

Corporate Medical Policy

Bariatric Surgery

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Description of Procedure or Service

Bariatric surgery, falls into two general categories: 1) gastric-restrictive procedures that create a small gastric pouch, resulting in weight loss by producing early satiety and thus decreasing dietary intake; and 2) malabsorptive procedures, which produce weight loss due to malabsorption by altering the normal transit of ingested food through the intestinal tract. Some bariatric procedures may include both a restrictive and a malabsorptive component.

Bariatric surgery is performed for the treatment of Class III (morbid [clinically severe]) obesity. Class III obesity, formerly known as morbid obesity, is defined as a body mass index (BMI) greater than 40 kg/m² or 35 kg/m² with at least one clinically significant obesity-related disease including, but not limited to diabetes, hypertension, coronary artery disease, or obstructive sleep apnea for which these complications or diseases are not controlled by best practice medical management. Class III obesity results in a very high risk for weight-related and metabolic complications, including but not limited to diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectum, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A man with Class III obesity at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

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 anti-diabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (GLP-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.

The following summarizes the different restrictive and malabsorptive procedures.

Gastric Restrictive Procedures

1. Vertical-Banded Gastroplasty (CPT code 43842) Vertical-banded gastroplasty 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 two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

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2. Adjustable Gastric Banding (CPT code 43770) Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple. Complications include slippage of the external band or band erosion through the gastric wall. Currently, two such devices are approved by the US Food and Drug Administration (FDA) for marketing in the United States. The first to receive FDA approval was the Lap-Band® (Apollo Endosurgery). The labeled indications for Lap Band devices are as follows:

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

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 the FDA through the Premarket Approval (PMA) process in September 2007 was the REALIZE model (Ethicon Endosurgery, Cincinnati, OH). Labeled indications for this device are as listed below:

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

3. Open Gastric Bypass (CPT code 43846) The original gastric bypass surgeries were based on the observation that post-gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a 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 compared to other gastric restrictive procedures, including iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

Note: In 2005, the CPT code 43846 was revised to indicate that the short limb must be 150 cm or less, compared to the previous 100 cm. This change reflects the common practice in which the Roux limb of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long or very, very long gastric bypass, as discussed further here.

4. Laparoscopic Gastric Bypass CPT code 43644 was introduced in 2005 and essentially described the same procedure as No. 3, but performed laparoscopically.

5. One Anastomosis Gastric Bypass (OAGB) (CPT code 43645) Recently, a variant of the gastric bypass, called the one anastomosis gastric bypass (OAGB) or mini-gastric bypass, has been popularized. One anastomosis gastric bypass (OAGB) is a "combined procedure", and it has both a "restrictive" and a "malabsorptive" component. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach as a loop, similar to a Billroth II procedure. This unique aspect of this procedure is

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not based on its laparoscopic approach but rather the type of anastomosis used. The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) issued a position statement on the role of one anastomosis gastric bypass (OAGB) in the field of bariatric/metabolic surgery in 2018. In order to avoid confusion between the Billroth II Gastrojejunostomy and the Roux en Y procedure, OAGB has been recommended as the preferred terminology. It should also be noted that CPT code 43846 does not accurately describe the mini-gastric bypass, since the CPT code explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

6. Sleeve gastrectomy (CPT code 43775). A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own, or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum, and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure can be done by the open or laparoscopic technique. Some surgeons have proposed this as the first in a two-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status, and thus reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

Endoluminal (also called endosurgical, endoscopic, or natural orifice) bariatric procedures. With these procedures access to the relevant anatomical structures is gained through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce the risks associated with open and laparoscopic interventions. Examples of endoluminal bariatric procedures include gastropasty using a transoral endoscopically guided stapler and placement of devices such as a duodenal-jejunal sleeve and gastric balloon.

Malabsorptive Procedures

The multiple variants of malabsorptive procedures differ in the lengths of the alimentary limb, the biliopancreatic limb, and the common limb, in which the alimentary and biliopancreatic limbs are anastomosed. These procedures also may include an element of a restrictive surgery based on the size of the stomach pouch. The degree of malabsorption is related to the length of the alimentary and common limbs. For example, a shorter alimentary limb (i.e., the greater the amount of intestine that is excluded from the nutrient flow) will be associated with malabsorption of a variety of nutrients, while a short common limb (i.e., the biliopancreatic juices are allowed to mix with nutrients for only a short segment) will primarily limit absorption of fat.

1. Biliopancreatic Bypass Diversion (also known as the Scopinaro procedure) (CPT code 43847).

Biliopancreatic bypass diversion (BPD) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, 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.

1. A distal gastrectomy functions to induce a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
2. A 200-cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.
3. A 300- to 400-cm "biliary tract," which connects the duodenum, jejunum, and remaining ileum to the common distal segment.
4. A 50- to 100-cm "common tract," where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, creating selective malabsorption. The length of the common segment will influence the degree of malabsorption.
5. Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

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Many potential metabolic complications are related to biliopancreatic bypass diversion, including most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition.

2. Biliopancreatic Bypass Diversion with Duodenal Switch (CPT code 43845), which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is essentially a variant of the biliopancreatic bypass diversion described here. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach, preserving the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the biliopancreatic bypass diversion, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass diversion; i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

A variation of this procedure is the single-anastomosis duodenal switch most accurately described as a single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), CPT code 43659. The SADI-S procedure uses the transected duodenum anastomosed to a loop of ileum as opposed to using a Roux-en-Y configuration.

3. Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847) Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

4. Laparoscopic Malabsorptive procedure (CPT code 43645) 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.

5. Laparoscopic Gastric Plication (no specific CPT code) Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves 2 main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized. CPT code 43843 Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty is commonly used for this procedure.

