

Coverage Policy Manual**Policy #:** 1998118**Category:** Surgery**Initiated:** May 1998**Last****Review:** March 2022**Surgery for Morbid Obesity**

Description: Surgery for morbid obesity, termed 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 gastrointestinal tract. Some bariatric procedures may include both a restrictive and a malabsorptive component.

Bariatric surgery is performed for the treatment of morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m² or a BMI greater than 35 kg/m² with associated complications including, but not limited to, diabetes, hypertension, cardiopulmonary conditions or obstructive sleep apnea. Morbid obesity results in a very high risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectum, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. The majority of patients find it difficult to comply with these lifestyle modifications on a long-term basis.

When conservative measures fail, some patients may consider surgical approaches. A 1991 National Institutes of Health (NIH) Consensus Conference defined surgical candidates as those patients with a BMI* of greater than 40 kg/m², or greater than 35 kg/m² in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes. (*See Policy Guidelines on how to calculate BMI.)

Resolution (cure) or improvement of type 2 diabetes mellitus after bariatric surgery and observations that glycemic control may improve immediately after surgery, before a significant amount of weight is lost, have promoted interest in a surgical approach to treatment of type 2 diabetes. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional anti-diabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (1GLP-1), glucose-dependent 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 this country but has more recently declined in popularity. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the

latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

2. Adjustable Gastric Banding (CPT code 43770—laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device [e.g., gastric band and subcutaneous port components])

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

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

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

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

3. Open Gastric Bypass (CPT code 43846—gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb [150 cm or less] Roux-en-Y gastroenterostomy)

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." Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications compared to other gastric restrictive procedures, including iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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 alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to

distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

4. Laparoscopic Gastric Bypass (CPT code 43644"laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy [roux limb 150 cm or less])

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

5. Mini-Gastric Bypass (no specific CPT code)

Recently, a variant of the gastric bypass, called the mini-gastric bypass, has been popularized. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. This unique aspect of this procedure is not based on its laparoscopic approach but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

6. Sleeve gastrectomy (CPT code 43775 "laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy [i.e., sleeve gastrectomy])

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

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

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

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 Procedure(also known as the Scopinaro procedure) (CPT code 43847" gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

Biliopancreatic bypass (BPB) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPB consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components.

- A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
- A 200 cm long alimentary tract consists of 200cm of ileum connecting the stomach to a common distal segment.
- A 300-400 cm biliary tract connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- A 50-100 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.
- Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to biliopancreatic bypass, including most prominently iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, there have been several case reports of liver failure resulting in death or liver transplant.

2. Biliopancreatic Bypass with Duodenal Switch (CPT code 43845 "gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy [50 to 100 cm common channel] to limit absorption [biliopancreatic diversion with duodenal switch])

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

3. Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847 "Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

Recently, variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (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 "Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)

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

**Policy/
Coverage:**

Bariatric surgery has contract limitations or is a contract exclusion in some member benefit certificates of coverage. The following Policy/Coverage statements apply to those members with contracts without these limitations and exclusions.

Note: This policy does not apply to members of the JB Hunt Plan. Please refer to the JB Hunt Transport Services, Inc. Summary Plan Document for specific benefit criteria for bariatric surgery.

Note: For ASE/PSE members prior to January 1, 2023, there is no coverage for bariatric procedures except for those members enrolled in the Bariatric Pilot Program. During time-periods when the enrollment into the Bariatric Pilot Program, is suspended, non-coverage of bariatric surgery services for ASE/PSE members is based on an exclusion in the Summary Plan Description (SPD).

Note: Beginning January 1, 2023, for bariatric services for ASE/PSE members, please see the member's Summary Plan Description (SPD) and Coverage Policy 2023001.

Note: For members of the Arkansas Blue Cross Blue Shield Health Advantage Self-Insured, Employee Group, please refer to the member's Summary Plan Description for requirements and eligibility criteria for services related to bariatric surgery.

Effective April 15, 2023

Any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration (FDA) approved indications.

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

I. The use of the below bariatric surgical procedures meet primary coverage criteria and are allowed when all of the following criteria are met for an adult individual [\geq 18 years old]:

A. The recommended surgery is **one** of the following procedures:

1. Biliopancreatic bypass with duodenal switch
2. Laparoscopic adjustable gastric banding
3. Roux-en-Y procedure up to 150 cm
4. Sleeve gastrectomy
5. Vertical banded gastroplasty; **AND**

B. Either of the below criteria:

1. Past participation in a weight loss program; pre-operative medical and mental health evaluations and clearances; pre-operative education which addresses the risks, benefits, realistic expectations and the need for long-term follow-up and adherence to behavioral modifications; and a treatment plan which addresses the pre and post-operative needs of an individual undergoing bariatric surgery; **OR**
2. Completion of a multidisciplinary surgical preparatory regimen, **AND**

C. The following eligibility criteria are met:

1. Morbid obesity (class III obesity as defined by BMI > 40, **OR**
2. Morbid obesity (class II obesity as defined by BMI > 35 to 39.9 with one or more of the following comorbid conditions:
 1. Type 2 diabetes mellitus, **OR**
 2. Cardiovascular disease as defined by one or more of the following documented diagnoses (including but not limited to): prior cerebrovascular infarction/hemorrhage, prior myocardial infarction, prior coronary artery bypass surgery, prior coronary artery stenting, prior ischemic cardiomyopathy, prior congestive heart failure, prior diagnosis of ischemic peripheral artery disease (e.g. claudication, prior stenting, and/or prior vascular surgery), **OR**
 3. Uncontrolled hypertension as defined by an average BP >140/90 on combination pharmacotherapy, **OR**
 4. Severe obstructive sleep apnea as defined by polysomnography with an AHI or RDI > 30; **AND**

D. There is no prior history of a bariatric surgical procedure

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery meets member benefit certificate primary coverage criteria for patients who have a pre-operatively diagnosed hiatal hernia with indications for surgical repair. **(Effective November 2014)**

For members with contracts without a bariatric surgery benefit, if a hiatal hernia repair is done concomitantly with a bariatric procedure, there is no coverage for either procedure **(Effective August 2017)**.

II. Revision Bariatric Surgery

A. Revision surgery as second surgeries or surgical interventions meeting medical necessity to manage a complication of a prior bariatric surgery procedure that was performed under the approval of the Plan are covered services. [e.g. this second surgery may require an intervention that is also performed for bariatric purposes such as to treat refractory Gastro Esophageal Reflux Disease following a sleeve bariatric procedure, a Roux-en-Y may be undertaken). **The complication must be from one of the above covered primary procedures.**

Does Not Meet Medical Necessity Or Is Investigational

The following procedures do not meet member benefit certificate medical necessity that there be scientific evidence of effectiveness in improving health outcomes:

- o Revision or second bariatric surgeries or surgical interventions not described above;
- o Revision or second bariatric surgery procedures, whether as a result of a prior surgery performed under the approval of the Plan or procured otherwise are **not covered**;
- o Revision or second bariatric surgery procedures or surgical interventions to manage complications of prior non-covered procedures are **not covered**.
- o Small bowel bypass procedures as stand-alone procedures;
- o Gastric wrapping;
- o The Garren-Edwards gastric bubble or any similar device;
- o Mini gastric bypass (one anastomosis gastric bypass);
- o Jejunioileal bypass;
- o Biliopancreatic bypass without duodenal switch;
- o Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera IntraGastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks;
- o Long-limb gastric bypass (greater than 150cm);
- o Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014);
- o Laparoscopic gastric plication (Effective November 2014);
- o Vagus (or vagal) nerve blocking devices;
- o Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016);
- o All other bariatric procedures not listed as covered.

For members with contracts without primary coverage criteria the services are considered investigational:

- o Revision (second) bariatric surgery procedures, whether as a result of a prior surgery performed under the approval of the Plan or procured otherwise;
- o Small bowel bypass procedures as stand-alone procedures;
- o Gastric wrapping;
- o The Garren-Edwards gastric bubble or any similar device;
- o Mini gastric bypass (one anastomosis gastric bypass);
- o Jejunioileal bypass;
- o Biliopancreatic bypass without duodenal switch;
- o Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera IntraGastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks;
- o Long-limb gastric bypass (greater than 150cm);

- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014);
- Laparoscopic gastric plication (Effective November 2014);
- Vagus (or vagal) nerve blocking devices;
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016);
- All other bariatric procedures not listed as covered.

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Effective November 2022 through April 14, 2023

Any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration (FDA) approved indications.

