Name of Policy:
Surgical Management of Morbid Obesity

Policy #: 053       Latest Review Date: May 2017
Category: Surgery       Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:

General Information

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous different surgical techniques available. These different techniques have heterogeneous mechanisms of action, with varying degrees of gastric restriction that creates a small gastric pouch, malabsorption of nutrients, and metabolic changes that result from gastric and intestinal surgery.

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 mellitus, hypertension, coronary artery disease or obstructive sleep apnea. BMI is calculated by dividing a patient’s weight (in kilograms) by height (in meters) squared.

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

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.

Documented failure of attempts to respond to conservative measures for weight reduction should be reviewed by the practitioner prior to seeking approval for the surgical procedure. Active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise may be used not only for documentation of structured attempts using conservative measures for weight reduction, but also for pre-procedure educational purposes and for gauging commitment to the lifestyle changes necessary following bariatric surgery.

Resolution (cure) or improvement of Type 2 diabetes mellitus (T2D) after bariatric surgery and observations that glycemic control may improve immediately after surgery, before a significant amount of weight is lost, have promoted interest in a surgical approach to treatment of T2D. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional antidiabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal
peptides, glucagon-like peptide-1 (1GLP-1), glucose-dependent insulino tropic peptide (GIP), and peptide YY (PYY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

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

**Types of Bariatric Surgery Procedures**
The following summarizes the different types of bariatric surgery procedures.

**Vertical-Banded Gastroplasty (CPT code 43842)**
Vertical-banded gastroplasty was formerly one of the most common gastric restrictive procedures performed in the U.S. but has now been essentially replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. Vertical-banded gastroplasty may be performed using an open or laparoscopic approach.

**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. Two such devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States. The first such
device that received FDA approval was the Lap-Band (original applicant, Allergan Inc, BioEnterics, Carpinteria, CA; sold to Apollo Endosurgery, Inc., Austin, TX, in 2013). 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 pounds or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs. Patients who elect to have this surgery must make the commitment to accept significant changes in their eating habits for the rest of their lives."

In 2011, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 with at least one obesity-related comorbid condition.

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.”

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

The original gastric bypass surgeries were based on the observation that postgastrectomy 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 gastrojejunostomy). 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 150cm or less, compared to the previous 100cm. This change reflects the common practice in which the alimentary (i.e., jejunal limb) of a gastric bypass has been lengthened to 150cm. This length also
serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

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

CPT code 43644 was introduced in 2005 and essentially described the same procedure as code 43846, but performed laparoscopically.

**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.

**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 2-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient’s overall medical status and thus, reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

**Endoluminal (also called endosurgical, endoscopic, or natural orifice) Bariatric Procedures (no specific CPT code)**

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.

**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. A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
b. A 200-cm long “alimentary tract” consists of 200 cm of ileum connecting the stomach to a common distal segment.
c. A 300- to 400-cm “biliary tract” connects the duodenum, jejunum, and remaining ileum to the common distal segment.
d. A 50- to 100-cm “common tract” is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.

e. Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to 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.

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

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 describe a laparoscopic malabsorptive procedure. However, the code is not specific for the type of malabsorptive procedure.

Laparoscopic Gastric Plication (no specific CPT code)
Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.
Policy:

NOTE: Verify contract benefits for coverage of bariatric surgery and complications.

Effective for dates of service on or after August 5, 2016:

I. GASTRIC RESTRICTIVE PROCEDURES

One of the following bariatric surgery procedures:
- Open gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis; OR
- Laparoscopic adjustable gastric banding; OR
- Sleeve gastrectomy (as a single step procedure)

meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when ALL of the criteria below are present:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following obesity-related co-morbid conditions: HTN on optimal drug therapy, atherosclerotic cardiovascular disease, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, or severe obstructive sleep apnea. (RDI of 50 or greater OR AHI >=30);

AND

2. The condition of morbid obesity (BMI ≥ 40 or BMI ≥ 35 with presence of comorbid conditions) must be of at least 3 years (36 months) duration.
   - There must be documentation in medical records by a qualified health care provider of patient height and weight for the past 3 years (36 months); or
   - If no medical record documentation is available, a letter from the primary care provider and dated photographs will be considered in lieu of recorded heights and weights;
   
   NOTE: Random reviews of these patients’ charts for accuracy of stated information will be conducted

AND

3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, Blue Cross and Blue Shield of Alabama recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:
   - Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for
a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

○ Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision, Not acceptable are self-directed programs such as joining a gym, Atkins’ diet, calorie counting, low fat, cutting back, internet programs, etc.; AND

4. A complete history and physical must be performed by the bariatric surgeon to include height and weight; AND

5. The patient must be at least 18 years of age; AND

6. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

If the adjustable gastric restrictive procedure does not meet medical criteria for coverage, or if the patient decides to pay for the adjustable gastric restrictive procedure, the adjustments of the devices do not meet medical criteria for coverage.