Vagus Nerve Blocking Therapy

Vagus nerve blocking therapy is another potential treatment option for obese patients. The vagus nerve consists of 2 long cranial nerves that extend from the brain stem to the viscera. The term *vagus* is Latin for wandering and the vagus nerve winds through the abdomen and has branches that come in contact with the heart, lung, stomach, and other body parts. The vagus nerve plays a major role in autonomic and sympathetic nervous system functioning including regulation of heartbeat and breathing. It is also involved in regulation of the digestive system, although its exact role in controlling appetite and feelings of satiety is unknown. Vagus nerve blocking therapy involves intermittent blocking of signals

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to the intra-abdominal vagus nerve, with the intent of disrupting hunger sensations and inducing feelings of satiety.

In 2015, FDA approved a medical device specifically designed to provide vagus nerve blocking therapy for weight regulation in obese patients. This device, the Maestro® Rechargeable System, includes a neuroblocking pulse generator that is implanted subcutaneously on the thoracic sidewall, and flexible leads approximately 47 cm in length that are placed on the abdominal anterior and posterior vagus nerve trunks. External components include a mobile charger, transmit coils, a programmable microprocessor and customized software. The system delivers high-frequency pulses of electrical current to vagus nerve trunks; therapy parameters and the treatment schedule can be customized by a clinician. Like other surgical interventions, there is the potential for adverse effects. In addition, there may be other unintended consequences of disrupting signals to a particular portion of the vagus nerve.

(Stimulation of the vagus nerve via a device implanted within the carotid artery sheath has also been evaluated as a treatment for obesity and is addressed in the policy titled Vagus Nerve Stimulation. Vagus nerve stimulation is FDA-approved to treat epilepsy and depression, not for obesity treatment.)

Regulatory Status

FDA approved the Maestro Rechargeable System (EnteroMedics, St. Paul, MN) through the premarket approval process on January 14, 2015. The device is indicated for use in adults age 18 years and older who have a BMI of 40 to 45 kg/m² or a BMI of 35 to 39.9 kg/m² with 1 or more obesity-related comorbidities and have failed at least 1 supervised weight management program within the past 5 years. Implantable components are incompatible with magnetic resonance imaging (MRI). In addition to need for MRI, contraindications to use of the device include conditions such as cirrhosis of the liver, portal hypertension and clinically significant hiatal hernia and the presence of a previously implanted medical device.

The commercial availability of the Maestro® System is unclear. On the FDA's Weight-Loss and Weight-Management Devices webpage (content noted as current as of 09/05/2019), the Maestro® Rechargeable System is described as "no longer marketed as of September 2018". Additionally, on the ReShape Lifesciences™ website (previously EnteroMedics), the Maestro® Rechargeable System, is not listed among their current portfolio of medical devices to treat obesity and metabolic disease. However, updates to the Maestro® Rechargeable System were noted in the FDA Premarket Approval database (P130019) subsequent to September 2018, including updates to the circuit assembly and application firmware of the mobile charger (01/25/2019) and approval of modifications to the follow-up schedule for the post-approval study protocol.

Other Therapies

FDA approved the Obalon™ intragastric balloon system (Obalon Therapeutics, Inc.) in September 2016 for use in obese adults (BMI, 30 to 40 kg/m²) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is six months. Balloon is encased in a capsule. The capsule is swallowed and begins to dissolve after exposure to fluids in the stomach. After verification of capsule placement in the stomach, the balloon is filled with a gas mixture. Up to three balloons can be used during the six month treatment period.

FDA approved the AspireAssist® (Aspire Bariatrics, King of Prussia, PA) through the premarket approval process on June 14, 2016. The device is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a body mass index of 35.0 – 55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgical weight loss therapy.

FDA approved the ORBERA® intragastric balloon system (Apollo Endosurgery) through the premarket approval process in August 2015 for use in obese adults (BMI, 30 – 40 kg/m²) who have failed weight

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reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 months. The balloon is placed endoscopically and inflated with saline.

FDA approved the ReShape® Integrated Dual Balloon System (ReShape Medical) through the premarket approval process in July 2015 for use in obese adults (BMI, 30 – 40 kg/m²) and one or more comorbid conditions who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 months. The balloon is delivered transorally and inflated with saline.

Related Policy

Gastric Electrical Stimulation

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for bariatric surgery when it is determined to be medically necessary because the medical criteria and guidelines shown below are met. Also see Policy Guidelines.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy. Criteria for medical necessity should not be applied in the absence of a member benefit for the service.

Effective 1/1/2020, a benefit requirement for one year of conservative medical management may either no longer be required or be removed at the time of the member's next benefit renewal. Refer to individual member's benefit booklet for additional information.

Benefits are provided for bariatric surgery if the individual has a BMI ≥ 40 or BMI ≥ 35 and has a significant comorbid condition including but not limited to diabetes mellitus, hypertension, sleep apnea, hyperlipidemia, severe osteoarthritis, metabolic syndrome, NASH etc., and has demonstrated evidence of attempts to lose weight through nonsurgical means. These methods include follow up with medical provider for weight related comorbid conditions, and/or behavioral counseling, and/or nutritional counseling and/or physical activity through a professional qualified to provide these services or through a proprietary weight loss program. Please refer to the sections below "When Bariatric Surgery is covered" and "Policy Guidelines" for detailed medical necessity criteria.

Judgment regarding the scope, depth, and adequacy of pre-surgical treatment during the year prior to surgery is at the discretion of the multidisciplinary weight loss surgery team, and BCBSNC does not specify the content of the treatment.

Bariatric Surgery requires prior review.

