MASSACHUSETTS

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Medical Policy

Medical and Surgical Management of Obesity including Anorexiants

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BCBSA Reference Number: 7.01.47
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Related Policies

- Gastric Electrical Stimulation, #636

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:
  - Is a well informed and motivated patient with acceptable operative risks, AND
  - Has a strong desire for substantial weight loss, AND
  - Has failed other non-surgical approaches to long-term weight loss, AND
  - 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:
  - Sleep apnea
  - Pickwickian syndrome
  - Pseudotumor cerebri
  - Obesity related cardiomyopathy
  - Type II Diabetes
  - At least Stage 1 Hypertension based on JNC-VII (SBP >140 and/or DBP >90) after combination pharmacotherapy
  - Coronary artery disease, or
  - 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
- Jejunoileal bypass[1]
- Horizontal gastric partitioning[1]
- Gastric wrapping[1]
- 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**.[1]

The following medical and pharmaceutical treatments for obesity are considered **NOT MEDICALLY NECESSARY**: [1]

- 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 Blue[SM] and Medicare PPO Blue[SM] Members

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

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)

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products.

See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

	Outpatient
Commercial Managed Care (HMO and POS)	Yes for surgical services. No for medical services.
Commercial PPO and Indemnity	No for surgical services. No for medical services.
Medicare HMO Blue℠	Yes for surgical services. No for medical services.
Medicare PPO Blue℠	No for surgical services. No for medical services.

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

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

CPT codes:	**Code Description**
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43848	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:	**Code Description**
0DB64Z3	Excision of Stomach, Percutaneous Endoscopic Approach, Vertical
0D160ZA	Bypass Stomach to Jejunum, Open Approach
0D160ZB	Bypass Stomach to Ileum, Open Approach
0D164ZA	Bypass Stomach to Jejunum, Percutaneous Endoscopic Approach
0D164ZB	Bypass Stomach to Ileum, Percutaneous Endoscopic Approach
0D190ZB	Bypass Duodenum to Ileum, Open Approach

0D194ZB	Bypass Duodenum to Ileum, Percutaneous Endoscopic Approach
0DB60Z3	Excision of Stomach, Open Approach, Vertical
0DB60ZZ	Excision of Stomach, Open Approach
0DB80ZZ	Excision of Small Intestine, Open Approach
0DB90ZZ	Excision of Duodenum, Open Approach
0DBB0ZZ	Excision of Ileum, Open Approach
0DM60ZZ	Reattachment of Stomach, Open Approach
0DM64ZZ	Reattachment of Stomach, Percutaneous Endoscopic Approach
0DM80ZZ	Reattachment of Small Intestine, Open Approach
0DM84ZZ	Reattachment of Small Intestine, Percutaneous Endoscopic Approach
0DM90ZZ	Reattachment of Duodenum, Open Approach
0DM94ZZ	Reattachment of Duodenum, Percutaneous Endoscopic Approach
0DMA0ZZ	Reattachment of Jejunum, Open Approach
0DMA4ZZ	Reattachment of Jejunum, Percutaneous Endoscopic Approach
0DMB0ZZ	Reattachment of Ileum, Open Approach
0DMB4ZZ	Reattachment of Ileum, Percutaneous Endoscopic Approach
0DQ60ZZ	Repair Stomach, Open Approach
0DQ64ZZ	Repair Stomach, Percutaneous Endoscopic Approach
0DQ80ZZ	Repair Small Intestine, Open Approach
0DQ84ZZ	Repair Small Intestine, Percutaneous Endoscopic Approach
0DQ90ZZ	Repair Duodenum, Open Approach
0DQ94ZZ	Repair Duodenum, Percutaneous Endoscopic Approach
0DQA0ZZ	Repair Jejunum, Open Approach
0DQA4ZZ	Repair Jejunum, Percutaneous Endoscopic Approach
0DQB0ZZ	Repair Ileum, Open Approach
0DQB4ZZ	Repair Ileum, Percutaneous Endoscopic Approach
0DV60CZ	Restriction of Stomach with Extraluminal Device, Open Approach
0DV64CZ	Restriction of Stomach with Extraluminal Device, Percutaneous Endoscopic Approach

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

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	**Code Description**
E66.01	Morbid (severe) obesity due to excess calories
Z68.35	Body mass index (BMI) 35.0-35.9, adult
Z68.36	Body mass index (BMI) 36.0-36.9, adult
Z68.37	Body mass index (BMI) 37.0-37.9, adult
Z68.38	Body mass index (BMI) 38.0-38.9, adult
Z68.39	Body mass index (BMI) 39.0-39.9, adult
Z68.41	Body mass index (BMI) 40.0-44.9, adult
Z68.42	Body mass index (BMI) 45.0-49.9, adult
Z68.43	Body mass index (BMI) 50-59.9 , adult
Z68.44	Body mass index (BMI) 60.0-69.9, adult
Z68.45	Body mass index (BMI) 70 or greater, adult

The following CPT codes are considered investigational for <u>Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:</u>

CPT Codes

CPT codes:	Code Description
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption

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 life span. 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.”[1]

Resolution (cure) or improvement of type 2 diabetes (T2D) 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 T2D. 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 (1GLP-1), glucose dependent insulin tropic 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.