II. Malabsorptive Procedures

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for treatment of the morbidly obese patients with BMI of 50 kg/m² or more when ALL of the following criteria are met:

1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, Blue Cross and Blue Shield of Alabama recognizes medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties. Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

   ○ Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement.
There must be medical records to document medically supervised weight loss attempts;

**OR**

- Acceptable with **medical record documentation** of medical supervision are: Weight Watchers, LA Weight Loss, Jenny Craig, EatRight etc. **Not** acceptable are **self-directed** programs such as joining a gym, Atkins’ diet, calorie counting, low fat, cutting back, internet programs, etc.; **AND**

2. A complete history and physical must be performed by the bariatric surgeon to include height and weight; **AND**

3. The patient must be at least 18 years of age; **AND**

4. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

### III. **PREOPERATIVE ASSESSMENTS**

Blue Cross and Blue Shield of Alabama will treat the pre-operative office visit or consult as medically necessary when the surgery is determined to be medically necessary. Claims for a decision for surgery should be filed with modifier 57.

Many times there will be an extended lapse of time between the decision for surgery and the pre-operative visit. Pre-operative testing and a pre-operative visit will also be covered if medically necessary and if the surgery is considered medically necessary. The correct diagnoses to report pre-operative testing and evaluations are ICD-9 codes: V72.81-V72.84 or ICD-10 codes: Z01.810-Z01.811, or Z01.818. The obesity diagnosis should be listed as the secondary diagnosis.

**NOTE:** A pre-operative psychological evaluation is not required by Blue Cross and Blue Shield of Alabama, but may be covered when requested by the surgeon for those patients with a history of severe psychiatric illness (schizophrenia, borderline personality disorder, suicidal ideation, severe depression), and those patients currently under the care of a psychiatrist/psychologist or on psychotropic medications. Any of the above conditions may impair the ability to give consent or be compliant post-operatively. Blue Cross and Blue Shield of Alabama will consider this medically necessary. Psychological evaluations should be reported with procedure code 90791 with type service 6 with ICD-9 diagnosis V72.83 or V72.84 or ICD-10 diagnosis of Z01.818 with a secondary diagnosis of obesity.

### IV. **Revisions and Conversions**

**Gastric Surgery**

**Revision or conversion of a prior bariatric procedure (excluding adjustable gastric banding)** meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage with documented evidence of **ONE or MORE** of the following:
• Weight loss of 20% or more below the ideal body weight following bariatric surgery; **OR**
• Vomiting (bilious); **OR**
• Stomal dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); **OR**
• Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); **OR**
• Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagogastroduodenoscopy (EGD); **OR**
• Stomal stenosis after vertical gastric banding, documented by endoscopy, with vomiting or weight loss of 20% or more below the ideal body weight; **OR**
• Obstruction; **OR**
• Stricture; **OR**
• Severe diarrhea following surgery; **OR**
• Severe dumping syndrome

AND

• The requested procedure must be a Blue Cross and Blue Shield of Alabama covered bariatric surgery/procedure; **and**
• The patient must be at least 18 years of age; **and**
• Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

**Revision or conversion** of a prior bariatric procedure **without complicating factors** to another bariatric procedure **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage **when requested due to lack of weight loss or less than anticipated weight loss after the prior bariatric procedure.**

**Treatment of complications (e.g., stomal dilatation, pouch dilatation, or staple line failure)** that arise due to **non-compliance** with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure **does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

**Adjustable Gastric Restrictive Devices**

**Revision, conversion or removal of adjustable gastric restrictive device meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the following indications:

• Band erosion or slippage; **OR**
• Infections around the port site

AND

• The requested procedure must be a Blue Cross and Blue Shield of Alabama covered bariatric surgery/procedure; **and**
• The patient must be at least 18 years of age; **and**
• Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked within the eight weeks prior to surgery.

Treatment of complications (e.g., stomal dilatation, pouch dilatation) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Revision or conversion of an adjustable gastric restrictive device without complicating factors to another bariatric procedure does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when requested due to lack of weight loss or less than anticipated weight loss with the adjustable gastric restrictive device.