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Open or laparoscopic Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, or Open or laparoscopic biliopancreatic bypass (ie, Scopinaro procedure) with duodenal switch (DS) meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness when ALL of the following criteria are met:

- Patients with morbid obesity with a Body Mass Index (BMI) greater than or equal to 40; **AND**
- Have failed a structured weight loss or diet program in the 2 years preceding the request for surgical treatment of morbid obesity
- Must have completed **one** structured weight loss or diet program for 6 consecutive months or **two** for 3 consecutive months **AND**
- The weight loss or diet program may be either a medical program or a commonly available program (e.g., including but not limited to Weight Watchers, Jenny Craig or Metabolic Research Center); **AND**
- Are well-motivated and understand the risks of the surgery and the restricted eating habits which follow the gastric restrictive or bypass surgery; **AND**
- Are over the age of 20.

Open or laparoscopic Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, or Open or laparoscopic biliopancreatic bypass (ie, Scopinaro procedure) with duodenal switch (DS) meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness for **adolescents (age 13-20 years)** when **ALL** the following criteria are met:

- BMI of 35 kg/m² (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant disease (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri or any life threatening or serious medical condition that is weight induced), **OR**
- BMI of 40 kg/m² (or 140% of the 95th percentile for age and sex, whichever is lower) with commonly present though not required comorbidities (e.g., hypertension, dyslipidemias, gastroesophageal reflux); **AND**
- Had unsuccessful physician-monitored weight loss attempts for at least 6 months; **AND**
- Has achieved 95% or more of his/her adult height by determination of bone age; **AND** A psychological assessment to determine decision-making capacity, ability to give informed consent, and willingness to adhere to requirements of postoperative care.

Body Mass Index of 35 to 39

Patients with Body Mass Index of 35 - 39 may be considered for coverage if they meet the other criteria above, and have high-risk co-morbid conditions (e.g., uncontrolled diabetes mellitus, uncontrolled obstructive sleep apnea as defined in the sleep apnea policy, uncontrolled hypertension, uncontrolled hyperlipidemia, pseudotumor cerebri).

Biliopancreatic Diversion with Duodenal Switch

Biliopancreatic diversion with duodenal switch for treatment of obesity that has not responded to conservative measures meets primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for members with BMI \geq 50.

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery meets member benefit certificate primary coverage criteria for patients who have a pre-operatively diagnosed hiatal hernia with indications for surgical repair. **(Effective November 2014)**

For members with contracts without a bariatric surgery benefit, if a hiatal hernia repair is done concomitantly with a bariatric procedure, there is no coverage for either procedure (**Effective August 2017**).

ASE/PSE Members

For **ASE/PSE** members with a health plan that is offered, issued or renewed on or after January 1, 2012, services for bariatric surgery are covered **only for those members enrolled in the Bariatric Pilot Program during a time period when the pilot program is open for enrollment. Program requirements and eligibility criteria in the member's Summary Plan Description (SPD) must be followed.** Coverage for bariatric surgery for these members includes:

- Gastric bypass surgery;
- Adjustable gastric banding surgery;
- Sleeve gastrectomy surgery; and
- Duodenal switch biliopancreatic diversion.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The following procedures do not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass (one anastomosis gastric bypass)
- Jejunioleal bypass
- Biliopancreatic bypass without duodenal switch
- Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera Intragastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass (greater than 150cm)
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- Laparoscopic gastric plication (Effective November 2014)
- Vagus (or vagal) nerve blocking devices
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)
- All other bariatric procedures not listed as covered

For members with contracts without primary coverage criteria the following services are considered investigational:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass (one anastomosis gastric bypass)
- Jejunioleal bypass
- Biliopancreatic bypass without duodenal switch
- Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera Intragastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass (greater than 150cm)
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- Laparoscopic gastric plication (Effective November 2014)
- Vagus (or vagal) nerve blocking devices
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)
- All other bariatric procedures not listed as covered

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Policy Guidelines:**Patient Selection Criteria**

Morbid obesity is defined as a body mass index (BMI) 40 kg/m² or more or a BMI 35 kg/m² or more with at least 1 clinically significant obesity-related disease such as diabetes, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

While there are limited evidence on which to assess the long-term impacts of bariatric surgery for patients younger than age 18 years, severely obese (BMI \geq 40 kg/m² or 140% of the 95th percentile for age and sex, whichever is lower) adolescents with commonly present though not required comorbidities, or who have a BMI of 35 kg/m² or greater (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant disease may be considered for bariatric surgery according to the American Academy of Pediatrics (Armstrong et al, 2019). U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND® System indicates it is intended for severely obese adults. (The clinical study submitted to FDA for approval of the LAP-BAND was restricted to adults ages 18-55 years.)

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.

Patients with a BMI of 50 kg/m² or more need a bariatric procedure to achieve greater weight loss. Thus, the use of adjustable gastric banding, which results in less weight loss, should be most useful as a procedure for patients with a 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.

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.

Policy History:**Effective August 2021 through October 2022**

Any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration (FDA) approved indications.

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness when ALL of the following criteria are met:

- o Patients with morbid obesity with a Body Mass Index (BMI) greater than or equal to 40; **AND**
- o Have failed a structured weight loss or diet program in the 2 years preceding the request for surgical treatment of morbid obesity
- o Must have completed **one** structured weight loss or diet program for 6 consecutive months or **two** for 3 consecutive months **AND**
- o The weight loss or diet program may be either a medical program or a commonly available program (e.g., including but not limited to Weight Watchers, Jenny Craig or Metabolic Research Center); **AND**
- o Are well-motivated and understand the risks of the surgery and the restricted eating habits which follow the gastric restrictive or bypass surgery; **AND**
- o Are over the age of 20.

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness for **adolescents (age 13-20 years)** when **ALL** the following criteria are met:

- o BMI of 35 kg/m² (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant disease (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri or any life threatening or serious medical condition that is weight induced), **OR**
- o BMI of 40 kg/m² (or 140% of the 95th percentile for age and sex, whichever is lower) with commonly present though not required comorbidities (e.g., hypertension, dyslipidemias, gastroesophageal reflux); **AND**
- o Had unsuccessful physician-monitored weight loss attempts for at least 6 months; **AND**

- Has achieved 95% or more of his/her adult height by determination of bone age; **AND** A psychological assessment to determine decision-making capacity, ability to give informed consent, and willingness to adhere to requirements of postoperative care.

Body Mass Index of 35 - 39

Patients with Body Mass Index of 35 - 39 may be considered for coverage if they meet the other criteria above, and have high-risk co-morbid conditions (e.g., uncontrolled diabetes mellitus, uncontrolled obstructive sleep apnea as defined in the sleep apnea policy, uncontrolled hypertension, uncontrolled hyperlipidemia, pseudotumor cerebri).

Biliopancreatic Diversion with Duodenal Switch

Biliopancreatic diversion with duodenal switch for treatment of obesity that has not responded to conservative measures meets primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for members with BMI \geq 50.

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery meets member benefit certificate primary coverage criteria for patients who have a pre-operatively diagnosed hiatal hernia with indications for surgical repair. **(Effective November 2014)**

For members with contracts without a bariatric surgery benefit, if a hiatal hernia repair is done concomitantly with a bariatric procedure, there is no coverage for either procedure **(Effective August 2017)**.

ASE/PSE Members

For **ASE/PSE** members with a health plan that is offered, issued or renewed on or after January 1, 2012, services for bariatric surgery are covered **only for those members enrolled in the Bariatric Pilot Program during a time period when the pilot program is open for enrollment. Program requirements and eligibility criteria in the member's Summary Plan Description (SPD) must be followed.** Coverage for bariatric surgery for these members includes:

- Gastric bypass surgery;
- Adjustable gastric banding surgery;
- Sleeve gastrectomy surgery; and
- Duodenal switch biliopancreatic diversion.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The following procedures do not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass (one anastomosis gastric bypass)
- Jejunioileal bypass
- Biliopancreatic bypass without duodenal switch
- Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera IntraGastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass (greater than 150cm)
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- Laparoscopic gastric plication (Effective November 2014)
- Vagus (or vagal) nerve blocking devices
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)
- All other bariatric procedures not listed as covered

For members with contracts without primary coverage criteria the following services are considered investigational:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass (one anastomosis gastric bypass)
- Jejunioileal bypass

- o Biliopancreatic bypass without duodenal switch
- o Endoscopic procedures (e.g., insertion of the StomaphyX™,† device, AspireAssist, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, Orbera IntraGastric Balloon System or the Transpyloric Shuttle, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- o Long-limb gastric bypass (greater than 150cm)
- o Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- o Laparoscopic gastric plication (Effective November 2014)
- o Vagus (or vagal) nerve blocking devices
- o Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)
- o All other bariatric procedures not listed as covered

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Effective March 2021 through July 2021

Any devices used for bariatric surgery must be used in accordance with the U.S. Food and Drug Administration (FDA) approved indications.