When Bariatric Surgery is covered

- I. **Criteria for Adults** – Bariatric Surgery is covered when **all four** of the following criteria are met:
 - A. The individual must have Class III obesity as defined below:
 1. have a BMI ≥ 40 **or**
 2. have a BMI ≥ 35 associated with at least one or more of the following problems which are generally expected to be improved, curtailed or reversed by surgical treatment:
 - a. The obesity interferes with daily function to the extent that performance is severely curtailed (i.e., impending job loss or job loss with documented disability); **or**

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- b. The obesity causes incapacitating pain and limitation of motion in any weight-bearing joint or the lumbosacral spine documented by physical examination in association with radiologic findings showing degenerative osteoarthritis; **or**
 - c. There is significant respiratory insufficiency as evidenced by pCO₂ > 50 mmHg, hypoxemia at rest, as evidenced by pO₂ < 55 mmHg on room air; FEV₁/FVC < 65%, or DLCO < 60% (e.g., Obesity Hypoventilation Syndrome); **or**
 - d. Clinically significant obstructive sleep apnea (i.e., Individual meets criteria for treatment of obstructive sleep apnea set forth in a separate policy, titled Sleep Apnea: Diagnosis and Medical Management; **or**
 - e. Type 2 diabetes mellitus; **or**
 - f. Documented coronary artery disease; **or**
 - g. Cardiomyopathy; **or**
 - h. Heart failure; **or**
 - i. Gastroesophageal reflux disease with secondary asthma or erosive esophagitis not controlled despite maximum dosages of proton pump inhibitors; **or**
 - j. Pseudotumor cerebri; **or**
 - k. Individual has at least one of the following:
 - i. Medically refractory hypertension (blood pressure > 140 mmHg systolic and/or > 90 mmHg diastolic measured with appropriate size cuff) that has not responded to medical management including at least two (2) anti-hypertensive drugs at maximum tolerated dosages.
 - ii. First degree relative with premature (age < 50) cardiovascular disease.
 - iii. Hypercholesterolemia > 240 mg/dL or hypertriglyceridemia > 400 mg/dL or low density lipoprotein (LDL) ≥160 mg/dL or high density lipoprotein (HDL) < 40 mg/dL; despite appropriate medical therapy defined as at least one appropriate drug at maximum dosage.
 - iv. Metabolic syndrome.
 - v. Pulmonary hypertension; **OR**
 - l. Nonalcoholic steatohepatitis (NASH)
- B. The individual has no specifically correctable cause for the obesity, e.g., an endocrine disorder; **AND**
- C. A thorough evaluation (see Policy Guidelines section) has been documented to assess the individual's suitability for surgery and their ability to comply with lifelong follow up; **AND**
- D. Bariatric Surgery is eligible for coverage when it is part of a comprehensive pre-surgical, surgical and post-surgical program (see Policy Guidelines Section).
- II. Criteria for Adolescents < 18 years of age:**
Bariatric surgery in adolescents may be considered **medically necessary** according to similar weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues. In addition, any devices used for bariatric surgery must be in accordance with the FDA-approved indications for use. (See Policy Guidelines.)
- III. Surgical Procedures (open or laparoscopic)-** The following surgical procedures are considered eligible for coverage for the individual with Class III obesity **who meets the preceding criteria:**
- A. **Short limb Roux-en-Y** - involves creating a small stomach pouch. A short limb of small bowel (150 cm or less) is divided and anastomosed to the small stomach pouch, bypassing a large part of the stomach and duodenum.
 - B. **Sleeve Gastrectomy**
 - C. **Long limb Roux-en-Y**, involving more than 150 cm of the small intestine, only when performed as a revision procedure after a standard gastric bypass has failed to resolve co-morbidities and/or result in satisfactory weight loss as defined by the National Heart Lung and Blood Institute (see link in IV-,C below).
 - D. **Adjustable Gastric Banding** - Additional criteria include the following:
Adults (Individuals 18 years of age or older). FDA approval for the LAP-BAND® Adjustable Gastric Banding (LAGB®) System indicates it is for use only in severely obese adult patients. It is contraindicated in non-adult patients (patients under 18 years of age). The REALIZE™ Adjustable Gastric Band is indicated for use only in morbidly obese adult patients.
 - E. **Biliopancreatic bypass with duodenal switch**

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- F. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)
- G. One anastomosis gastric bypass (OAGB) using the Billroth II gastrojejunostomy with gastric partitioning

IV. Revision Bariatric Surgery -

- A. **Revision surgery** to address perioperative or late complications of the original bariatric procedure is considered medically necessary. These include, but are not limited to, staple-line failure, obstruction, stricture, erosion, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, band herniation, and band slippage that cannot be corrected with manipulation or adjustments.
- B. Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band or other restrictive procedure (documented by upper gastrointestinal examination or endoscopy) is considered medically necessary if the initial procedure was successful in inducing weight loss prior to dilation, and the patient has been compliant with a prescribed nutrition and exercise program.
- C. Repeat surgical procedures for revision or conversion to another surgical procedure (that is also considered medically necessary within this document) for inadequate weight loss, (that is, unrelated to a surgical complication of a prior procedure) are considered medically necessary when all the following criteria are met:
 - o The individual continues to meet all the medical necessity criteria for bariatric surgery, including current pre-operative nutritional assessment; and
 - o There is documentation of compliance with the previously prescribed postoperative dietary and exercise program; and
 - o Weight loss following the original surgery is less than 50% of pre-operative excess body weight and weight remains at least 30% over ideal body weight (taken from standard tables for adult weight ranges based on height, body frame, gender and age; an example is available from the National Heart Lung and Blood Institute [NHLBI] at: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm).

When Bariatric Surgery is not covered

Bariatric Surgery is considered not medically necessary in the following situations:

- A. When the preceding criteria for coverage are not met.
- B. For individuals with a BMI less than 35 kg/m²

Procedures considered investigational, and therefore not covered, include but are not limited to:

- a. Biliopancreatic bypass without duodenal switch.
- b. Adjustable Gastric Banding in non-adult patients (patients under 18 years of age);
- c. Vertical-banded gastroplasty
- d. Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding
- e. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time).
- f. Long limb Roux-en-Y, involving more than 150 cm of the small intestine, when performed as a primary bariatric procedure.

Intra-abdominal vagus nerve blocking therapy is considered **investigational** in all situations, including but not limited to the treatment of obesity.