Elective removal (i.e., removal not due to the above complications) of the adjustable gastric restrictive device does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

V. CONCOMITANT HIATAL HERNIA REPAIR WITH BARIATRIC SURGERY

Repair of a hiatal hernia at the time of bariatric surgery meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

VI. DOES NOT MEET MEDICAL CRITERIA FOR COVERAGE & INVESTIGATIONAL

The following, including but not limited to, situations and procedures do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational:

**Situations:**

1. Bariatric surgery in patients under age 18 years;
2. Bariatric surgery performed as a cure for type II diabetes;
3. Bariatric surgery revisions due to complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendation such as dietary restrictions, patient activity and/or lifestyle following the initial procedure.
4. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions and Conversions section above)
5. Revision, conversion or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions and Conversions section above)

**Procedures:**

7. Biliopancreatic Bypass without Duodenal Switch
8. Endoscopic procedures (including but not limited to insertion of the StomaphyX™ device, insertion of gastric balloon(s) (i.e., Orbera, Reshape), endoscopic gastroplasty, or use of an endoscopically placed duodenal-jejunal sleeve) as a primary bariatric procedure or as a revision or conversion procedure.
9. Vertical Banded Gastric Bypass, Fobi-Pouch (FPOO) Transected (Silastic Ring Vertical Gastric Bypass)
10. Gastric Electrical Stimulation
11. Gastric Wrapping
12. Jejunoileal Bypass
13. Mini-gastric Bypass
14. Long Limb Gastric Bypass (i.e., >150cm)
15. Loop Gastric Bypass
16. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
17. Laparoscopic gastric plication
18. Balloon-in-a-Pill systems (i.e., Obalon, Elipse, etc)
19. Laparoscopic distalization
20. Weight loss stomach pumps (i.e., AspireAssist, A-tube™)

If the bariatric procedure does not meet medical criteria for coverage, or if the patient decides to self-pay for the bariatric procedure, the treatment of complications that may arise from the bariatric procedure, regardless of cause, does not meet medical criteria for coverage.

Any repeat surgery for morbid obesity for other than the stated surgical complications does not meet Blue Cross and Blue Shield of Alabama’s criteria for coverage.

Effective for dates of service prior to August 5, 2016:

I. GASTRIC RESTRICTIVE PROCEDURES

Adjustable Gastric Restrictive Device, Gastric Bypass (Roux-en-Y), Vertical Banded Gastroplasty and Sleeve Gastrectomy (as a single step procedure) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the surgical treatment of morbid obesity when the following criteria are met:

1. BMI of 40 or greater, or BMI of 35 or greater with one or more of the following co-morbid conditions: HTN on optimal drug therapy, atherosclerotic cardiovascular disease, diabetes (must be treated with insulin or oral agents), pulmonary hypertension, or severe obstructive sleep apnea. (RDI of 50 or greater). (NIH, 1998 and American Society for Bariatric Surgery). For BMI calculation see www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm.
2. The condition of morbid obesity (BMI ≥ 40 or BMI ≥ 35 with presence of comorbid conditions) must be of at least 3 years duration. There must be documentation in medical records by a primary care or attending physician of patient height and weight for the past 3 years. A letter from the primary care physician and dated photographs will be considered in lieu of recorded heights and weights. Random reviews of these patients’ charts for accuracy of stated information will be conducted.
3. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize medical supervision of the
diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties (medically supervised weight loss or activity programs generally are not a covered benefit). Documentation provided by these health care providers will be recognized in the review process. At least \textbf{one} attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for \textbf{six} consecutive months. The following criteria must be met for this participation:

- Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record no less than monthly for a period of 6 consecutive months by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

\textbf{OR}

- Medical record documentation of a 6 consecutive month, nutrition-led weight loss program (Weight Watchers, LA Weight Loss, Jenny Craig, EatRight, etc.) with a minimum of 3 physician visits during that 6 month period documenting medical supervision, \textbf{Not acceptable are self-directed programs} such as joining a gym, Atkins’ diet, calorie counting, low fat, cutting back, internet programs, etc.

4. A complete history and physical must be performed by the bariatric surgeon to include height and weight.
5. The patient must be at least 18 years of age.
6. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked in less than eight weeks prior to surgery.

If the \textbf{adjustable gastric restrictive procedure does not meet} medical criteria for coverage, or if \textbf{the patient decides to pay for the adjustable gastric restrictive procedure}, the \textbf{adjustments of the devices do not meet medical criteria for coverage}.

\textbf{II. Malabsorptive Procedures}

\textbf{Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro) procedure with duodenal switch meets} Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for treatment of the morbidly obese patients with \textbf{BMI of 50 kg/m}^2 \textbf{or more} when the following criteria are met:
1. Documentation must be present of participation in medically supervised weight loss program. For purposes of coverage, we (BCBS) recognize medical supervision of the diet and activity program by practicing MD's who are not bariatric surgeons, such as family practitioners, internists, and other primary care specialties. Documentation provided by these health care providers will be recognized in the review process. At least one attempt must occur during the one year prior to request for surgery or date of surgery. Documentation must support participation in the program for six consecutive months. The following criteria must be met for this participation:

a. Documentation of participation in a physician supervised program of nutrition and increased physical activity (including dietitian consultation, low calorie diet, increased physical activity and behavioral modification). Documentation of program participation must appear in the medical record by the attending physician. Documentation should include comments by the physician regarding patient progress or lack of progress. A letter does not meet this requirement. There must be medical records to document medically supervised weight loss attempts;

OR

b. Acceptable with medical record documentation of medical supervision are: Weight Watchers, LA Weight Loss, Jenny Craig, EatRight etc. Not acceptable are self-directed programs such as joining a gym, Atkins’ diet, calorie counting, low fat, cutting back, internet programs, etc.