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness when ALL of the following criteria are met:

- o Patients with morbid obesity with a Body Mass Index (BMI) greater than or equal to 40; **AND**
- o Have failed a structured weight loss or diet program in the 2 years preceding the request for surgical treatment of morbid obesity
- o Must have completed **one** structured weight loss or diet program for 6 consecutive months or **two** for 3 consecutive months **AND**
- o The weight loss or diet program may be either a medical program or a commonly available program (e.g., including but not limited to Weight Watchers, Jenny Craig or Metabolic Research Center); **AND**
- o Are well-motivated and understand the risks of the surgery and the restricted eating habits which follow the gastric restrictive or bypass surgery; **AND**
- o Are over the age of 20.

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness for **adolescents (age 13-20 years)** when **ALL** the following criteria are met:

- o BMI of 35 kg/m² (or 120% of the 95th percentile for age and sex, whichever is lower) with clinically significant disease (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri or any life threatening or serious medical condition that is weight induced), **OR**
- o BMI of 40 kg/m² (or 140% of the 95th percentile for age and sex, whichever is lower) with commonly present though not required comorbidities (e.g., hypertension, dyslipidemias, gastroesophageal reflux); **AND**
- o Had unsuccessful physician-monitored weight loss attempts for at least 6 months; **AND**
- o Has achieved 95% or more of his/her adult height by determination of bone age; **AND** A psychological assessment to determine decision-making capacity, ability to give informed consent, and willingness to adhere to requirements of postoperative care.

Body Mass Index of 36 – 39

Patients with Body Mass Index of 36 - 39 may be considered for coverage if they meet the other criteria above, and have high-risk co-morbid conditions (e.g., uncontrolled diabetes mellitus, uncontrolled obstructive sleep apnea as defined in the sleep apnea policy, uncontrolled hypertension, uncontrolled hyperlipidemia).

Biliopancreatic Diversion with Duodenal Switch

Biliopancreatic diversion with duodenal switch for treatment of obesity that has not responded to conservative measures meets primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for members with BMI \geq 50.

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery meets member benefit certificate primary coverage criteria for patients who have a pre-operatively diagnosed hiatal hernia with indications for surgical repair. **(Effective November 2014)**

For members with contracts without a bariatric surgery benefit, if a hiatal hernia repair is done concomitantly with a bariatric procedure, there is no coverage for either procedure **(Effective August 2017)**.

ASE/PSE Members

For **ASE/PSE** members with a health plan that is offered, issued or renewed on or after January 1, 2012, services for bariatric surgery are covered **only for those members enrolled in the Bariatric Pilot Program during a time period when the pilot program is open for enrollment. Program requirements and eligibility criteria in the member's Summary Plan Description (SPD) must be followed.** Coverage for bariatric surgery for these members includes:

- o Gastric bypass surgery;
- o Adjustable gastric banding surgery;
- o Sleeve gastrectomy surgery; and
- o Duodenal switch biliopancreatic diversion.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The following procedures do not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

- o Small bowel bypass procedures as stand-alone procedures
- o Gastric wrapping
- o The Garren-Edwards gastric bubble or any similar device
- o Mini gastric bypass
- o Biliopancreatic bypass without duodenal switch
- o Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- o Long-limb gastric bypass
- o Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- o Laparoscopic gastric plication (Effective November 2014)
- o Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)
- o All other bariatric procedures not listed as covered

For members with contracts without primary coverage criteria the following services are considered investigational:

- o Small bowel bypass procedures as stand-alone procedures
- o Gastric wrapping
- o The Garren-Edwards gastric bubble or any similar device
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- o Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
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- o Laparoscopic gastric plication (Effective November 2014)
- o Single anastomosis duodenoileal bypass with sleeve gastrectomy (Effective March 2016)

- o All other bariatric procedures not listed as covered

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Effective January 1, 2019 to March 2021

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness when ALL of the following criteria are met:

- Patients with morbid obesity with a Body Mass Index (BMI) greater than or equal to 40; **AND**
- Have failed a structured weight loss or diet program in the 2 years preceding the request for surgical treatment of morbid obesity
- Must have completed **one** structured weight loss or diet program for 6 consecutive months or **two** for 3 consecutive months **AND**
- The weight loss or diet program may be either a medical program or a commonly available program (e.g., including but not limited to Weight Watchers, Jenny Craig or Metabolic Research Center); **AND**
- Are well-motivated and understand the risks of the surgery and the restricted eating habits which follow the gastric restrictive or bypass surgery; **AND**
- Are over the age of 20.

Roux-en Y gastroenterostomy, sleeve gastrectomy or LAP-BAND or Realize adjustable gastric banding, meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness for **adolescents (age 13-20 years)** when ALL of the following criteria are met:

- BMI of 40 kg/m² or more with serious comorbidities (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri or any life threatening or serious medical condition that is weight induced), **OR**
- BMI of 50 kg/m² or more with less severe comorbidities (e.g., hypertension, dyslipidemias, gastroesophageal reflux); **AND**
- Had unsuccessful physician-monitored weight loss attempts for at least 6 months; **AND**
- Has achieved 95% or more of his/her adult height by determination of bone age; **AND**
- A psychological assessment to determine decision-making capacity, ability to give informed consent, and willingness to adhere to requirements of postoperative care.

Biliopancreatic Diversion with Duodenal Switch

Biliopancreatic diversion with duodenal switch for treatment of obesity that has not responded to conservative measures meets primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for members with BMI \geq 50.

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery meets member benefit certificate primary coverage criteria for patients who have a preoperatively-diagnosed hiatal hernia with indications for surgical repair. **(Effective November 2014)**

For members with contracts without a bariatric surgery benefit, if a hiatal hernia repair is done concomitantly with a bariatric procedure, there is no coverage for either procedure **(Effective August, 2017)**.

Body Mass Index of 36 - 39

Patients with Body Mass Index of 36 - 39 may be considered for coverage if they meet the other criteria above, and have high-risk co-morbid conditions (e.g., uncontrolled diabetes mellitus, uncontrolled obstructive sleep apnea as defined in the sleep apnea policy, uncontrolled hypertension, uncontrolled hyperlipidemia).

For **ASE/PSE** members with a health plan that is offered, issued or renewed on or after January 1, 2012, services for bariatric surgery are covered **only for those members enrolled in the Bariatric Pilot Program during a time period when the pilot program is open for enrollment. Program requirements and eligibility criteria in the member's Summary Plan Description (SPD) must be followed.** Coverage for bariatric surgery for these members includes:

- Gastric bypass surgery;
- Adjustable gastric banding surgery;

- Sleeve gastrectomy surgery; and
- Duodenal switch biliopancreatic diversion.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The following procedures do not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass
- Biliopancreatic bypass without duodenal switch
- Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- Laparoscopic gastric plication (Effective November 2014)
- Single anastomosis duodenal bypass with sleeve gastrectomy (Effective March 2016)
- All other bariatric procedures not listed as covered

For members with contracts without primary coverage criteria the following services are considered investigational:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
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- Biliopancreatic bypass without duodenal switch
- Endoscopic procedures (e.g., insertion of the StomaphyX[®] device, insertion of a gastric balloon, including but not limited to the Obalon Balloon System, endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair (Effective November 2014)
- Laparoscopic gastric plication (Effective November 2014)
- Single anastomosis duodenal bypass with sleeve gastrectomy (Effective March 2016)
- All other bariatric procedures not listed as covered

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Effective Prior to January 1, 2019

Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Vertical banded gastroplasty, Roux-en Y gastroenterostomy, LAP-BAND or Realize adjustable gastric banding, or sleeve gastrectomy meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness when ALL of the following criteria are met:

- Patients with morbid obesity with a Body Mass Index (BMI) greater than or equal to 40; AND
- Have failed a structured weight loss program; AND
- Are well-motivated and understand the risks of the surgery and the restricted eating habits which follow the gastric restrictive or bypass surgery; AND
- Are over the age of 20.

Vertical banded gastroplasty, Roux-en Y gastroenterostomy, LAP-BAND or Realize Adjustable gastric banding, or sleeve gastrectomy meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness for **adolescents (age 13-20 years)** when ALL of the following criteria are met:

- o BMI of 40 kg/m² or more with serious comorbidities (e.g., type 2 diabetes mellitus, obstructive sleep apnea, pseudotumor cerebri), OR
- o BMI of 50 kg/m² or more with less severe comorbidities (e.g., hypertension, dyslipidemias, gastroesophageal reflux); AND
- o Had unsuccessful physician-monitored weight loss attempts for at least 6 months; AND
- o Has achieved 95% or more of his/her adult height by determination of bone age; AND
- o A psychological assessment to determine decision-making capacity, ability to give informed consent, and willingness to adhere to requirements of postoperative care.