Endoscopic procedures are 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). These procedures include, but are not limited to:

- a. Insertion of the StomaphyX™ device
- b. Endoscopic gastroplasty

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- c. Use of an endoscopically placed duodenojejunal sleeve
- d. Intra-gastric balloons
- e. Aspiration therapy device.
- f. Natural Orifice Transluminal Endoscopic Surgery (NOTES™)

Bariatric surgery is considered not medically necessary for patients with a BMI less than 35 kg/m².

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

Policy Guidelines

General Criteria for Adults and Adolescents

A thorough preoperative evaluation for bariatric surgery must include **all** of the following:

1. Evaluation of the individual's understanding of the procedure to be performed, including the procedure's risks and benefits, length of stay in the hospital, behavioral changes required prior to and after the surgical procedure (including dietary and exercise requirements), follow up requirements with the performing surgeon, and anticipated psychological changes.
2. Evaluation of the individual's family/caregivers support and understanding of the information in #1.
3. Within 12 months prior to surgery, a thorough nutritional evaluation by a physician, registered dietician, or other licensed professional experienced in the issues of bariatric surgery, who has had a meaningful conversation with the individual regarding the dietary and lifestyle changes required to ensure a successful outcome over time. Nutritional assessment must follow American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines. Pre-operative assessment must document that the individual has a good understanding of the diet and nutritional changes that are associated with bariatric surgery and has the capacity to comply with these changes. Per the ASMBS guidelines, "...it is essential to determine any preexisting nutritional deficiencies, develop appropriate dietary interventions for correction, and create a plan for postoperative dietary intake that will enhance the likelihood of success. Not only should the practitioner review the standard assessment components (i.e., medical co-morbidities, weight history, laboratory values, and nutritional intake), it is also important to evaluate other issues that could affect nutrient status, including readiness for change, realistic goal setting, general nutrition knowledge, as well as behavioral, cultural, psychosocial, and economic issues." 2019 guidelines for perioperative nutrition, metabolic and nonsurgical support are available at: <https://journals.aace.com/doi/pdf/10.4158/GL-2019-0406>
4. Within 12 months prior to surgery, a formal psychosocial-behavioral evaluation performed by a qualified behavioral health professional (i.e., licensed in a recognized behavioral health discipline, such as psychology, social work, psychiatry, psychiatric nursing, etc., with specialized knowledge and training relevant to obesity, eating disorders, and/or bariatric procedures), which assesses environmental, familial, and behavioral factors, as well as risk for suicide. Any individual considered for a bariatric procedure with a known or suspected psychiatric illness, or substance abuse or dependence, should undergo a formal mental health evaluation before the procedure. 2019 guidelines for perioperative nutrition, metabolic and nonsurgical support are available at <https://journals.aace.com/doi/pdf/10.4158/GL-2019-0406>.
5. Appropriate medical work up may include a chest x-ray, upper gastrointestinal series, endoscopy, appropriate pre-op labs and ECG. A complete physical examination by the attending surgeon. If the individual has comorbid conditions (e.g. diabetes or cardiovascular disease) the individual must be capable of undergoing the procedure.
6. Anesthesia clearance for surgery.

The first five criteria must be met before seeking prior plan approval for adults and adolescents; the sixth must be met prior to surgery. Surgical procedures must be performed at a facility capable of providing gastrointestinal and biliary surgery (preferably JCAHO accredited), AND that has equipment and

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staff capable of managing an individual with Class III obesity (appropriate instruments, beds, lifts, monitoring equipment) AND that can manage short and long term complications of bariatric surgery.

The performing surgeon must be qualified and experienced in performing the procedure to be undertaken.

Follow up programs must include regular follow up with a commitment to lifetime management and behavior change, including postoperative nutrition follow-up.

Significant weight loss following bariatric surgery can lead to redundant skin and fat folds in varied anatomic locations (e.g., breasts, medial upper arms, and medial thighs, lower abdominal area also called “abdominal apron” or pannus). Surgical removal of redundant skin and fat folds is generally considered cosmetic and is not covered. Coverage may be considered for panniculectomy in patients who meet criteria specified in separate policy, Abdominoplasty and Panniculectomy.

For individuals who are diabetic and do not have Class III obesity who receive gastric bypass, sleeve gastrectomy, biliopancreatic diversion, or adjustable gastric banding, the evidence includes systematic reviews of RCTs and observational studies. 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 one to three years of follow-up; with a few having five year follow-up data.

However, 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 do not have Class III obesity is considered not medically necessary.

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

Prior to consideration of a second bariatric procedure, individuals who have undergone adjustable gastric banding must demonstrate that appropriate band adjustments in conjunction with regular post-operative visits and nutritional compliance has failed to result in adequate weight loss.

Adolescent Criteria

For individuals who are adolescent children with Class III obesity who receive gastric bypass or LAGB, or 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 studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB, or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents are similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m². In addition, greater consideration should be placed on patient developmental stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the

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individual can provide fully informed consent. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adolescent children with Class III 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 that the technology results in an improvement in the net health outcome.

For individuals who are preadolescent children with Class III obesity who receive bariatric surgery, there are 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. A recent (2021) cohort study included 801 children ages 5 to 14 years in their total cohort of children and adolescents, and excess weight loss and comorbidity resolution were substantial and long-lasting without safety concerns across all age groups. However, comparative studies are still lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The Endocrine Society published recommendations for the following for prevention and treatment of pediatric obesity in 2008. In 2017, the Society sponsored an update of these guidelines by the Pediatric Endocrine Society and the European Society of Endocrinology. These guidelines contained the following recommendations for bariatric surgery:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI > 40 kg/m² or has BMI above 35 kg/m² and significant, extreme comorbidities.
- Extreme obesity and comorbidities persist despite compliance with a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a pediatric bariatric surgery center of excellence that provides the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.
- Bariatric surgery is not recommended for preadolescent children, for pregnant or breast-feeding adolescents, and for those planning to become pregnant within 2 years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved substance abuse, eating disorder, or untreated psychiatric disorder.