2. A complete history and physical must be performed by the bariatric surgeon to include height and weight.
3. The patient must be at least 18 years of age.
4. Due to the surgical morbidity associated with concomitant pulmonary disease coverage will not be provided for anyone who has smoked in less than eight weeks prior to surgery.

III. Preoperative Assessments

Blue Cross and Blue Shield of Alabama will treat the pre-operative office visit or consult as medically necessary when the surgery is determined to be medically necessary. Claims for a decision for surgery should be filed with modifier 57.

Many times there will be an extended lapse of time between the decision for surgery and the pre-operative visit. Pre-operative testing and a pre-operative visit will also be covered if medically necessary and if the surgery is considered medically necessary. The correct diagnoses to report pre-operative testing and evaluations are ICD-9 codes: V72.81-V72.84 or ICD-10 codes: Z01.810-Z01.811, or Z01.818. The obesity diagnosis should be listed as the secondary diagnosis.

A pre-operative psychological evaluation is not required by Blue Cross and Blue Shield of Alabama, but may be covered when requested by the surgeon for those patients with a history of...
severe psychiatric illness (schizophrenia, borderline personality disorder, suicidal ideation, severe depression), and those patients currently under the care of a psychiatrist/psychologist or on psychotropic medications. Any of the above conditions may impair the ability to give consent or be compliant post-operatively. Blue Cross and Blue Shield of Alabama will consider this medically necessary. Psychological evaluations should be reported with procedure code 90801 with type service 6 with ICD-9 diagnosis V72.83 or V72.84 or ICD-10 diagnosis of Z01.818 with a secondary diagnosis of obesity.

IV. DOES NOT MEET MEDICAL CRITERIA FOR COVERAGE OR INVESTIGATIONAL

The following procedures do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered either non-covered or investigational:

Investigational
1. Bariatric surgery in patients under age 18 years
2. Bariatric surgery performed as a cure for type II diabetes
3. Biliopancreatic Bypass without Duodenal Switch
4. Endoscopic Procedures for weight gain or to remedy large gastric stoma or large gastric pouches after bariatric surgery (e.g. StomaphyX™, ROSE procedure)
5. Fobi-Pouch (FPOO) Transected Vertical Banded Gastric Bypass (Silastic Ring Vertical Gastric Bypass)
6. Garren-Edwards Gastric Bubble (Intra-Gastric Balloon)
7. Gastric Electrical Stimulation
8. Gastric Wrapping
9. Jejunoileal Bypass
10. Mini-gastric Bypass
11. Long Limb Gastric Bypass
12. Loop Gastric Bypass

Does not meet medical criteria for coverage
13. Bariatric surgery revisions due to complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendation such as dietary restrictions, patient activity and/or lifestyle following the initial procedure.
14. Repeat surgery for morbid obesity for other than the stated accepted surgical complications. (see Revisions section below)
15. Elective removal of the adjustable gastric band.
16. Revision or removal of the adjustable gastric band for other than the stated accepted complications. (see Revisions section below)
V. REVISIONS

Gastric Surgery
Revision of a prior bariatric procedure (excluding adjustable gastric banding) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage with documented evidence of one or more of the following:

- Weight loss of 20% or more below the ideal body weight following bariatric surgery, OR
- Vomiting (bilious), OR
- Stomal dilatation documented by either upper gastrointestinal (UGI) series or esophagastroduodenoscopy (EGD), OR
- Pouch dilatation documented by either upper gastrointestinal (UGI) series or esophagastroduodenoscopy (EGD), OR
- Stomal stenosis after vertical gastric banding, documented by endoscopy, with vomiting or weight loss of 20% or more below the ideal body weight, OR
- Staple line failure, documented by either upper gastrointestinal (UGI) series or esophagastroduodenoscopy (EGD); OR
- Severe diarrhea following surgery, OR
- Severe dumping syndrome

AND

- The requested procedure must be a Blue Cross and Blue Shield of Alabama covered bariatric surgery/procedure

Complications (e.g., stomal dilatation, pouch dilatation, or staple line failure) that arise due to non-compliance with medical recommendations such as dietary restrictions, patient activity and/or lifestyle following the procedure do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Adjustable Gastric Restrictive Devices
Revision or removal of adjustable gastric restrictive device meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the following indications:

- Band erosion or slippage; OR
- Infections around the port site

Elective removal of the adjustable gastric restrictive device does not meet Blue Cross and blue Shield of Alabama’s medical criteria for coverage.