For **ASE/PSE** members with a health plan that is offered, issued or renewed on or after January 1, 2012, services for bariatric surgery are covered. Coverage for bariatric surgery includes:

- Gastric bypass surgery;
- Adjustable gastric banding surgery;
- Sleeve gastrectomy surgery; and
- Duodenal switch biliopancreatic diversion.

Patients with Body Mass Index of 36 - 39 may be considered for coverage if they meet the other criteria above, and have high-risk co-morbid conditions (e.g., uncontrolled diabetes mellitus, uncontrolled obstructive sleep apnea as defined in the sleep apnea policy, uncontrolled hypertension, uncontrolled hyperlipidemia).

Biliopancreatic diversion with duodenal switch for treatment of obesity that has not responded to conservative measures meets primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes for members with BMI \geq 50.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

The following procedures do not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass
- Biliopancreatic bypass without duodenal switch
- 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, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass

For members with contracts without primary coverage criteria the following services are considered investigational:

- Small bowel bypass procedures as stand-alone procedures
- Gastric wrapping
- The Garren-Edwards gastric bubble or any similar device
- Mini gastric bypass
- Biliopancreatic bypass without duodenal switch
- 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, as primary surgical treatment for morbid obesity, or to repair gastric leaks
- Long-limb gastric bypass

Investigational services are specific contract exclusions in most member benefit certificates of coverage.

Due to the length of the policy, criteria for dates of service prior to January 2019, is not online. If you would like a hardcopy print, please email: codespecificinquiry@arkbluecross.com

Rationale:

Definition of Outcomes

Outcomes of bariatric surgeries are notoriously difficult to evaluate due in part to the constantly evolving nature of the surgery. Small modifications are commonly made to decrease the incidence of postoperative and long-term complications. In addition, other than one exception (discussed here), no controlled studies have directly measured the weight loss and complications associated with the

different surgical approaches, particularly comparing gastric restrictive procedures with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. The outcomes for specific surgeries may widely differ among institutions or surgeons, perhaps due to small variations in surgical technique, intensity of follow-up, or patient selection criteria. However, during the 1970s and 1980s both vertical-banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These 2 procedures were the focus of the 1991 NIH Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass. Therefore, vertical-banded gastroplasty and gastric bypass are considered the gold standards for the purpose of this discussion, and the results of these procedures will be compared to the newer procedures not addressed by the 1991 conference; i.e., gastric banding and biliopancreatic bypass with or without duodenal switch. The following outcomes are considered relevant for bariatric surgery:

Weight loss

There is no uniform standard for reporting results of weight loss, and no uniform standard 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 methods are generally preferred over the absolute amount of weight loss, since they reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. The following table summarizes the variation in reporting weight loss outcomes.

Outcome Measure	Definition	Clinical Significance
Decrease in weight outcomes, pre- and post-treatment	Absolute difference in weight especially in morbidly obese	Unclear relationship to
Decrease in BMI	Absolute difference in BMI	May be clinically significant if change pre- and post-treatment in BME clearly leads to change in risk category
% of excess weight loss clinical (%EWL) by excess body weight	Amount of weight loss divided by excess body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance
% patients. Losing >50% of EBW	No. patients losing >50% EBW	Additional advantage of framing on per divided by total patients. Patient basis. Threshold for significance (>50%) arbitrary %
ideal body weight Final weight divided by ideal weight	Has anchor to help frame clinical body weight significance; unclear threshold for clinical significance	

Durability of weight loss

Weight change (i.e., gain or loss) at yearly intervals is often reported. The weight loss with gastric restrictive procedures is thought to be less durable compared to malabsorptive procedures, due to the dilation of the gastric pouch.

Operative and peri-operative complications

There is an increased incidence of operative and peri-operative complications in obese patients in general and particularly in thromboembolism and problems with wound healing.

Reoperation rate

Reoperation may be required to either “take down” or revise the original procedure. Reoperation may be particularly common in vertical-banded gastroplasty due to pouch dilation.

Metabolic side effects

Metabolic side effects are of particular concern in malabsorptive procedures.

Final health outcomes in terms of complications of obesity

Aside from psychosocial concerns, which may be considerable, one of the motivations 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. (See further discussion in summary.)

Surgical Procedures

The following discussion provides a representative summary of the literature on bariatric surgery, focusing on improvements in co-morbidities of obesity.

Vertical-Banded Gastroplasty

As a representative example of a large case series with long-term follow-up, MacLean and colleagues reported on 201 patients who underwent vertical-banded gastroplasty and who were followed up for a minimum of 2 years. Staple line perforation occurred in 48% of patients and 36% underwent reoperation either to repair the perforation or to repair a stenosis at the rate limiting orifice. However, the more than 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight. The procedure was less successful in the super obese, defined as a BMI of $>50 \text{ kg/m}^2$, in whom only 8% achieved an excellent result. These results suggest that failures of vertical-banded gastroplasty are primarily technical in nature. Based on these results, the authors have altered their surgical technique by reinforcing the staple lines to reduce the incidence of perforation. It is this type of small change in surgical technique that can markedly affect results among different surgeons. In a 1987 case series of 305 patients undergoing vertical banded gastroplasty, there was a mean weight loss of 60% of excess weight at 2-year follow-up. In contrast to MacLean's report, there was only a 1.3% incidence of staple line disruption. Significant decreases in cardiovascular risk factors and incidence of diabetes and sleep apnea have also been reported. For example, Melissas and colleagues evaluated obesity's comorbid conditions in 62 patients who had undergone a vertical-banded gastroplasty. All patients were followed up for 12 to 48 months, with 84% of patients losing at least 50% of their excess weight. Of the 218 weight-related pathologic conditions existing before the operation, 83% were either cured or improved.

Gastric Bypass with Short Limb (<100 cm)

While vertical banded gastroplasty was perhaps the dominant bariatric surgery in the 1980s, it has been surpassed in this country by the gastric bypass procedure, based on a variety of studies that report improved weight loss with a gastric bypass procedure. For example, in 1990, Hall and colleagues reported on the results of a trial that randomized 310 morbidly obese patients to gastric bypass, vertical banded gastroplasty or horizontal gastroplasty. The percent of patients with greater than 50% excess weight loss at 3 years' follow-up was 67% for gastric bypass, 48% for vertical banded gastroplasty, and 17% for horizontal gastroplasty.

Griffen summarized the experience of over 10,000 gastric bypass operations from a number of bariatric surgeons. It was estimated that 85% of patients reduced their weight to at least 50% above the ideal weight. In about 5,000 patients who were followed up for 10 years, 80% were able to maintain this result. Pories and colleagues reported on 608 patients who underwent a gastric bypass procedure and were followed up for 1–14 years. One of the unique features of this report is that only 3% of patients were lost to follow-up. The average weight loss was 75% of excess weight at 1 year, declining to 50% by the eighth year. The authors observed an immediate drop in both blood glucose and exogenous insulin requirements after surgery. Long-term observation of 298 patients with preoperative diabetes or impaired glucose intolerance revealed that 91% had normal values for blood glucose and hemoglobin A1C after surgery. The incidence of hypertension declined from 58% before surgery to 14% after gastric bypass. Flickinger and colleagues reported on the incidence of diabetes and hypertension in a case series of 397 patients. Prior to surgery, 22% had diabetes mellitus and 13% had impaired glucose intolerance. After surgery, all but one of the patients remained euglycemic. A total of 57% of patients were hypertensive before surgery compared to only 18% after surgery. Similarly, Pories and colleagues reported that of 163 obese patients with diabetes or impaired glucose tolerances, only 5% remained with inadequate control after gastric bypass surgery and associated weight loss. Other studies have reported that gastric bypass surgery and weight loss are associated with improvements in the lipid profile.

In the 1 controlled trial reported, Sugeran and colleagues randomized 40 patients to receive either a vertical-banded gastroplasty or a gastric bypass procedure. After 9 months, the gastric bypass patients had significantly greater weight loss that persisted at 3-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight. In this study, technical differences could not explain the discrepancy, since small, intact gastric pouches were seen in patients who experienced unsuccessful vertical banded gastroplasty procedures. The authors hypothesized that the unpleasant dumping syndrome, seen most frequently in sweets eaters, may have been responsible for the increased success of the gastric bypass procedure. A nonrandomized study of 200 patients reported that gastric bypass and vertical-banded gastroplasty may be equally effective in achieving 40% excess weight loss, while a greater percentage of gastric bypass patients may achieve 50–60% of excess weight loss.