The U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND System indicates it is for use only in severely obese adult patients. Devices that are used for laparoscopic adjustable gastric banding do not have FDA-approval in the U.S. for individuals younger than age 18 years. As in adults, laparoscopic gastric bypass is the most common procedure in adolescents. Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions in adolescents because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that biliopancreatic diversion not be done in adolescents.

Staged Procedures

For individuals who are adults with Class III obesity who receive 2-stage bariatric surgery procedures, the evidence includes a small RCT, observational 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 a lack of evidence that 2-stage bariatric procedures

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improve outcomes compared with 1-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months postsurgery. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Vagus Nerve Blocking Therapy

For individuals with obesity who receive vagus nerve blocking therapy, the evidence includes two sham-controlled randomized trials. Relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. The primary efficacy outcome (at least a 10% difference between groups at 12 months) was not met for either trial. In the first trial (EMPOWER), the observed difference in excess weight loss (EWL) between groups at 12 months was 1%. In the more recent trial (ReCharge), the observed difference in EWL between groups at 12 months was 8.5%; a post hoc analysis found this difference statistically significant, but the magnitude of change may not be viewed as clinically significant according to investigators' original trial design decisions. Post hoc analyses of longer term data have been published and are subject to various biases including missing data and unblinding at 12 months. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0813T, 43290, 43291, 43644, 43645, 43659, 43770, 43771, 43772, 43773, 43774, 43775, 43842, 43843, 43845, 43846, 43847, 43848, 43886, 43887, 43888, 43999, 47379, 49329, 44202, C9784, C9785, S2083.

Hernia repair (43280, 43281, 43332, 43334, 43336) is considered an incidental procedure when performed during the same operative session as bariatric surgery (43644, 43645, 43770, 43775, 43842, 43843, 43845, 43846, 43847, 43999). Modifiers 58, 59, 78 and 79 (or XE, XS, XP, XU) will not allow additional payment when appended to these codes. An incidental procedure is not eligible for separate reimbursement. See also corporate medical policy "Bundling Guidelines".

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Specialty Matched Consultant Advisory Panel 4/2024

Medical Director Review 4/2024

Policy Implementation/Update Information

- | | |
|-------|--|
| 5/83 | Original policy issued. |
| 5/95 | Revised: coding changes. |
| 9/96 | Revised: Combined Local and National policies. |
| 11/96 | Reaffirmed. |
| 4/99 | Policy updated with Milliman & Robertson Surgical Authorization Guidelines from the December 1997 Healthcare Management Guidelines Vol. Added no correctable cause for obesity and patient has attained full growth criteria. |
| 5/99 | Medical Policy Advisory Group |
| 6/99 | Reformatted, Medical Term Definitions added. |
| 9/00 | Policy criteria reviewed for clarity. Re-outlined to clarify criteria requirements. System coding changes. |
| 01/01 | Specialty Matched Consultant Advisory Panel 11/00. BMI added to criteria. |
| 3/01 | Policy updated to indicate that the Mini-Gastric Bypass is considered investigational. Medical Policy Advisory Group meeting 3/1/2001. Approve. |
| 6/01 | Medical Policy Advisory Group. |
| 7/01 | Medical Policy Advisory Group recommended changes to criteria. Revised criteria to eliminate specific reference to medical weight loss programs as a requirement for surgery for morbid obesity and added criteria for evaluation and documentation of the patient's ability to comply with lifelong follow up. System coding changes. |
| 11/01 | Added the following criteria for coverage of Surgery for Morbid Obesity: "Gastric Bypass, involving more than 100 cm but less than 160 cm of the small intestine, will be reviewed on an individual consideration basis." |
| 4/02 | Revised. Changed A. under when it is covered to include " <u>all six</u> " criteria must be met. Added statement number six to include, "Surgery for morbid obesity is eligible for coverage when it is part of a comprehensive pre-surgical and post-surgical program". |

