidence includes RCTs and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of duodenojejunal sleeves included 5 RCTs and found significantly greater short-term weight loss (12-24 weeks) with the sleeves compared with medical therapy. There was no significant difference in symptoms associated with diabetes. All RCTs were small and judged by systematic reviewers to be at high-risk of bias. High-quality comparative studies are needed to permit conclusions on the safety and efficacy of the procedure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive IGB devices, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. RCTs assessing the 2 IGB devices approved by the Food and Drug Administration (FDA) have found significantly greater weight loss with IGB than with sham treatment or lifestyle therapy alone after 6 months (maximum length of device use). Some adverse events were reported, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional 6 months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long-term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how 6 months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes an RCT and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at 1 year. Forty of 58 patients (69%) achieved at least 10% total weight loss at 4 years or at time of study withdrawal; however, only 15/111 initial aspiration therapy patients completed the study through 4 years. In addition to a high degree of missing data, the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study noted a potentially large number of adverse events related to A-tube malfunction, an element of the therapy which
is expected to require replacement within approximately 3.5 years post gastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. One small case series reported on 15 patients at 2 years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism, safety, nutrition, and long-term durability of treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Revision Bariatric Surgery**

For individuals who are adults with morbid obesity and failed bariatric surgery who receive revision bariatric surgery, the evidence includes case series and registry data. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Adults with Type 2 Diabetes**

For individuals who are diabetic and not morbidly obese who receive gastric bypass, SG, BPD, or LAGB, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for type 2 diabetes in obese patients, including those with a body mass index (BMI) between 30 and 34.9 kg/m². The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 3 years of follow-up; 1 RCT that included patients with BMI between 30 and 34.9 kg/m² had 5-year follow-up data. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

There are clinical concerns about durability and long-term outcomes at 5 to 10 years as well as potential variation in observed outcomes in community practice versus clinical trials. As a result, bariatric surgery for individuals who are diabetic and not morbidly obese is considered not medically necessary.

**Nondiabetic and Nonobese Adults**

For individuals who are not diabetic and not morbidly obese who receive any bariatric surgery procedure, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. A few small RCTs and case series have reported a loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Adolescent Children with Morbid Obesity Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy**

For individuals who are adolescent children with morbid obesity who receive gastric bypass, or LAGB, or SG, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents are similar to that for adults. Most experts and clinical practice guidelines have
recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m2. Also, greater consideration should be placed on the patient developmental stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Bariatric Surgery Other Than Gastric Bypass, Laparoscopic Adjustable Gastric Banding, or Sleeve Gastrectomy**

For individuals who are adolescent children with morbid obesity who receive bariatric surgery other than gastric bypass, or LAGB, or SG, the evidence includes systematic reviews and a cohort study. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Studies using bariatric surgery other than gastric bypass, LAGB, or SG, have small sample sizes. Results from a meta-analysis including patients using other procedures have shown significant improvements in BMI reduction, fasting blood insulin, and total cholesterol, although the estimates have wide confidence intervals, limiting interpretation. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Preadolescent Children with Morbid Obesity**

For individuals who are preadolescent children with morbid obesity who receive bariatric surgery, the evidence includes no studies focused on this population. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old, but findings were not reported separately for preadolescent children. Moreover, clinical practice guidelines have recommended against bariatric surgery for preadolescent children. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Hiatal Hernia Repair with Bariatric Surgery**

For individuals with morbid obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes cohort studies and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

**Policy History**

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<td>3/2016</td>
<td>Policy statement removed: Medical management of obesity may be medically necessary including laboratory services and other diagnostic tests prescribed by the physician specialist, and nutritional counseling in accordance with the member’s subscriber certificate. Clarified coding information. Effective 3/1/2016.</td>
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<td>Date</td>
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<td>1/2016</td>
<td>Prior authorization information clarified. 1/1/2016.</td>
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<td>10/2015</td>
<td>Clarified coding information.</td>
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<td>10/2014</td>
<td>Language on Health Management Resources clarified.</td>
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<tr>
<td>9/2014</td>
<td>Clarified coding information. Surgical Management of Obesity Services Preauthorization Request Form transferred to #047.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<td>1/2012</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
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<tr>
<td>3/2010</td>
<td>Review of Medicare NCD. Changes to policy statement.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
Medical Technology Assessment Guidelines

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123. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Laparoscopic adjustable gastric banding in patients with body mass index less than 35 kg/m². TEC Assessments. 2012;Volume 27:Tab 3.


Endnotes

1 Based on expert opinion