MEDICAL POLICY

POLICY TITLE	BARIATRIC SURGERY
POLICY NUMBER	MP-1.015

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I. POLICY

Bariatric Surgery for Morbid Obesity

The following bariatric procedures may be considered **medically necessary** when performed by surgeons who are competent in specific techniques and when the surgery is part of a comprehensive bariatric surgery program:

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

The above bariatric procedures may be considered to be **medically necessary** for the treatment of morbid obesity adults in individuals who have met **ALL** of the following:

1. Patient is at least 18 years of age (see adolescent criteria below); **and**
2. The requesting physician documents that the patient affirms they have not used tobacco products within the previous six (6) months; **and**
3. Patient is not currently pregnant and has been counseled to avoid pregnancy for a minimum of one (1) year following bariatric surgery; **and**
4. Patient has been unable to achieve sustainable weight loss over the past two years despite active use of conservative measures:
   a. Sustainable weight loss will be defined as achieving a Body Mass Index (BMI) of less than 35; **and**
   b. An attestation from the member's primary care provider or complete history by the bariatric surgery team will be considered adequate documentation of a patients attempt to lose weight using more conservative measures.
5. The patient meets **one** (1) of the following BMI categories:
   a. BMI greater than or equal to thirty-five (**35)** with **any one** of the following obesity-related comorbidities:

i. Type 2 diabetes mellitus; **or**
ii. Obstructive sleep apnea; **or**
iii. Hypertension; **or**
iv. Venous stasis disease; **or**
v. Hyperlipidemia; **or**
vi. Weight related arthropathies; **or**
vii. Intertriginous soft issue infections; **or**
viii. Stress urinary incontinence; **or**
ix. Obesity related psychosocial disorders;

b. BMI greater than forty (**40**);

6. Patient must successfully participate in a multi-disciplinary pre-operative bariatric surgery program for a period of at least four (4) consecutive months within the six (6) months prior to surgery. The program must be well documented and include **ALL** of the following elements:
   a. A thorough medical history and physical examination; **and**
   b. An evaluation with a mental health professional that assesses the patient's ability to comply with treatment and documents the recommendation for surgery; **and**
   c. A behavior modification program; **and**
   d. Consultation with a dietician or nutritionist; **and**
   e. An exercise program; **and**
   f. A reduced-calorie diet that is supervised by a physician, dietician, or nutritionist that demonstrates the patient's ability to comply with post-operative diet; **and**
   g. A documented post-operative care plan, which demonstrates plans for continued involvement in the multi-disciplinary comprehensive bariatric surgery program.
7. Patient attends all required appointments and does not gain weight during participation in the multi-disciplinary pre-operative bariatric surgery program.

Note (as per BCBSA):

Patients should have documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure. As a result, some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. However, there is a lack of evidence on the optimal timing, intensity, and duration of nonsurgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Bariatric Surgery in Adolescents

Bariatric surgery may be considered **medically necessary** for the treatment of morbid obesity in adolescents who have met **ALL** of the following:

1. The patient has attained a score of four (4) or five (5) on the Tanner Development Scale and is at final or near-final adult height; **and**
2. The patient meets **any one** (1) of the following BMI thresholds:

a. BMI greater than thirty-five (**35)** with one of the following **severe** obesity related comorbidities:
   i. Type 2 diabetes mellitus; **or**
   ii. Obstructive sleep apnea that requires positive airway pressure; **or**
   iii. Obesity hypoventilation syndrome (OHS); **or**
   iv. Coronary artery disease that can be demonstrated with a stress test or echocardiogram; **or**
   v. Congestive heart failure or history of a myocardial infarction; **or**
   vi. Medically refractory hypertension, that is at over 140 mmHg systolic and 90 mmHg diastolic with concurrent use of at least three (3) anti-hypertensive agents from different classes; **or**
   vii. Hyperlipidemia refractory to diet and maximum doses of lipid lowering agents; or
   viii. Non-alcoholic steatohepatitis (NASH); **or**
   ix. Severe arthropathy of spine or weight bearing joints; **or**
   x. Pseudotumor cerebri; **or**