Repeat surgery for morbid obesity for other than the stated surgical complications does not meet Blue Cross and Blue Shield of Alabama’s criteria for coverage.

Please verify contract benefits for coverage of bariatric surgery and complications.
Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:
Morbid obesity, also referred to as “clinically severe obesity” or “extreme obesity” was defined as the criteria for bariatric surgery by the 1991 NIH Consensus Conference Statement on Gastrointestinal Surgery for Severe Obesity as a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² in the presence of high-risk comorbid conditions. Obesity was further classified in the 1998 NIH clinical guidelines on the Identification, Evaluation, and treatment of Overweight and Obesity in adults into Class I (BMI 30 kg/m² to 34.9 kg/m²), Class II (BMI 35 kg/m² to 39.9 kg/m²), and Class III (BMI ≥ 40 kg/m²). Morbid obesity is estimated to afflict 20% of the obese population or over 8 million of the U.S. population. Obesity should be considered a chronic disease that has serious health consequences. Patients with obesity are at an increased risk of developing other diseases, including hypertension, heart disease, Type II diabetes, stroke, osteoarthritis, respiratory problems, sleep apnea, and certain types of cancer. Weight loss, even moderate weight loss of only 10% of body weight, has been shown to reverse many of the adverse consequences of obesity.

Weight loss surgery, also known as bariatric surgery, may be an option for carefully selected patients with clinically severe obesity (BMI ≥ 40 or ≥ 35 with co-morbid conditions) when less invasive methods of weight loss have failed and the patient is at high-risk for obesity-associated morbidity or mortality (National Institutes of Health). As the number of people with severe weight problems has increased, the number of weight loss surgeries has also risen. Surgical patients should be well informed and motivated since they will need to be monitored for complications and major lifestyle adjustments for the remainder of their lives.

The most recent update with literature review covers the period through December 22, 2016.

Definition of Outcomes
Outcomes of bariatric surgeries are notoriously difficult to evaluate in part due 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, few 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 two procedures were the focus of the 1991 National Institutes of Health (NIH) Consensus
Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass (BPB).

A 2003 TEC Assessment summarized studies comparing open gastric bypass and VBG. These comparisons demonstrated that open gastric bypass resulted in a greater amount of weight loss than VBG, with no definite differences in complication rates. Therefore, gastric bypass is considered the criterion standard for the purpose of this discussion, and this is supported by the increasing acceptance of gastric bypass by the surgical community, representing greater than 80% of all bariatric surgery procedures performed in 2002. Therefore, the results of open gastric bypass will be compared with the newer procedures not addressed by the 1991 NIH conference; i.e., gastric banding and BPB 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, because they reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 1 summarizes the variation in reporting weight loss outcomes.

**Table 1: Weight Loss Outcomes**

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>Definition</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease in weight</td>
<td>Absolute difference in weight pre- and posttreatment</td>
<td>Unclear relationship to outcomes, especially in morbidly obese</td>
</tr>
<tr>
<td>Decrease in BMI</td>
<td>Absolute difference in BMI pre- and posttreatment</td>
<td>May be clinically significant if change in MBI clearly leads to change in risk category</td>
</tr>
<tr>
<td>Percent excess weight loss</td>
<td>Amount of weight loss divided by excess body weight</td>
<td>Has anchor to help frame clinical significance; unclear threshold for clinical significance</td>
</tr>
<tr>
<td>Percent patients losing &gt;50% of EBW</td>
<td>No. patients losing &gt;50% EBW divided by total patients</td>
<td>Additional advantage of framing on per patient basis. Threshold for significance (&gt;50%) arbitrary</td>
</tr>
<tr>
<td>Percent ideal body weight</td>
<td>Final weight divided by ideal body weight</td>
<td>Has anchor to help frame clinical significance; unclear threshold for clinical significance</td>
</tr>
</tbody>
</table>

BMI: body mass index; EBW: excess body weight.
Durability of Weight Loss
Weight change (i.e., gain or loss) at yearly intervals is often reported. Weight loss at one year is considered the minimum length of time for evaluating these procedures; weight loss at three to five years is considered an intermediate time period for evaluating weight loss; and weight loss at five to ten years or more is considered to represent long-term weight loss following bariatric surgery.

Short-Term Complications (Operative and Perioperative Complications Occurring Within 30 Days)
In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and problems with wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications such as pneumonia or myocardial infarction.

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

Long-Term Complications (Metabolic Adverse Effects, Nutritional Deficiencies)
Metabolic adverse effects are of particular concern in malabsorptive procedures. Other long-term complications include anastomotic ulcers, esophagitis, and procedure-specific complications such as band erosion or migration for gastric-banding operations.