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- 9/02 Clarified statement to indicate that this procedure may require Prior Plan Approval.
- 3/03 Specialty Matched Consultant Advisory Panel review - 8/15/02. System coding changes.
- 4/03 The following were omitted from the 3/03 entry above. Under "When Covered" A.1.b.iii - added sleep apnea documented by sleep studies; added A.1.b.iv - Poorly controlled hypertension despite medication; B.2. added "(typically considered for patients with BMI equal to or greater than 55)". Added Body Mass Index definition to Medical Term Definition section. Added statement regarding redundant skin and fat folds to Policy Guidelines section. Also referred to Cosmetic and Reconstructive Surgery policy.
- 5/03 Policy reformatted for clarity. Under "When Covered section": A.1.a. - Changed BMI>40 to BMI \geq 40; A.1.b - Statement revised to "have a BMI \geq 35..."; A.1.b.v. - Added hypertension, etc. is significantly complicated by morbid obesity.; A.1.b.vi. - deleted; B. - Added #4. Policy Guidelines revised to provide details re: comprehensive pre-surgical, surgical and post-surgical program. Tables 1-6 deleted and BMI Table added. Key words added.
- 4/22/04 Under "Description of Procedure" reversed position of malabsorptive procedures and gastric restrictive procedures. Under "When Covered" the following changes were made: A.1.a. - deleted "at least 100% overweight". Policy is referencing BMI rather than weight. A.1.b.v. - added "(e.g. requiring prescription drug treatment)". A.2 changed to "Morbid obesity (BMI \geq 35 associated with at least one of the problems listed in A.1.b. or BMI \geq 40) has been present for four of the previous five years." A.4. - added "(for adolescents-bone age shows closure of epiphyseal plates)". A.5. - added "(see Policy Guidelines section)". Under "Policy Guidelines" the following changes were made: In second sentence, "adequate" changed to "thorough". Number 4, Psychological assessment - changed wording following "to include" to "assessment of any diagnosable mental health conditions that may affect treatment, readiness and ability to adhere to required lifestyle modifications and follow up/social support". Following numbers 1) through 6) added "The first four criteria above must be met before seeking prior plan approval, the last two criteria must be met prior to surgery." Benefits Application and Billing/Coding sections revised. CPT code 43659 added to Billing/Coding section as this code may be billed for the Mini-Gastric Bypass procedure. Also added HCPCS codes S2082 and S2085. Notification given 4/22/04. Effective date 7/1/04.
- 10/28/04 Specialty Matched Consultant Advisory Panel review 8/2004. Medical Policy Advisory Group review 9/16/04. Added HCPCS code S2083 No changes to the policy.
- 12/23/04 Codes 43644, 43645, 43845 added to Billing/Coding section of policy.
- 2/02/06 Removed deleted codes S2082 & S2085 from Billing/Coding section and added 2006 CPT codes 43770, 43771, 43772, 43773, 43774, 43886, 43887, & 43888.
- 11/13/06 Description section revised to include detailed description of surgical procedures for morbid obesity. When covered section revisions: Removed B.3. Vertical-banded gastric partition (also called vertical banded gastroplasty); Added C. Reoperation and Surgical Revision which includes the most common complications/conditions/diagnoses for which reoperation or surgical revisions are performed. When not covered section revisions: Added 2.f. Sleeve gastrectomy, either as the sole procedure or as one step in a staged procedure; 2.g. Gastric bypass using a Billroth II type of anastomosis, popularized as the mini-gastric bypass (this replaced the previous wording re: mini-gastric bypass which was removed); 2.h. Gastric electrical stimulation; 2.i. Garren-Edwards Gastric Bubble (aka, intra-gastric balloon); 2.j. Roux-en-Y is not indicated for a failed Nissen Fundoplasty unless the patient meets the other criteria for surgery for morbid obesity; 3. Vertical-banded gastroplasty was once the most common type of gastric restrictive procedure performed in the U.S., but has fallen out of favor due to a high reoperation rate. Therefore, vertical-banded gastroplasty is no longer a standard of care and is therefore considered not medically necessary. Reference sources and medical terms added. Notification given 11/13/06. Effective date 1/17/07. (pmo)
- 1/29/07 Covered and non-covered criteria added for adjustable gastric banding. Reference source added. (pmo)

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- 2/12/07 Added the following to When covered section: B.4 Biliopancreatic bypass with or without duodenal switch may be considered on an individual consideration basis for patients with a BMI > 50. This was inadvertently deleted during the 1/29/07 revisions. (pmo)
- 6/4/07 Reference source added. (pmo)
- 10/6/08 "When Covered" section revisions:

Section A: Criteria for *Adults*....A.1.b. have a BMI ≥ 35 associated with at least one or more of the following problems *which are generally expected to be improved, curtailed or reversed by surgical treatment*: Revisions under A.1.b.: ii The obesity causes incapacitating *pain and limitation of motion in any weight-bearing joint or the lumbosacral spine* documented by *physical examination in association with radiologic findings showing degenerative osteoarthritis*; iii. There is significant respiratory insufficiency *as evidenced by pCO₂ > 50 mmHg, hypoxemia at rest, as evidenced by pO₂ < 55 mmHg on room air; FEV1/FVC < 65%, or DLCO < 60% (e.g., Obesity Hypoventilation Syndrome)*; iv. Clinically significant obstructive sleep apnea (i.e., Patient meets criteria for treatment of obstructive sleep apnea set forth in policy number OTH8138, titled Sleep Apnea and Breathing Related Sleep Disorders in Adults); v. Type 2 diabetes mellitus; vi. Documented coronary artery disease; vii. Cardiomyopathy; viii. Heart failure; ix. Gastroesophageal reflux disease with secondary asthma or erosive esophagitis not controlled despite maximum dosages of proton pump inhibitors; x. Pseudotumor cerebri; xi. Patient has at least one of the following: Medically refractory hypertension (blood pressure > 140 mmHg systolic and/or > 90 mmHg diastolic measured with appropriate size cuff) that has not responded to medical management including at least two (2) anti-hypertensive drugs at maximum tolerated dosages; First degree relative with premature (age < 50) cardiovascular disease; Hypercholesterolemia > 240 mg/dL or hypertriglyceridemia > 400 mg/dL or low density lipoprotein (LDL) ≥ 160 mg/dL or high density lipoprotein (HDL) < 40 mg/dL; despite appropriate medical therapy defined as at least one appropriate drug at maximum dosage; Metabolic syndrome; Pulmonary hypertension. A.4. has been deleted "~~Patient has achieved full growth (for adolescents bone age shows closure of epiphyseal plates.~~

Section B. is now "Criteria for Adolescents < 18 years of age: Coverage for adolescents under 18 years of age may be provided only in a covered clinical trial offering a multidisciplinary team approach capable of managing the unique challenges posed by the adolescent age group. For the purpose of this policy, severe adolescent morbid obesity is considered a life threatening condition. Refer to Clinical Trial policy (MED1093) for other criteria a covered clinical trial must meet.

Section C. is now "Surgical Procedures" (changed from B. to C.). C.1. Will now be "Short limb Roux-en-Y" (moved from end to beginning of C.1); C.2. Will now be "Long limb Roux-en-Y" (moved from end to beginning of C.2); Deleted C.3.b. BMI < 50 (Patients with BMI > 50 need a procedure to achieve greater weight loss. Thus the 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 < 50.)

Section D. is now Surgical Revision (changed from C. to D. and deleted "~~Reoperation and~~"; D.2.o. Deleted "~~Disrupted staple line provided there has been prior weight loss~~". D.2.o. is now "Intractable ulcer".