b. BMI greater than forty (**40)**; **and**

3. Patient must successfully participate in a multi-disciplinary pre-operative bariatric surgery program for a period of at least four (4) consecutive months within the six (6) months prior to surgery. The program must be well documented and include **all** of the following elements:
   a. A thorough medical history and physical examination; **and**
   b. An evaluation with a mental health professional that assesses the patient and the patients' family's ability to comply with treatment and documents the recommendation for surgery; **and**
   c. A behavior modification program; **and**
   d. Consultation with a dietician or nutritionist; **and**
   e. An exercise program; **and**
   f. A reduced-calorie diet that is supervised by a physician, dietician, or nutritionist that demonstrates the patient's ability to comply with post-operative diet; **and**
   g. A documented post-operative care plan, which demonstrates plans for continued involvement in the multi-disciplinary comprehensive bariatric surgery program.
4. Patient attends all required appointments and does not gain weight during participation in the multi-disciplinary pre-operative bariatric surgery program.

Note for Adolescents: Greater consideration should be given to psychosocial and informed consent issues (see Policy Guidelines section). In addition, any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration (FDA)–approved indications.

Bariatric Surgery in Preadolescent Children

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

Revision Bariatric Surgery

Revision surgery to address perioperative or late complications of a bariatric procedure may be considered **medically necessary**. These include, but are not limited to staple-line failure, obstruction, stricture, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, and band slippage that cannot be corrected with manipulation or adjustment (see Policy Guidelines).

Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch, dilation of the gastric sleeve, or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) may be considered **medically necessary** if the initial procedure was successful in inducing weight loss prior to the occurrence of the dilation, and the patient has been compliant with a prescribed nutrition and exercise program.

Bariatric Surgery in Patients with a BMI less than 35 kg/m^2

Bariatric surgery is considered **not medically necessary** for patients with a BMI less than 35 kg/m^2.

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

- Vertical-banded gastroplasty
- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., greater than 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

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

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

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 (see Policy Guidelines).

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**.

Note: Bariatric surgery is covered **once per lifetime**, except when revision or reoperation may be considered medically necessary.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above **investigational** procedures.

Policy Guidelines (Adapted from BCBSA)

Patient Selection Criteria

Morbid obesity is defined as a BMI greater than or equal to 40 kg/m^2 or a BMI greater than or equal to 35 kg/m^2 with at least one (1) clinically significant obesity-related disease such as diabetes mellitus, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

FDA premarket approval for the LAP-BAND® System indicates it is for use only in severely obese adult patients. (The clinical study that was submitted to FDA for approval of the LAP-BAND was restricted to adults aged 18-55 years.)

The patient must have documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts must be reviewed by the practitioner prior to seeking approval for the surgical procedure. Some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise.

The patient must have participated in preoperative surgical care by the practitioner or through a multidisciplinary surgical preparatory regimen, including **ALL** of the following:

- A thorough medical history and physical examination; **and**
- Consultation and instruction by a professional provider on nutrition and an exercise program based on the patient's capability; **and**
- An evaluation by a licensed mental health professional provider that evaluates **all** of the following: any mental health or substance abuse conditions; the emotional readiness and the ability of the individual to make and sustain lifestyle changes. The licensed mental health professional provider should also document their recommendation for bariatric surgery.

Patients with a BMI of 50 kg/m^2 or more need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m^2. Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

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

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

Patients who undergo adjustable gastric banding and fail to achieve adequate weight loss must show evidence of postoperative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.

Hiatal Hernia Repair Guidelines

The Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia (Kohn et al, 2013). The authors note that the general methodologic quality of available studies is low. 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 now always be indicated. Consideration for surgery should include the patient's age and comorbidities (moderate quality evidence, weak recommendation).

Hiatal hernia repair performed at the time of bariatric surgery would not be reported with the hiatal hernia repair code. There is no code for this specific surgery, therefore it should be reported with code 43289 - Unlisted laparoscopy procedure, esophagus.

Cross-references:

MP-2.045 Diagnosis and Medical Management of Obstructive Sleep Apnea
MP-2.069 Gastric Electric Stimulation

II. PRODUCT VARIATIONS

TOP

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to the FEP Service Plan Benefit Brochure for covered indications for bariatric surgery. The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

CHIP (aka Capital Cares 4Kids): Bariatric is not a covered service.

III. DESCRIPTION/BACKGROUND (ADOPTED FROM BCBSA) TOP

Bariatric Surgery

Bariatric surgery is performed to treat morbid (clinically severe) obesity. Morbid obesity is defined as a BMI greater than 40 kg/m^2 or a BMI greater than 35 kg/m^2 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/m^2, or greater than 35 kg/m^2 in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes.