Improved Health Outcomes in Terms of Weight-Related Comorbidities
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.

Bariatric Surgery in Adults with Morbid Obesity
There is a vast literature published over the last few decades on bariatric surgery for adults with morbid obesity. This literature is characterized by a preponderance of single-arm clinical series from individual institutions. These types of studies can be used to determine the amount of weight loss expected from surgery, the durability of the weight loss, and the rate of adverse events (AEs). However, these studies are not adequate for determining the comparative efficacy of bariatric surgery versus conservative treatment, or the comparative efficacy of different bariatric surgery techniques. There are some comparative trials, including randomized and nonrandomized designs, which compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedures. The emphasis for this literature review will be on comparative trials that compare bariatric surgery with nonsurgical therapy or that compare different types of bariatric surgery procedures.

Randomized controlled trials (RCTs) of bariatric surgery have been performed but are limited and insufficient to draw conclusions about the comparison of bariatric surgery with conservative treatments for weight loss. RCTs are difficult in bariatric surgery because many experts consider
it inappropriate or unethical to randomize patients to bariatric surgery. Also, most patients and clinicians have strong feelings about their preference for treatment, which results in a select population that might agree to randomization and therefore, limited generalizability. As a result, the literature that is most important in determining the efficacy of bariatric surgery is from nonrandomized studies.

**Swedish Obese Subjects Trial**
The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/m² at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients were self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of comorbidities in the surgery group. There were a total of 2010 people who chose surgery and 2037 people who chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each individual surgeon chose the surgical procedure offered. Most of the procedures were VBG (>70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. The patients are followed at regular intervals with repeat questionnaires and physical examinations for at least ten years.

Many publications from this trial have reported on methods, weight loss, and clinical outcomes. The following general conclusions can be drawn from the SOS study:

- Weight loss is greater with bariatric surgery compared with conservative treatment. At ten years of follow-up, weight loss in the surgery group was 16% of total body weight, compared with a weight gain of 1.6% in the conservative treatment group.
- There is definite improvement in glucose control for diabetics and a reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors, e.g., hypertension and lipidemia is also positive, but less marked than that seen for diabetes.
- Mortality is reduced by 29% after a mean follow-up of 10.9 years.
- Quality of life shows improvement in the 2- to 10-year follow-up period, with the degree of improvement in quality of life correlated with the amount of weight loss.

**Longitudinal Assessment of Bariatric Surgery Consortium**
The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding with follow-up through three years postprocedure. The study enrolled 2458 subjects, with median BMI 45.9 (interquartile range [IQR], 41.7-51.5). For their first bariatric surgical procedure, 1738 participants underwent Roux-en-Y gastric bypass, 610 laparoscopic adjustable gastric banding, and 110 other procedures. At 3-year follow-up, for 1533 Roux-en-Y patients with available data, percentage of baseline weight lost was 31.5% (IQR, 24.6%-38.4%). For the 439 adjustable gastric banding patients with
available data at three years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At three years post surgery, 67.5% and 28.5% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the Roux-en-Y gastric bypass patients and 17.5% (95% CI, 13.8% to 21.9%) of laparoscopic adjustable gastric banding patients.

Systematic Reviews
Numerous systematic reviews have been published on the efficacy of bariatric surgery compared with conservative therapy, some of which are older and do not include the full range of available studies.

In 2014, Colquitt et al published an update to a Cochrane review of bariatric surgery for obesity, which was originally published in 2003 and most recently updated in 2009. The authors identified 22 randomized trials that compared bariatric surgery with nonsurgical obesity management or that compared different bariatric surgery procedures, with 1798 participants, with sample sizes from 15 to 250. All seven RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at one- to two-year follow-up. However, the authors note that AE rates and reoperation rates were poorly reported across trials, and long-term follow-up (beyond one-two years) is limited.

Gloy et al (2013) conducted a systematic review and meta-analysis of RCTs comparing current bariatric surgery techniques with nonsurgical treatment for patients with BMI of 30 or more. A total of 11 studies with 796 patients were included. Overall, patients after bariatric surgery lost more body weight than patients after nonsurgical treatment (mean difference, -26 kg; 95% CI, -31 to -21; p<0.001). Remission of Type II diabetes mellitus (T2D) was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of remission with T2D, 22.1; 95% CI, 3.2 to 154.3; p<0.000); similarly remission of metabolic syndrome was more likely for bariatric surgery patients (RR=2.4; 95% CI, 1.6 to 3.6; p<0.001). After bariatric surgery, 21 of 261 (8%) patients required reoperations (5/124 after adjustable gastric banding, 4/69 after Roux-en-Y gastric bypass, 1/49 after sleeve gastrectomy, 1/19 after BPD). Similar to the Colquitt et al meta-analysis, no studies reported longer-term follow-up (beyond two years) and heterogeneity between studies was high.