Types of Bariatric Surgery Procedures

The following summarizes the most common types of 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 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, the 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 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, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m2 with at least 1 obesity-related comorbid condition.

The second adjustable gastric banding device approved by FDA through the premarket approval process is the REALIZE® model (Ethicon Endo-Surgery, Cincinnati, OH). Labeled indications for this device are:

"The [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/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."

Sleeve Gastrectomy
A sleeve gastrectomy (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 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 sleeve gastrectomy as the first in a 2-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 (eg, BPD).

Biliopancreatic Bypass 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 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, ie, 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 BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, 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 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 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 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 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. 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 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 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 methods are generally preferred over the absolute amount of weight loss, because they reflect the ultimate goal of surgery: to reduce weight into 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 1. Weight Loss Outcomes

Outcomes **Outcome Measure**	**Definition**	**Clinical Significance**
Decrease in weight	Absolute difference in weight preand posttreatment	Unclear relation to outcomes, especially in morbidly obese
Decrease in BMI	Absolute difference in BMI preand posttreatment	May be clinically significant if change in BMIclearly leads to change in risk category

Percent EBW loss	Amount of weight loss divided by EBW	Has anchor to help frame clinical significance; unclear threshold for clinical significance
Percent patients losing >50% of EBW	No. patients losing >50% EBW divided by total patients	Additional advantage of framing on per patient basis. Threshold for significance (>50%) arbitrary.
Percent ideal body weight	Final weight divided by ideal body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance

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 either “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 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, 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 overall survival, 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, but the procedure 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, and systematic reviews. Relevant outcomes are overall survival, 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 or gastric bypass. Long-term weight loss was greater after gastric bypass but SG is associated with fewer AEs. 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, the evidence includes observational studies and a systematic review. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Non-randomized comparative studies found significantly higher weight loss after BPD with duodenal switch 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 duodenal switch, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without duodenal switch or gastric bypass. However, there are concerns about complications associated with BPD without duodenal switch, 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, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, 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 observational studies and systematic reviews. Relevant outcomes are overall survival, 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. 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 overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. A 2014 systematic review identified only 1 small comparative

study (unrandomized) comparing laparoscopic gastric plication with other bariatric surgery procedures. Since the systematic review, 2 RCTs have been published, one 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 duodenoileal bypass with SG (SADI-S), the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, 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 overall survival, 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 overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. RCTs on the 2 IGB devices approved by the Food and Drug Administration have found significantly better weight loss with IGB compared with sham treatment or lifestyle therapy alone after 6 months (maximum length of device use). There are some adverse events, 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.

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 overall survival, 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 overall survival, 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 certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a 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 HbA1c 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 of the 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 outcome at 5-10 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 Non-obese 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 overall survival, 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 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, LAGB, or SG
For individuals who are adolescent children with morbid obesity who receive gastric bypass or LAGB, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, 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, 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 is 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. In addition, greater consideration should be placed on patient development 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, LAGB, or SG
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 overall survival, 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 overall survival, 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 overall survival, 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

Date	Action
3/2018	New references added from BCBSA National medical policy. Background and summary clarified.
9/2017	BCBSA National medical policy review. Investigational statement on endoscopic procedures rewritten for clarity; aspiration therapy device added to the investigational statement. Investigational statement on bariatric surgery in preadolescent children added. Effective 9/1/2017.
7/2016	BCBSA National medical policy review. Single anastomosis duodenoileal bypass with sleeve gastrectomy added to investigational statement. Effective 7/1/2016.
3/2016	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.
1/2016	Prior authorization information clarified. 1/1/2016.
10/2015	Clarified coding information.
6/2015	Medically necessary statements on revision bariatric surgery retired. Coding information clarified. Effective 6/1/2015.
3/2015	BCBSA National medical policy review. New medically necessary and investigational indications described. Statement on bariatric surgery in patients with BMI <35 changed from investigational to not medically necessary. Effective 3/1/2015.
10/2014	Language on Health Management Resources clarified.
9/2014	Clarified coding information. Surgical Management of Obesity Services Preauthorization Request Form transferred to #047.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
3/2014	BCBSA National medical policy review. Language added to policy statement on revision surgery to include complications of laparoscopic adjustable gastric banding. Effective 3/1/2014.
11/2013	Removed facility certification requirement for coverage of covered bariatric surgery procedures for Medicare Advantage. Effective 9/24/2013.

4/2013	Added coverage for stand-alone laparoscopic sleeve gastrectomy for Medicare HMO Blue and Medicare PPO Blue members. Retroactive to June 27, 2012.
4/2013	BCBSA National medical policy review. Changes to policy statement. Effective 4/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	BCBSA National medical policy review. Changes to policy statements.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
11/2010	BCBSA National medical policy review. Changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
3/2010	Review of Medicare NCD. Changes to policy statement.
11/2009	BCBSA National medical policy review. Changes to policy statements.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ Transplantation. No changes to policy statements.
9/2008	BCBSA National medical policy review. Changes to policy statements.
4/2008	BCBSA National medical policy review. Changes to policy statements.
2/2008	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
5/2007	BCBSA National medical policy review. Changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
5/1996	New policy, effective 5/1996, describing covered and non-covered indications.

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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Endnotes

[1] Based on expert opinion