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, e.g., glucagon-like peptide-1 (1GLP-1), glucose-dependent insulinotropic 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 (i.e., 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 B_{12} deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the blind bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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

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 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 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/m^2 with at least one (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/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 (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 (e.g., 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, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.
e. Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to 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, i.e., 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 (i.e., greater than 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 (e.g., 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 (less than150 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. These two (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 (1) 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

Outcome Measures	Definition	Clinical Significance

Decrease in weight	Absolute difference in weight pre- and post-treatment	Unclear relation to outcomes, especially in morbidly obese
Decrease in BMI	Absolute difference in BMI pre- and post-treatment	May be clinically significant if change in BMI clearly 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 greater than 50% EBW	No. patients loosing greater than 50% EBW divided by total patients	Additional advantage to help framing on per patient basis. Threshold for significance (greater than 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 (i.e., gain or loss) at yearly intervals is often reported. Weight loss at one (1) year is considered the minimum length of time for evaluating these procedures; weight loss at three (3) to five (5) years is considered an intermediate time period for evaluating weight loss; and weight loss at five (5) to ten (10) years or more is considered to represent long-term weight loss following bariatric surgery.

Short-Term Complications (Operative and Perioperative Complications less than 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 (e.g., 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, one (1) motivation for bariatric surgery is to decrease the incidence of complications of obesity, such as diabetes, cardiovascular risk factors (i.e., increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, is not subject to regulation by the FDA.

Table 2 shows forms of bariatric surgery with implantable devices approved by FDA through the premarket approval process.

Table 2: FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
AspireAssist System ®	Aspire Bariatrics	Jin 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults less than 22 y, with a BMI of 35.0 to 55.0 kg/m² and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy
ORBERA ® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30-40 kg/m²) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
ReShape ® Integrated Dual Balloon System	ReShape Medical	Jul 2015	For use in obese adults (BMI, 30-40 kg/m²) and greater than or equal to one (1) comorbid conditions who have failed weight reductions with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon delivered trans orally and inflated with saline.
REALIZE ® Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly, obese patients and for individuals with BMI of at least 40 kg/m², or a BMI of at least 35 kg/m² with greater than or equal to 1 comorbid conditions, or those who are greater than or equal to 45.4 kg over their estimated ideal weight, indicated for use only in morbidly obese adults who have failed more

			conservative weight-reduction alternatives (e.g. supervised diet, exercise, behavior modification programs).
LAP-BAND ® Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults who BMI of at least 40 kg/m or a BMI of at least 30 kg/m with greater than or equal to 1 severe comorbid conditions who have failed more, conservative weight-reduction alternatives (e.g. supervised diet, exercise, behavior modifications programs)

BMI: body mass index: FDA: Food and Drug Administration, PMA: premarket approval.

IV. RATIONALE

Summary of Evidence (Adopted from BCBSA)

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. Technology Evaluation Center (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 (T2D). 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 (VBG), 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 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. Additional comparative studies and especially RCTs 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, 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 were published evaluating single anastomosis duodenoileal bypass with SG. There are a few case series, the largest of which had fewer than 100 patients. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of single anastomosis duodenoileal bypass with SG. 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 intragastric balloon (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.

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes 1 RCT 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. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at 1 year. 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 and 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 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 type 2 diabetes in obese patients, including those with a BMI between 30 and 34.9 kg/m^2. The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A_{1c} 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/m^2 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.

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 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 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.

POLICY TITLE	BARIATRIC SURGERY
POLICY NUMBER	MP-1.015

V. DEFINITIONS TOP

N/A

VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members.Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

POLICY TITLE	BARIATRIC SURGERY
POLICY NUMBER	MP-1.015

Investigational; therefore, not covered for bariatric surgery procedures listed as investigational above (Vertical-banded gastroplasty, Two stage gastric procedures, etc.):

CPT Codes®								
43659	43842							

Covered when medically necessary:

CPT Codes®								
43289	43644	43645	43770	43771	43772	43773	43774	43775
43843	43845	43846	43847	43848	43886	43887	43888	

HCPCS Code	Description
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD-10-CM Diagnosis Codes	Description
E66.01	Morbid (severe) obesity due to excess calories
K95.09	Other complications of gastric band procedure
K95.89	Other complications of other bariatric procedure
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z98.84	Bariatric surgery status