Chang et al (2014) published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery. The authors included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean presurgery BMI was 45.62, and among the studies that provided information about obesity-related comorbidities, 26.2% of patients had T2D, 47.39% had hypertension, 27.97% had dyslipidemia, 7.15% had cardiovascular disease, and 25.30% had sleep apnea. Perioperative complications were relatively low, with a perioperative mortality rate in RCTs of 0.08% (95% CI, 0.01% to 0.24%) and in observational studies of 0.22% (95% CI, 0.14% to 0.31%). Complication rates were 17% (95% CI, 11% to 23%) for RCTs, compared with 10% for observational studies (10% [95% CI, 7% to 13%]). At one-year follow-up, mean change in BMI was -13.53 (95% CI, -15.51 to -11.55) in RCTs and -11.79 (95% CI, -13.89 to -9.69) in observational studies. Decreases in
BMI were generally sustained over two to four years of follow-up among the studies with longer term follow-up.

Many systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery. These reviews rely primarily on the results of observational studies and include the outcomes of hypertension, T2D, hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease.

Puzziferi et al conducted a systematic review of studies of bariatric surgery reporting follow-up beyond two years, which included 29 studies with 7971 patients. At follow-up, which ranged from two to five years postprocedure, the mean sample size–weighted percentage of excess weight loss was higher for gastric bypass than for gastric banding (65.7% vs 45.0%). The authors note that few studies report long-term results with enough follow-up to minimize bias.

Section Summary: Bariatric Surgery in Adults with Morbid Obesity
There is a lack of large-scale RCTs with long-term follow-up comparing bariatric surgery with nonsurgical treatment for the general population of patients with morbid obesity. Evidence from nonrandomized comparative studies and case series and from meta-analyses of existing RCTs has consistently reported that bariatric surgery results in substantially greater weight loss than nonsurgical therapy. Data from the largest comparative study, the SOS study, has reported that bariatric surgery is associated with improvements in mortality, diabetes, cardiovascular risk factors, and quality of life.

Evidence for Specific Types of Bariatric Surgical Procedures

Vertical-Banded Gastroplasty
VBG is one of the early types of bariatric surgery developed in the 1980s. This is a purely restrictive procedure that has been largely replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there is a high rate of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. The overall rates of revisions and reoperations at up to 10 years may be as high as 50%.

A small body of literature compares outcomes between VBG and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study, randomized 310 morbidly obese patients to gastric bypass, VBG, or horizontal gastroplasty. The percent of patients with greater than 50% excess weight loss (EWL) at three-year’ follow-up was 67% for gastric bypass, 48% for VBG, and 17% for horizontal gastroplasty (p<0.001). There were no demonstrable differences in AEs among groups. A second, smaller RCT by Sugerman et al randomized 40 patients to receive either a VBG or a gastric bypass procedure. After nine months, the gastric bypass patients had significantly greater weight loss that persisted at three-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight.

A number of other nonrandomized, comparative studies of open gastric bypass versus VBG were included in the 2003 TEC Assessment (N=8 studies, 3470 patients). All eight of these studies reported greater amounts of weight loss with open gastric bypass. These studies reported a 44%
to 70% improvement in total weight loss, a 28% to 43% improvement in the percent EWL, and 19% to 36% more patients with greater than 50% EWL for those undergoing gastric bypass compared with VBG. Comparison of AEs was more difficult, as the data in these studies did not allow rigorous comparison of AEs. Nevertheless, the data suggested that the mortality rate for both operations was low overall. Serious perioperative AEs were also infrequently reported but were possibly somewhat higher for gastric bypass. Long-term AEs were inconsistently reported, although it appeared that revision rates were higher for VBG.

Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the United States. An example of these results is a large case series with long-term follow-up by MacLean et al, who reported on 201 patients undergoing VBG who were followed up for a minimum of two 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.

In 2014, Hseih et al reported a systematic review of studies reporting greater than 10-year follow-up for VBG, which included three studies with extractable data. Mean EWL was 61.4% (±13.5%) from baseline to follow-up in the three included studies, but the authors note a lack of long-term evidence related to outcomes following VBG.

Section Summary: Vertical-Banded Gastroplasty

A TEC Assessment identified eight nonrandomized comparative studies evaluating VBG and these studies found that weight loss was significantly greater with open gastric bypass. However, VBG has relatively high rates of complications, revisions, and reoperations.

Gastric Bypass with Short Limb (<150 cm)

The body of literature has been instrumental in establishing that gastric bypass should be the reference procedure to which other procedures are compared. Practice patterns in the United States have adopted this approach, with gastric bypass now composing most of all bariatric procedures performed.