Metabolic abnormalities are seen more frequently in gastric bypass patients compared to those receiving a vertical-banded gastroplasty. Anemia, iron deficiency, vitamin B 12 deficiency, and red blood cell folate deficiency are commonly seen. Marginal ulcerations are also seen in gastric bypasses, particularly in those whose gastric pouches are too large and include acid-secreting parietal cells.

Laparoscopic gastric bypass is intended to reproduce the open procedure via minimally invasive techniques. This is a technically complex operation that requires a dedicated team and a relatively high degree of skill and experience in laparoscopic surgery. In addition, laparoscopic surgery is more difficult in general in obese patients compared to those closer to their ideal body weight. The data on the comparative efficacy of open versus laparoscopic bypass is limited by the lack of high-quality comparative studies, and the lack of systematic data collection on adverse events. Analysis of clinical series data suggests that weight loss at one year is similar for both procedures. However, the data raise concerns that serious short-term adverse events such as anastomotic leaks may be more frequent with the laparoscopic approach. The comparative rates of long-term adverse events cannot be reliably estimated from the available data.

The mini-gastric bypass has been primarily advocated by 1 surgeon. In 2001, Rutledge published his experience with 1,274 patients who underwent the mini-gastric bypass procedure. The mean operating time was 36 minutes, and the mean hospital stay was 1.5 days. Mean excess weight loss was 51% at 6 months, 68% at 12 months, and 77% at 2 years. The overall complication rate reported was 5.2%. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices away from the stomach.

Adjustable Gastric Banding

Adjustable gastric banding, using an externally adjustable band placed around the stomach, has been extensively used in Europe, and 1 such device, the Lap-Band, has received approval from the U.S. Food and Drug Administration (FDA) in this country. The procedure is designed to mimic the vertical-banded gastroplasty, but be an easier, reversible, and flexible surgery. Similar to all gastric surgeries, the literature is dominated by large case series from individual surgeons who report varying results. In addition, gastric-banding surgery is still an evolving procedure with issues of band migration addressed by altering the position of the band and band erosion addressed by stabilizing the placement of the band. Therefore, it is very difficult to compare one series to another. For example, in this country, Doherty and colleagues reported on an initial experience with adjustable gastric banding in 40 patients.

The authors reported an unacceptable reoperation rate of 80%, primarily due to technical problems with the subcutaneously implanted reservoir. While those with an intact gastric band achieved 41% excess weight loss, the authors concluded that revisions to the surgical procedure and improvements in the device itself must be implemented. In a subsequent study, the authors reported several surgical modifications, including location of the gastric band and modifications in the device itself. Also, the surgery was performed laparoscopically. Seven of the 22 patients (33%) required reoperation, a considerable improvement. In contrast to this American experience, as a representative example, Miller and Hell report a reoperation rate of only 7% in a case series of 158 patients. Median BMI decreased from 44 kg/m² preoperatively to 28 kg/m² after 36 months. Suter and colleagues compared vertical-banded gastroplasty with laparoscopic gastric banding in consecutive case series and reported that laparoscopic gastric banding was associated with significant decrease in postoperative morbidity, primarily due to a decrease in thromboembolism and wound infections. After 2 years of follow-up, there was no significant difference in weight loss between the 2 groups.

The data presented to the FDA as part of the FDA-approval process for the Lap-Band is summarized in the package insert. In a group of 299 patients, the mean excess weight loss was 36.2% at 3 years. This figure contrasts with a 40%–60% excess weight loss reported in other series of vertical-banded gastroplasty and 50% for gastric bypass. One of the challenges of vertical-banded gastroplasty is dilation of the pouch, which may prompt surgical revision. The Lap-Band procedure is intended to address this complication, as any pouch dilation can be altered by percutaneous adjustment of the inflatable band. The incidence of adjustment of the band or how this maneuver affected weight loss is not provided in the package insert. For example, although a 24% incidence of band slippage or pouch dilation was reported, it was not reported whether this complication was resolved with adjustment of the gastric band. There was a 9% incidence of surgical revision procedures and an additional 24% of patients had their entire LapBand systems explanted, most commonly due to band slippage or pouch dilation, but also due to erosion, infection, or gastrointestinal disorders. It is very difficult to compare complication rates between procedures. The surgical complication rate for bariatric surgery varies widely from surgeon to surgeon, and the results reported for individual case series, typical of the literature of gastric bypass and vertical-banded gastroplasty, may not reflect the overall experience, as reported for the Lap-Band. However, without any comparative data, it cannot be determined whether the Lap-Band, particularly with its adjustable feature, is equivalent or offers any advantage over the accepted standard of vertical-banded gastroplasty or gastric bypass.

Biliopancreatic Bypass

The largest experience with biliopancreatic bypass is reported by Scopinaro, who developed the procedure. In 1996, Scopinaro summarized his experience with 1,217 patients. The authors report that

during the first 3 to 4 months after the surgery, patients have decreased appetites related to the dumping syndrome. These symptoms regressed with time, to the point that the majority of patients could resume eating large meals, with most patients eating more than they did before the operation. With follow-up of up to 9 years, the authors reported a durable excess weight loss of 75%, suggesting that weight loss is greater with this procedure compared to gastric restrictive procedures. In addition, the vast majority of patients reported disappearance of improvement of such complications as obstructive sleep apnea, hypertension, hypercholesterolemia, and diabetes. The authors considered protein malnutrition the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity, and presumably eating habits, of the patients, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation, but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients are encouraged to maintain an oral calcium intake of 2 g daily, with monthly vitamin D supplementation.

Totte and colleagues in Belgium reported their experience with biliopancreatic bypass in 180 patients. Prior to surgery the mean BMI was 48.8 kg/m², falling to 28.8 kg/m² at 36 months, corresponding to about 70% of excess weight loss. Six patients (3.3%) experienced serious perioperative complications including acute dilation of the stomach, diffuse peritonitis, and acute pancreatitis. Late complications included incisional hernia in 17%, anastomotic ulcers in 10%, and severe protein malnutrition requiring total parenteral nutrition in 1.1%. Obesity-related complications, such as diabetes, hypertension, or arthritis, resolved or improved in all patients. Nanni and colleagues reported on a case series of 59 patients. Weight loss was similar, with 78% of excess weight loss after 2 years. Protein deficiency was noted in 2 (3.4%) patients.

The bulk of the experience with biliopancreatic bypass appears to be in Europe, particularly Italy. There are no case series reported in this country. According to Murr and colleagues, biliopancreatic bypass has not been widely accepted in this country due to unacceptable serious long-term morbidities. For example, biliopancreatic bypass has largely been abandoned at the Mayo Clinic due to the occurrence of steatorrhea, diarrhea, foul-smelling stools, severe bone pain, and the need for a life-long commitment to supplemental vitamins and minerals. In addition, there have been scattered case reports of liver damage, resulting either in death or liver transplant. In addition, Murr hypothesizes that the incidence of protein malnutrition may be higher in this country compared to Scopinaro's™ Italian series, since the North American diet has a higher percentage of fat and lesser amounts of carbohydrates.

Gastric Bypass with Long Limb (>100 cm)

As discussed in the Description section, the degree of malabsorption associated with long limb gastric bypass will vary with the length of the alimentary and biliary limbs. These modifications have been developed in an effort to decrease the metabolic side effects associated with biliopancreatic bypass. However, there has been limited reported experience. Murr reported on 26 patients who underwent a "very very long limb Roux-en-Y gastric bypass." In comparison to a case series of 11 patients who underwent biliopancreatic bypass, the authors reported similar weight loss but decreased metabolic or nutritional abnormalities, attributed in part to the increased length of the common segment, 100 cm, compared to 50 cm used in biliopancreatic bypass. Sugerman also attributes increasing the length of the common segment to decreasing metabolic morbidities.

Biliopancreatic Bypass with Duodenal Switch

The largest case series of the above procedure is reported by Marceau, who reported on 465 patients who underwent the duodenal switch procedure compared to 252 who underwent the biliopancreatic bypass. It should be noted that in addition to the preservation of the duodenum, the common segment was elongated to 100 cm. The authors noted similar weight loss in the 2 groups. Also, in the duodenal switch group, there was a lower incidence of metabolic abnormalities such as protein malnutrition, which prompted reversal of the procedure in 1.7% of those undergoing biliopancreatic bypass versus. Only 0.1% after the duodenal switch procedure. However, it is not known whether this outcome is attributed to the lengthening of the common segment versus retention of the pylorus. Hess reported on a case series of 440 patients with variable lengths of the common channel. The percentage excess weight loss varied between 60% and 90%, depending on the length of the common segment and alimentary limb. There were 2 late deaths, 1 due to septic shock secondary to an infected panniculus and 1 related to liver failure. A total of 10 patients underwent revision to lengthen the common segment secondary to low protein or excessive diarrhea. Seven patients underwent shortening of the common segment due to inadequate weight loss. Baltasar and colleagues reported on a case series of 60

patients undergoing the duodenal switch procedure with a common segment length of 75 cm. One patient succumbed to liver failure and another due to malnutrition. The authors questioned the safety of the procedure.