"When Not Covered" section revisions:

2.d. Adjustable Gastric Banding: Deleted ~~d.ii. in patients with a BMI ≥ 50 .~~ Added 2.k. "*Endoscopic procedures (e.g., insertion of the StomaphyX™ device) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches.*"

"Policy Guidelines" section revisions:

3 now reads "*Within 12 months prior to surgery, a thorough nutritional evaluation by a physician or registered dietician experienced in the issues of bariatric surgery, who has had a meaningful conversation with the individual regarding the dietary and lifestyle changes required to ensure a successful outcome over time.*"

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#4 now reads "Evaluation by a licensed psychologist or psychiatrist that documents the absence of significant psychopathology that can limit the patient's understanding of the procedure or the ability to comply with medical/surgical recommendations and to adhere to required lifestyle modifications and follow up/social support. Psychologist/Psychiatrist must document the patient's suitability for the proposed bariatric surgery and the lifetime commitment required for a successful outcome.

#5 now reads "Appropriate medical work up may include a chest x-ray, upper gastrointestinal series, endoscopy, appropriate pre-op labs and ECG. A complete physical examination by the attending surgeon and an assessment of thyroid levels is required. If the patient has comorbid conditions (e.g. diabetes or cardiovascular disease) the patient must be capable of undergoing the procedure.

Statement under #6 now reads "The first five criteria must be met before seeking prior plan approval, the sixth must be met prior to surgery."

Other:

Description section revised. Medical term definitions and Reference sources added.

Notification given 10/6/08. Effective date 1/5/2009. (pmo)

- 3/2/09 A.2. under "When Covered" section revised as follows: "Morbid obesity (BMI \geq 35 associated with at least one of the problems listed in A.1.b. or BMI \geq 40) has been present for *at least the previous two* ~~four of the previous five~~ years;" (pmo)
- 1/5/10 Policy reformatted. CPT code 43775 effective January 1, 2010 added to Billing/Coding section. System Application Guidelines not updated due to conversion to the QMP real time database. (pmo)
- 4/27/10 Description section updated to include information regarding endoluminal bariatric procedures. Revised criteria for Revision Bariatric Surgery in the When Covered section. In the When Not Section, statement regarding Sleeve Gastrectomy revised to read: [it is not covered] either as a stand-alone procedure or as the first step in a planned staged procedure for high-risk, super-obese patients. Also added the statement: Surgery for Morbid Obesity [is not covered] As a cure for type 2 diabetes mellitus. Added "licensed clinical social worker" to the Policy Guidelines section. Notification given 4/27/2010 for effective date 8/3/2010. (adn)
- 12/21/10 Specialty Matched Consultant Advisory Panel review meeting 11/29/10. Policy accepted as written. (adn)
- 7/1/2011 Policy updated. New indication for "Sleeve gastrectomy" added to the list in Item III in the When Surgery for Morbid Obesity Is Covered section. The reference to sleeve gastrectomy, item 2.f. in the Not Covered section, was deleted. (adn)
- 5/29/12 Specialty Matched Consultant Advisory Panel 5/16/12. No change to policy statement. (sk)
- 11/13/12 Reference added. Description Section updated with information about type II diabetes mellitus following bariatric surgery. Added Related Policy. Criteria for Adolescents revised. Policy Guidelines updated to include information on Adolescents. Medical Director review. (sk)
- 12/11/12 Added "Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)" to the When Surgery for Morbid Obesity is Not Covered section. Added information related to 2-stage bariatric surgery procedures to the Policy Guidelines section. Notification given 12/11/12. Policy effective 3/12/13. (sk)
- 7/1/13 Medical Director review. Removed the following statement from the When Covered section "Morbid obesity (BMI $>$ 35 associated with at least one of the problems listed in A.2. or BMI $>$ 40) has been present for at least the previous two years". Clarified Revision Bariatric Surgery criteria in Section IV. Added "erosion" and "and band slippage that cannot be corrected with manipulation or adjustments" to the statement in IV.A. Added "or dilation proximal to an adjustable gastric band" to IV.B. Deleted "and the patients still meets criteria (BMI) for bariatric surgery" in IV.B. Under the When Not Covered section deleted the following statement; "If it is

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determined that the surgery for morbid obesity is not medically necessary or investigational, and the gallbladder is removed during the same operative session, the removal of the gallbladder would not be covered.”. Clarified General Criteria for Adults and Adolescents in the Policy Guidelines. Statements added to clarify guideline; “Patients with a BMI greater than or equal to 50 kg/m² need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m². Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.” and “Patients who undergo adjustable gastric banding and fail to achieve weight loss must show evidence of post-operative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.” Updated the paragraph that begins with the US. Food and Drug Administration (FDA) premarket approval statement for the LAP-Band. (sk/btw)

- 7/1/13 Added the following to the General Criteria for Adults and Adolescents in the Policy Guidelines section; “5. To determine whether or not patients have responded to conservative measures for weight reduction, patients must have been active participants in non-surgical weight reduction programs that include frequent, e.g., monthly, documentation of weight, dietary regimen, and exercise, for at least 6 months prior to consideration for bariatric surgery. These conservative attempts must be reviewed by the practitioner seeking approval for the surgical procedure.” Notification given 7/1/2013, policy effective 9/10/2013. (btw)
- 7/15/14 References added. Specialty Matched Consultant Advisory Panel review 5/14/2014. Coverage criteria for long limb Roux-en-Y and biliopancreatic bypass with duodenal switch added to When Covered section. Under Revision Bariatric Surgery in When Covered section, additional criteria added at C. Under When Not Covered section, removed biliopancreatic bypass and Roux-en-Y for failed Nissen Fundoplasty from list. Added "Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding" to When Not Covered section. Clarification added to nutritional evaluation guidelines. Requirement that patient be an active participant in non-surgical weight reduction program for at least 6 months prior to surgery removed. (sk)
- 2/10/15 Information on laparoscopic gastric plication added to Description section. Reference added. No change to Policy statement. (sk)
- 3/10/15 Outdated hyperlink updated under Policy Guidelines #3. (sk)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/15. (sk)
- 12/30/15 References added. Vagal nerve blocking therapy added to When Not Covered section. Notification given 12/30/2015 for policy effective date 2/29/2016. (sk)
- 4/1/16 References added. Policy Guidelines updated. Single anastomosis duodenoileal bypass with sleeve gastrectomy added to list of investigational procedures. Code 44202 added to Billing/Coding section. (sk)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Reference added. Information regarding the AspireAssist® device added to Description section. Surgically-placed gastric tubes intended to drain a portion of the stomach contents added to When Not Covered section. (sk)
- 7/26/16 Added codes 47379 and 49329 to Billing/Coding section. Policy noticed 7/26/2016 for effective date 9/30/2016. (sk)
- 10/25/16 Specialty Matched Consultant Advisory Panel review 11/2016. Under Benefits Application section, added statements “Benefits are provided for surgical treatment of morbid obesity (bariatric surgery) if the individual has a BMI ≥ 40 or BMI ≥ and has a significant comorbid condition including but not limited to diabetes mellitus, hypertension, sleep apnea, hyperlipidemia, severe osteoarthritis, metabolic syndrome, NASH etc., and has demonstrated evidence of attempts to lose weight through non-surgical means. These methods include follow up with medical provider for weight related comorbid conditions, and/or behavioral counseling, and/or nutritional