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.015	**CAC 4/29/03**
	CAC 5/25/04
	CAC 6/28/05
	CAC 3/28/06
	CAC 10/31/06
	CAC 11/28/06
	CAC 11/27/07 Consensus review and Communication Issued 11/01/07
	CAC 5/27/08
	CAC 11/25/08
	CAC 7/28/09
	12/30/09 Administrative update. On Facility List
	7/27/10CAC Minor revision. Revision surgery added as medically necessary for specific indications. Added clarification to the statement on endoscopic procedures that they are considered investigational as a primary bariatric

	procedure or as a revision procedure. FEP variation added. Removed S2083 from preauthorization list.
	CAC 10/25/11 Minor revision. Policy statement on sleeve gastrectomy changed to medically necessary from investigational. 2/13/12 FEP variation revised to refer to the FEP Service Plan Benefit Brochure.
	11/15/12 Admin update.Medicare variation added to reference NCD 100.1 Codes reviewed 11/26/2012
	6/17/13 Admin update. Medicare variation revised to refer to LCD L33077 Bariatric Surgical Management of Morbid Obesity after 8/1/13.
	Administrative posting 12/17/13. Revisions to remove Medicare requirement that procedures must be performed in a Medicare certified facility. LCD variation revised to refer to LCD L34495 previously LCD L 33077. References updated**.**
	1/28/14 CAC BCBSA adopted. Title changed to "Bariatric Surgery". Revision surgery to address perioperative or late complications of a bariatric procedure further clarified to address band slippage that cannot be corrected with manipulation or adjustment. Medicare variation revised to indicate that **e**ffective for dates of service on and after September 24, 2013, CMS no longer requires that covered bariatric surgery procedures be performed in facilities that are certified. Also, LCD number has been changed to LCD L34495. Requirements for Centers of Excellence for commercial members also removed from policy. Rationale added. Comorbidity codes removed from policy.
	12/2/14Admin update - Removed cross reference to 2.044 (retired).
	3/24/15 CAC Minor revision. Laparoscopic gastric plication added to list of investigational procedures. Statement added related to the repair of incidentally identified hiatal hernias. Statement on bariatric surgery in patients with BMI <35 changed from investigational to not medically necessary. References and rationale updated. Coding reviewed.
	11/2/15 Administrative update. LCD number changed from L34495 to L35022 due to Novitas update to ICD-10.
	5/31/16 CAC Minor revision. Single ansastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) added as investigational**.** Background, references, and rationale updated. Patient Selection Criteria in the Policy Guidelines revised to indicate that a BMI of 40 kg/m^2 or 35 kg/m^2 with at least 1 clinically significant obesity-related disease is included in the definition of morbid obesity. Coding reviewed.
	1/1/17Admin update. Product variation section reformatted.
	7/25/17 CAC Minor revision. The bullet point in the first investigational policy statement on endoscopic procedures was rewritten as a separate statement for clarity and aspiration therapy device was added to this statement. A policy statement was added that bariatric surgery as a treatment of obesity in preadolescent children is considered investigational. Variation section revised. Description/Background, Rationale and Reference sections updated. Coding reviewed.

POLICY TITLE	BARIATRIC SURGERY
POLICY NUMBER	MP-1.015

	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	1/4/18 Minor review. The patient selection criteria was updated. The patient must have documented failure to respond to ≥6 months of conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts must be reviewed by the practitioner prior to seeking approval for the surgical procedure. Some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. • The patient must have participated in preoperative surgical care by the practitioner or through a multidisciplinary surgical preparatory regimen, including **all** of the following: o A thorough medical history and physical examination. o Consultation and instruction by a professional provider on low-calorie diets and an exercise program based on the patient's capability. o An evaluation by a licensed mental health professional provider that evaluates all of the following: any mental health or substance abuse conditions; the emotional readiness and the ability of the individual to make and sustain lifestyle changes. Coding reviewed and updated.
	10/1/18 Admin update: Product variation section updated. HMO variation removed.
	11/29/18 Consensus review. No change to policy statements. Background and references updated. Rationale condensed.
	5/31/2019 Major review. Criteria updated to further define conservative weight loss attempts and pre-operative program. Added smoking and age requirements. References updated. Effective 1/1/2020.
	3/18/2020 Minor review. Updated criteria to revised BMI requirements, defined requirements for conservative weight loss attempt, removed 6-month program requirement and added requirement for patient participation. References updated. Coding reviewed, no changes. Effective 7/1/2020.

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