Bariatric Surgery in the Super Obese

Two comparative studies were identified that compared the outcomes of standard short limb gastric bypass with long limb gastric bypass. While both of these studies were considered to be of poor quality, due to non-comparability of groups, the reported % excess weight loss at 1 year was in the range of 55%–77%, similar to that seen with open gastric bypass. The limited data did not allow any conclusions about the comparative rates of complications of these procedures to standard gastric bypass.

Summary

As noted in the Policy section, this policy suggests that malabsorptive procedures for treatment of morbid obesity remain investigational. This interpretation of the term investigational may be questioned by those who would point out the procedure, particularly the Scopinaro procedure, has been performed for some 20 years with results of large case series reported in the peer-reviewed literature. The percent of excess weight loss, typically at or above 70%, may be higher than that reported with gastric restrictive procedures, reported at around 60%, but higher among those patients who maintain intact stomas. One of the criteria used to define the term investigational, is whether the malabsorptive procedures are at least as good as the alternatives; i.e., gastric restrictive procedures. This involves a judgment as to whether the acknowledged increased metabolic risks associated with malabsorptive procedures are more than outweighed by an increased benefit associated with potentially greater weight loss. While most of the studies of bariatric surgeries report results in terms of weight loss, the degree of weight loss is essentially an intermediate outcome. For questions that ask whether surgery improves health outcomes, and/or how much surgery improves outcomes, weight loss by itself is useful only if the relationship between the amount of weight loss and the degree of improvement in health outcomes has been established. The underlying medical rationale for the surgery, and thus the basis for its coverage eligibility, is not the degree of weight loss, but the decreased risk of the morbid complications of obesity, i.e., a decreasing incidence of diabetes and cardiac risk factors, among others. While the psychosocial benefits of achieving normal weight may be compelling, they are not necessarily equivalent to the medical benefit. As noted by Brolin, a substantial number of morbidly obese patients experience marked improvement of medical problems with a relatively modest amount of weight loss. For example, in his case series of 130 patients undergoing bariatric surgery, over 90% experienced resolution or improvement in associated symptoms, even though only 41% of patients lost weight to within 50% of their ideal weight.

Ideally, one would like to compare the incidence of morbidities in gastric restrictive versus malabsorptive procedures. However, there is no report of a head-to-head comparison among similar patients. It is difficult to compare results between case series due to variations in surgical procedures and different outcome measurements. In addition, the literature focuses on the degree of weight loss and not the incidence of obesity-related morbidities. However, it appears that the reduction in incidence of diabetes and cardiovascular risk factors is excellent with either a gastric restrictive or malabsorptive procedure. Therefore, this policy regarding the investigational status of malabsorptive procedures is based on the judgment that there is insufficient evidence to demonstrate that the increased risks of malabsorptive procedures compared to restrictive procedures are outweighed by a significantly greater reduction in obesity-related morbidities.

In the future, further modifications of malabsorptive procedures, including further experience with long limb gastric bypasses and refinement of surgical technique, may be associated with a declining risk of metabolic complications.

Obesity and obesity-related disease is increasing among adolescents in the United States. There is no firm consensus on recommendations for the appropriate timing of bariatric surgery and optimal surgical and postoperative management of this patient group. Several authors have recommended that adolescents who are candidates for bariatric surgery should be referred to centers with multidisciplinary weight management teams that have expertise in meeting the unique needs of overweight adolescents.

It is hypothesized that the major and sustained weight loss for extremely obese adolescents who undergo bariatric surgery will result in improved overall health and quality of life just as it does for adults.

In summarizing evidence for the U. S. Preventive Services Task Force, Whitlock and associates stated: “No acceptable quality evidence is available for adolescents, evaluating surgical approaches to

overweight. There are no controlled treatment outcome data on bariatric surgery approaches among adolescents.â€

2008

The sleeve gastrectomy attempts to proportionately reduce both gastric size and the length of the small intestine so that all digestive functions are preserved and metabolic complications are less likely.

(Santoro et al). This approach is based on the assumption that gastric capacity and the permeability of the small intestine exceed what is necessary for modern diets.

Vidal et al reported on severely obese T2DM patients, 35 had SG and 50 had RYGB. At 4 months both groups lost a similar amount of weight. TSDM had resolved in 51.4% of those having SG and 62.0% of those having RYGB.

In 2006 Himpens et al published results of a study comparing laparoscopic gastric banding (GB) with laparoscopic sleeve gastrectomy (SG).

Sample	GB		SG	
	7M, 33 F		9 M, 31 F	
Median age	36		40	
Mediam BMI	37		39	
Median wt loss(kg)	1 yr	3 yr	1yr	3 yr
	14	17	26	29.5
Loss of feeling hunger (% of patients)	42.5	2.9	75	46.7
de novo GERD	8.8%	20.5%	21.8%	3.1%

2008 Update - Endoscopic procedures

Drs. R.P. Petersen and A.D. Pryor, from the Duke Center for Weight Loss and Metabolic Surgery, Duke University Medical Center, and Dr. B. Chand, from the Bariatric and Metabolic Institute, Department of General Surgery, Cleveland Clinic recently reviewed the StomaphyX device along with other new morbid obesity procedures: â€œThe StomaphyX device is currently available for the treatment of a dilated gastric pouch following gastric bypass. This device uses T-fasteners to create endoluminal plications that will decrease pouch size. The morbidity of this procedure appears minimal, but the benefit has yet to be proven.â€

2009 Update StomaphyX

The StomaphyX device was FDA approved in June 2007 for tissue approximation, ligation and full-thickness plication in the G.I. tract. There are literature reports of its use for revisions in patients who have a dilated gastric pouch or stoma post gastric bypass surgery and more recently, for repair of gastric leaks. This type of procedure is also known as: Natural Orifice Surgery (NOS)(Overcash, 2008); Natural Orifice Transluminal Endoscopic Surgery (NOTES)(de la Fuente, 2007); or Revision Obesity Surgery Endoscopic (ROSE)(Mullady, 2009).

The American Society for Gastrointestinal Endoscopy (SAGE) published a guideline in 2008, Role of endoscopy in the bariatric surgery patient. In the section Weight regain the following statement is made: Emerging technologies may allow endoscopic revision of the gastrojejunal anastomosis and reduction of the pouch size in patients with weight regain after an RYGB.

There are reports of this procedure in small numbers of patients, case or small case series, with short-term follow-up (Overcash, 2008; Mullady, 2009). There is also an ongoing trial, sponsored by EndoGastric Solutions, NCT00939055. This is a phase II/III trial to evaluate the safety and effectiveness of a revisional incisionless natural orifice surgery of the gastric pouch and stoma in producing weight loss in post-RNYGB patients who have experienced weight regain. This randomized controlled trial will compare StomaphyX versus sham in post-Roux-en-Y patients to reduce regained weight.

Nguyen and colleagues published results of a randomized controlled trial of laparoscopic gastric bypass versus laparoscopic adjustable gastric banding for the treatment of morbid obesity. The trial randomized 197 subjects to either laparoscopic bypass or laparoscopic banding. The percentage of weight loss was greater in the gastric bypass group with a treatment failure rate of 0%. Treatment failure (<20% of excess weight loss) occurred in 16.7% of the patients that underwent gastric banding. The complication rate, however, was higher in the gastric bypass group. Major complications after bypass were bowel obstruction and stricture. Interestingly, the male gender was a predictive factor of poor weight loss in this study. The authors concluded, â€œLaparoscopic gastric bypass and gastric banding are both safe and effective approaches for the treatment of morbid obesity. Gastric bypass resulted in better weight loss at medium- and long-term follow-up but was associated with more perioperative and late complications and a higher 30-day readmission rateâ€ (Nguyen, 2009).

2011 Update

The policy was updated with a literature search using MEDLINE through February 2011.