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counseling and/or physical activity through a professional qualified to provide these services or through a proprietary weight loss program. Please refer to the section below “When Surgery for Morbid Obesity is covered” and “Policy Guidelines” for detailed medical necessity criteria. “Judgement regarding the scope, depth, and adequacy of pre-surgical treatment during the 12 months prior to surgery is at the discretion of the multidisciplinary weight loss surgery team, and BCBSNC does not specify the content of the treatment..” Notification given 10/25/2016 for policy effective date 1/1/2017. (sk)

- 6/30/17 References added. Vagal nerve changed to vagus nerve throughout policy. Extensive wording changes to When Surgery for Morbid Obesity is Not Covered section. Policy Guidelines extensively updated. No changes to Policy intent. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 1/26/18 Medical Director review. When Not Covered section revised to a list format for additional clarity. Natural Orifice Transluminal Endoscopic Surgery added to list. (sk)
- 6/29/18 References added. Policy Guidelines updated. Endocrine Society published recommendations updated. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 7/1/19 References added. Regulatory Status updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)
- 7/1/19 Added the following to the Billing/Coding section: “Hernia repair (43280, 43281, 43332, 43334, 43336) is considered an incidental procedure when performed during the same operative session as bariatric surgery (43644, 43645, 43770, 43775, 43842, 43843, 43845, 43846, 43847). Modifiers 58, 59, 78 and 79 (or XE, XS, XP, XU) will not allow additional payment when appended to these codes. An incidental procedure is not eligible for separate reimbursement. See also corporate medical policy “Bundling Guidelines”. Notification given 7/1/2019 for policy effective date 8/30/2019. (sk)
- 12/10/19 Benefit language revised to remove requirement of one year conservative medical management prior to bariatric surgery. Title of policy changed to “Bariatric Surgery”. (sk)
- 6/23/20 References added. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)
- 8/25/20 Medical Director review. Updated Policy Guideline #4 for consistency with established 2019 Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures. (sk)
- 10/27/20 Medical Director review. Description section updated. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) added to list of covered procedures. Code 43999 added to Billing/Coding section. (sk)
- 5/18/21 References added. Policy guidelines updated. Specialty Matched Consultant Advisory Panel review 4/21/2021. (sk)
- 12/30/21 Medical Director review. Added nonalcoholic steatohepatitis (NASH) to list of covered comorbidities. (sk)
- 6/14/22 Reference added. Specialty Matched Consultant Advisory Panel review 4/20/2022. (sk)
- 6/30/22 References added. Medical Director review. Amended statement 5 on page 2 by adding the words “one anastomosis gastric bypass (OAGB)” and removing the words “mini gastric bypass”. Code 43659 added. The following statements were added: “One anastomosis gastric bypass (OAGB) is a “combined procedure”, and it has both a “restrictive” and a “malabsorptive” component”, “The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) issued a position statement on the role of one anastomosis gastric bypass (OAGB) in the field of bariatric/metabolic surgery in 2018. In order to avoid confusion between the Billroth II

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Gastrojejunostomy and the Roux en Y procedure, OAGB has been recommended as the preferred terminology”, and “The unlisted stomach code, CPT 43659, is most appropriate for the OAGB at this time”. On page 7 under When Bariatric Surgery is covered, added “One anastomosis gastric bypass (OAGB) using the Billroth II gastrojejunostomy with gastric partitioning”. On page 8 under When Bariatric Surgery is not covered, removed “Gastric bypass using a Billroth II type of anastomosis, popularized as the mini gastric bypass”. (sk)

- 12/30/22 Medical Director review. Replaced code 43659 with code 43645 in paragraph describing OAGB. Deleted “The unlisted stomach code, CPT 43659, is most appropriate for the OAGB at this time” from the same paragraph. Deleted “There is no specific code describing the Mini-Gastric Bypass or OAGB (one anastomosis gastric bypass) procedures. Providers should bill the most appropriate unlisted code (i.e., CPT code 43659)” from the Billing/Coding section. Under Malabsorptive Procedures #2, replaced code 43999 with code 43659. Deleted codes 0312T, 0313T, 0314T, 0315T, 0316T, 0317T from Billing/Coding section. Added codes 43290, 43291 to Billing/Coding section. (sk)
- 6/30/23 Policy updated with terminology change from “morbid” obesity to “Class III” obesity. Description section updated. Regulatory Status updated. Other Therapies updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 4/19/2023. Added codes C9784 and C9785 to Billing/Coding section. Medical Director review. (sk)
- 11/7/23 Policy Guidelines section updated to remove “an assessment of thyroid levels is required” from A thorough preoperative evaluation. No change to coverage criteria. Medical Director Review. (rp)
- 12/29/23 New CPT code 0813T added to the Billing/Coding section effective 01/01/2024. (rp)
- 5/1/24 Reference added. Specialty Matched Consultant Advisory Panel review 4/2024. Medical Director review 4/2024. (rp)

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