Sleeve Gastrectomy

Brethauer and colleagues reviewed 36 studies (n=2,570) for a systematic review of SG as staged and primary procedure, the largest number (Rutledge, 2001) coming from European centers (Brethauer, 2009). Two RCTs, 1 nonrandomized matched cohort analysis, and 33 case series were examined. Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (n=1,749) on SG as primary procedure. Mean percentage of excess weight loss (% EWL) was reported in 24 studies (n=1,662) and was 55.4% overall (range, 33%–85%). Mean postoperative BMI was reported in 26 studies (n=1,940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. Follow-up periods were 3–60 months. Ten studies included detailed postoperative co-morbidity data (n=754); more than 70% of patients had improvement or remission of type 2 diabetes, and significant reductions were seen in hypertension and hyperlipidemia, sleep apnea, and joint pain. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with greater than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies reporting detailed complication data (n=2,570). All extracted studies reported mortality data with 5 deaths within 30 days of surgery (overall mortality rate 0.19%, 2 in the high-risk/staged group and 3 in the primary procedure group). The authors comment that long-term follow-up is limited.

Recent additional case series that report similar outcomes with at least 2-year outcomes include the following. Sanchez-Santos et al. report on short and mid-term outcomes for 540 patients recorded in a National Registry in Spain (Sanchez-Santos, 2009). Mean follow-up was 16.5 ± 10.6 months (1–73). Mean percent excess BMI loss (EBL) at 3 months was 38.8 ± 22, 55.6 ± 8 at 6 months, 68.1 ± 28 at 12 months, and 72.4 ± 31 at 24 months. Percentage of EWL was superior in patients with lower initial BMI and lower age. The morbidity rate was 5.2% and mortality rate 0.36%. Diabetes was remitted in 61% of patients and hypertension improved in 63.2%. Eighteen patients had a second-stage surgery. Complications presented more frequently in super-obese patients (odds ratio [OR], 2.8), male (OR, 2.98), and patients older than 55 years (OR, 2.8). The authors noted that more homogeneous and long-term studies are needed to determine the precise role of the procedure in bariatric surgery. Arias and colleagues report mid-term outcomes of 130 SGs (Arias, 2009). Mean BMI decreased to 36.9, 32.8, 29.5, 28, and 27.1 at 3, 6, 12, 18, and 24 months, respectively. Percent of excess weight loss (% EWL) was 33.1, 50.8, 62.2, 64.4, and 67.9 at 3, 6, 12, 18, and 24 months, respectively.

Recently reported long-term studies show extensive weight loss; although, as with other procedures, weight gain often recurs over time. For example, in a study from Europe, Himpens and colleagues reported on 4- to 6-year follow-up results in a series of patients who had SG performed in 2001 and 2002 (Himpens, 2010). This study evaluated 53 consecutive morbidly obese patients who (according to the authors' algorithm) qualified for restrictive surgery and were selected for LSG. Of the 53 patients, 11 received an additional malabsorptive procedure at a later stage because of weight regain. At six years, follow-up was obtained in 41 patients (78%). After 3 years, a mean EWL of 72.8% was documented, after 6 years EWL had dropped to 57.3%. These results included 11 patients who had benefited from an additional malabsorptive procedure (DS) and 2 patients who underwent a "resleeve" between the third and sixth postoperative year. In analyzing the results for the 30 patients receiving only SG, the authors found a 3-year % EWL of 77.5% and 6+ year % EWL of 53.3%. In addition, new gastroesophageal reflux complaints appeared in 21% of patients. In another study from Europe, D'Amico et al. reported on long-term follow-up (median of 49 months) from review of 102 patients who underwent LSG (D'Amico, 2011). A total of 83 patients (81.4%) were eligible for follow-up evaluation. The mean initial BMI was 39.3 kg/m². At a median follow-up point of 49 months (range, 17–80 months), the mean % EWL was 72.3% ± 29.3%. For the 23 patients who reached the 6-year follow-up point, the mean % EWL was 55.9% ± 25.55%.

Three publications report findings for obese patients who had SG compared to other bariatric procedures. In a comparative study from France, Chouillard et al. performed a comparative analysis with 200 patients who had undergone either SG or RYGB between 2005 and 2008 (Chouillard, 2011). Patients in each group were matched for age, gender, and BMI. The postoperative complications, percentage of EWL, and the resolution of co-morbidities in each group were compared at 6, 12, and 18 months postoperatively. The overall mortality rates were similar in both groups. However, the morbidity rate was significantly greater in the RYGB group (20.5%) as compared to the SG group (6.5%; P<0.05). The overall remission of type 2 diabetes was significantly better in the RYGB group. However, the percentage of EWL at 6, 12, and 18 months, as well as the resolution of non-diabetic comorbidities, were comparable in both groups. The authors concluded that in this study, compared with SG, RYGB was associated with a greater short-term morbidity rate and RYGB could be associated with better diabetes control. They also note that additional studies are needed to evaluate the comparative efficacy of SG and RYGB for the treatment of morbid obesity and its co-morbidities. Leyba and colleagues reported on a series of 117 patients from Venezuela who were treated with either SG or RYGB (Leyba, 2011). From January 2008 to December 2008, 117 obese patients who met criteria for bariatric surgery were assigned by patient choice after informed consent to either a laparoscopic RYGB procedure (n=75) or an LSG procedure. Both groups were comparable in age, sex, BMI, and co-morbidities. Mean operative time of LSG was 82 minutes while LRYGB was 98 minutes (p<0.05). Differences in length of stay, major complications, improvement in co-morbidities, and EWL were not significant (p>0.05). One year after surgery, average EWL was 86% in LRYGB and 78.8% in LSG (p>0.05). The authors concluded that in the short term, both techniques are comparable regarding safety and effectiveness. In a comparative study from India, Lakdawala and colleagues compared 50 patients who underwent LSG and LRYGB from 2007 to 2008 (Lakdawala, 2010). Groups were matched for age, sex, and BMI. Patients were evaluated at 6 months and 1 year post-operatively. Resolution of most comorbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, joint pain, and percentage of EWL in both groups was comparable at the end of 6 months and 1 year. Early resolution of type 2 diabetes was better in the LRYGB group; the results were comparable at 1 year. There was increased incidence of GERD in LSG patients. Chiu et al. reported a systematic review on the effect of SG on symptoms of GERD (Chiu, 2010). A total of 15 reports were retrieved; two reports analyzed GERD as a primary outcome, and 13 included GERD as a secondary study outcome. Of the 15 studies, 4 showed an increase in GERD after SG, 7 found reduced GERD prevalence after SG, 3 included only the postoperative prevalence of GERD, and 1 did not include data on prevalence of GERD. The authors concluded that the studies showed differing outcomes and that studies that objectively evaluate GERD after SG are needed.

Revision Procedures

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities with somewhat higher complication rates than for primary surgery. Mognol et al.

reported on conversion of AGB to Roux-en-Y in 70 patients (Mognol, 2004). Indications for conversion were insufficient weight loss or weight regain after band deflation for gastric pouch dilatation in 34 patients (49%), inadequate weight loss in 17 patients (25%), symptomatic proximal gastric pouch dilatation in 15 patients (20%), intragastric band migration in 3 patients (5%), and psychological band intolerance in 1 patient. Median excess body weight loss was 70%. Sixty percent of patients achieved a BMI of less than 33 with mean follow-up 18 months. The early complication rate was 14.3% (10/70). Late major complications occurred in 6 patients (8.6%). Brolin and Cody, reporting on a series of 151 revision surgeries, observed that "Weight loss after revision of pure restrictive operations is significantly better than after revision of operations with malabsorptive components. Improvement of comorbidities in the great majority of patients justifies revision of all types of bariatric operations for unsatisfactory weight loss." (Brolin, 2008) Beuter et al. reported that of 172 patients who underwent adjustable gastric band placement between May 1997 and June 2006, 41 had one or more revision procedures (Bueter, 2009). There were no deaths following the reoperations. Band replacement (n=18), band repositioning (n=7), conversion to SG (n=2) and Roux-en-Y gastric bypass (RYGBP, n=2) or band removal without any further substitution (n=12) were performed as first reoperation. Seven patients had a second reoperation. Median follow-up since reoperation was 56 months (range 7-113). Excess weight loss (EBWL %) of patients was 59.4% after RYGBP (n=5), 45.1% after re-banding (n=18), and 33.4% after SG (n=2). Comorbidities were further reduced or even resolved after reoperation.

Endoluminal/Endoscopic Procedures

Evidence of efficacy of endoluminal primary or revision bariatric procedures is very limited, consisting only of reports of a small number of case series, most from non-U.S. centers and with 20 or fewer subjects. The FDA has not cleared the gastric balloon for marketing in the United States. A survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons have different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures (Brethauer, 2009). They were "willing to accept less weight loss and more risk for revisional endoluminal procedures than for primary endoluminal procedures." Durability of the procedures was a concern, and most surgeons were unwilling to consider the procedures until their efficacy has been proven.

Use of adjustable banding for BMI greater than 50

Updated information on selection of candidates for AGB, particularly with respect to the relationship between preoperative BMI and postoperative resolution of comorbidities, was also sought for this update. As noted in previous updates, comparative studies consistently demonstrate that patients who undergo AGB experience slower and smaller weight loss than those having gastric bypass or malabsorptive procedures. Brancatisano and colleagues (Brancatisano, 2008) identified 682 patients with type 2 diabetes, impaired glucose tolerance, and metabolic syndrome and at least a 6-month follow-up in their database of patients who received the Swedish Adjustable Band. They report that remission of type 2 diabetes was dependent on both the magnitude of excess weight loss (p=0.008) and the duration of existing diabetes (Brancatisano, 2008). Kadera et al. tested the hypothesis that RYGB improves type 2 diabetes by way of metabolic changes before significant weight loss occurs (Kadera, 2009). Of 1,546 patients with at least 12 months follow-up, 71 had type 2 diabetes and were taking insulin. Patients who achieved remission, defined as a cessation of diabetic medications and a hemoglobin A1c level of less than 7%, were compared with those who did not achieve remission. All 71 patients achieved a reduction in the dose of and/or number of medications at 30 months, and 35 (49%) demonstrated remission. By multivariate analysis, the significant factors associated with remission were preoperative insulin dose and percent of EWL. The % EWL was greater in the remission group as early as 3 months after surgery (p=0.04) and at 6, 12, 18, and 24 months. Citing a number of studies, Snyder et al. state that "it has become clear through most physicians' clinical experience that those with a greater starting body mass index do not lose as much excess weight as those with a lower starting BMI." (Snyder, 2009) To determine at what point the BMI is too great for effective weight loss, they collected weight loss data for 430 patients who had had an adjustable gastric band placed and stratified the % EWL within 1 year for patients with a BMI of 30-59, for BMI groups of 30-39, 30-49, and 50-59 and compared it with the average % EWL over time. Patients with a BMI less than 46 had a 50% EWL at 1 year, while those with a BMI greater than 46 had a 33% EWL. The % EWL was significantly different between groups at all measured intervals (p<0.0001). The authors conclude that "a BMI of 46 kg/m² identifies those at high risk of failure to lose a significant percentage of excess weight after adjustable banding and who require closer follow-up" and that "patients should be advised that their weight loss might be suboptimal at 1 year". Buchwald et al. conducted a systematic review that included 621 studies with 888 treatment arms and 135,246 patients; 103 treatment arms with 3,188 patients reported on resolution of diabetes (Buchwald, 2009). Nineteen studies with 43 treatment arms and 11,175 patients reported both weight loss and diabetes resolution separately for 4,070 diabetic patients. Percent of EWL was greatest for patients who had biliopancreatic diversion/duodenal switch, followed by gastric bypass, gastroplasty, and least for banding procedures. Overall, 78.1% of diabetic patients had complete resolution and 86.6% had improvement or resolution. Diabetes resolution by procedure was as follows: biliopancreatic diversion/duodenal switch (95.1% resolved), gastric bypass (80.3%), gastroplasty (79.7%), and laparoscopic AGB (56.7% resolved). With few exceptions, studies of AGB include patients with preoperative mean BMIs less than 45 and only a very few include patients with BMIs greater than 50. Few papers report detailed outcomes on resolution of comorbidities in patients with BMIs greater than 50 who received AGBs; sample sizes are very small, resolution in comorbidity is not defined, or reduction and resolution may be combined in outcome measures. Angrisani et al. performed a retrospective analysis of the multicenter Italian experience in patients with BMI greater than 50 who had AGB over a 4-year period (Angrisani, 2002). Of 1,797 having the procedure, 239 had BMI greater than 50 (mean 54.6). Mean % EWL was 34.1 (198 of 198 patients available for follow-up) at 12 months. Of the 12 patients who were diagnosed with diabetes preoperatively, 1 achieved resolution (fasting glycemia <110 mg/dL and HbA1c <6% without medication) at 1 year. Tice et al. compared outcomes of LAGB and RYGB in a systematic review (Tice, 2008). In 5 of the 14 included studies, BMI was 50 or more, comparative data on comorbidities was reported in 1. In that study, (reviewed in the 2008 update [Bowne, 2006]) 100% of patients in the RYGB group achieved resolution of diabetes versus 40% of those in the LAGB group. Resolution of hypertension was reported in 63% of RYGB and 27% of LAGB patients. The EWL was 52% in the RYGB group compared to 31% in the LAGB group. In another study reviewed in the previous update, Prarikh et al. compared resolution of diabetes after gastric banding (LAGB), gastric bypass (RYGB), and biliopancreatic diversion (BPD/DS) in 282 patients (Parikh, 2007). Preoperative BMIs were 47.2 in the LAGB group (n=218), 47.2 in the BPD/DS group (n=11). Percent EWL at 2 years was 50% in the LAGB group (68% of patients evaluated), 68% in the RYGB group (56% of patients evaluated), and 77% in the BPD/DS group (64% of patients evaluated). Preoperatively, oral hypoglycemics were used by 83% of the LapBand, 87% of the RYGB, and 82% of the BPD/DS patients and insulin was required by 18%, 28%, and 18%, respectively. At the 2-year follow-up, 34% of the LAGB group, 13% of the RYGB group, and 13% of the BPD/DS group required oral hypoglycemics and 18%, 13%, and 13%, respectively, required insulin.

Other Issues

Benotti and colleagues evaluated the impact of preoperative weight loss on surgical complications in a series of 881 patients undergoing open or laparoscopic gastric bypass from 2002 to 2006 (Benotti, 2009). Of the 881 patients, 592 (67.2%) lost 5% or more EBW and 423 (48.0%) lost more than 10% EBW. Controlling for age, sex, baseline BMI, and type of surgery in a multiple logistic regression model, increased preoperative weight loss was a predictor of reduced complications for any ($p=0.004$) and major ($p=0.03$) complications.

Oâ€™Brien et al. reported on a prospective, randomized trial from Australia of 50 adolescents between the ages of 14 and 18 with BMI greater than 35 who received either a lifestyle intervention or gastric banding and were followed up for 2 years (Oâ€™Brien, 2010). Twenty-four of 25 patients in the gastric-banding group and 18 of 25 in the lifestyle group completed the study. Twenty-one (84%) in the gastric banding group and 3 (12%) in the lifestyle group lost more than 50% of excess weight. Overall, the mean changes in the gastric-banding group were a weight loss of 34.6 kg (95% confidence interval [CI], 30.2-39.0), representing an excess weight loss of 78.8% (95% CI, 66.6-91.0%). The mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1-8.1), representing EWL of 13.2% (95% CI, 2.6%-21.0). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 operations (33%) were required in 7 patients for revisional procedures either for proximal pouch dilatation or tubing injury during follow-up. The authors concluded that among obese adolescent participants, use of gastric banding compared with lifestyle intervention resulted in a greater percentage achieving a loss of 50% of excess weight.

Practice Guidelines and Position Statements

In November 2009, the ASMBS updated its position on sleeve gastrectomy to state that it has accepted sleeve gastrectomy as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients. They cite the need for long-term data to confirm the effectiveness of the procedure as a stand-alone intervention.

In January 2009 the ASMBS Emerging Technologies and Clinical Issues Committee issued a Position Statement on Emerging Endosurgical Interventions for Treatment of Obesity. The committee stated that "use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention." It calls for trials to generate data for risk-benefit analysis, assessments of disability, durability, and resource utilization and notes that dramatic reduction in risk may allow for acceptance of interventions that do not provide durable benefits comparable to currently accepted bariatric procedures.

Updates 2012 and Later

Due to the detail of the rationale, the complete document is not online. If you would like a hardcopy print, please email: codespecificinquiry@arkbluecross.com

CPT/HCPCS:	43631	Gastrectomy, partial, distal; with gastroduodenostomy
	43632	Gastrectomy, partial, distal; with gastrojejunostomy
	43633	Gastrectomy, partial, distal; with Roux en Y reconstruction
	43634	Gastrectomy, partial, distal; with formation of intestinal pouch
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux en Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or

less) Roux en Y gastroenterostomy

- 43847 Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
- 43886 Gastric restrictive procedure, open; revision of subcutaneous port component only
- 43887 Gastric restrictive procedure, open; removal of subcutaneous port component only
- 43888 Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

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Group specific policy will supersede this policy when applicable. This policy does not apply to the Wal-Mart Associates Group Health Plan participants or to the Tyson Group Health Plan participants.

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