Comparative trials summarized in the 2003 TEC Assessment consistently report favorable outcomes for open gastric bypass when compared with VBG, including two RCTs. Some nonrandomized trials that compare open gastric bypass with procedures other than VBG were also summarized in the 2003 TEC Assessment. While there are fewer trials for these other procedures, comparisons of open gastric bypass to gastric banding, horizontal gastroplasty, and silastic ring gastroplasty all reported that weight loss was superior with open gastric bypass.

Metabolic abnormalities are seen more frequently in gastric bypass patients compared with those receiving a VBG. Anemia, iron deficiency, vitamin B12 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.

A 2005 TEC Assessment focused on the issue of laparoscopic gastric bypass, which intends 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. This Assessment reviewed seven comparative trials of open gastric bypass and laparoscopic gastric bypass, including three RCTs. In addition, 18 large clinical series of laparoscopic gastric bypass were included in the review.

The 2005 TEC Assessment on laparoscopic gastric bypass concludes that weight loss at one year is similar between laparoscopic and open gastric bypass approaches. Weight loss at longer follow-up periods has been less well-reported but appears to be similar as well. While comparisons of complication rates are less certain, certain patterns are evident and relatively consistent across the data examined. The profile of AEs differs between the two approaches, with each having its advantages and disadvantages. Laparoscopic gastric bypass offers a less-invasive procedure that is associated with decreased hospital stay and earlier return to usual activities. The mortality may be lower with the laparoscopic approach, although both procedures have mortality rates less than 1%. Postoperative wound infections and incisional hernias are also less common with laparoscopic gastric bypass. On the other hand, anastomotic problems, gastrointestinal tract bleeding, and bowel obstruction appear to be higher with the laparoscopic approach, but not markedly higher. Given these data, it is not possible to say that one procedure is superior to the other, and overall the benefit-risk ratio for these two approaches appears to be similar.

In 2016, Yan et al published a systematic review of RCTs comparing gastric bypass and medical treatment in obese patients (ie, BMI ≥30 kg/m²) with T2D. The primary study outcome was remission of T2D, which was reported in five of the six studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment (odds ratio [OR], 76.37; 95% CI, 20.70 to 271.73; p<0.001). In addition, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD = -6.54 kg/m²; 95% CI, -9.28 to -3.80 kg/m²; p<0.001).

Section Summary: Gastric Bypass
Gastric bypass has been extensively studied. TEC Assessments and other systematic reviews found that gastric bypass improved health outcomes, including weight loss and remission of T2D. A TEC Assessment also found similar weight loss with open and laparoscopic gastric bypass.

Laparoscopic Adjustable Gastric Banding
A 2006 TEC Assessment updated the evidence on LAGB, and compared outcomes with those of gastric bypass. This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the two procedures to allow the optimal choice to be made based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at one year is less for LAGB compared with GBY. The percentage of EWL at one year is in the range of approximately 40%, compared with 60% or higher for GBY. At time points longer than one year, some of the comparative studies report that
the difference in weight loss between LAGB and GBY lessens, but others do not. Weight loss outcomes from the nine single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss between the procedures begins to lessen after one to two years of follow-up. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

These studies also confirm that short-term (perioperative) complications are very low with LAGB and lower than with either open or laparoscopic GBY. Death is extremely rare, and serious perioperative complications probably occur at rates of less than 1%.

The reported rates of long-term AEs vary considerably. In the comparative trials, reoperations are reported in approximately 25% of patients, while in the single-arm studies, the composite rate for reoperations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the range of rates for band slippage is 1% to 36%, and the range for port access problems is 2% to 20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are underreported in many studies due to incomplete follow-up and a lack of systematic surveillance. The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit-risk ratio for LAGB.

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the benefits, as defined by the amount of weight loss, will also be less for LAGB. The patterns of long-term complications also differ between the two procedures. For LAGB, longer-term AEs related to the presence of a foreign body in the abdomen will occur and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

A 2012 systematic review by Chakravarty et al comparing LAGB with other bariatric surgery procedures had a conclusion similar to the TEC Assessment. Reviewers included five RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (e.g., gastric bypass or sleeve gastrectomy [SG]). However, the short-term complication rate was lower with LAGB and no difference was found in quality of life after LAGB versus other procedures.

Section Summary: Laparoscopic Adjustable Gastric Banding
Systematic reviews of the literature have concluded that evidence suggests LAGB is a reasonable alternative to gastric bypass; there is less weight loss with LAGB, which is less invasive and is associated with fewer serious adverse events.
Sleeve Gastrectomy

Systematic Reviews

Sleeve gastrectomy (SG) may be performed as a stand-alone procedure or in combination with a malabsorptive procedure, such as the biliopancreatic diversion with duodenal switch. It has also been proposed as the first step in a two-stage procedure, with gastric bypass or biliopancreatic diversion as the second stage.

A 2016 systematic review by Juodeikis and Brimas summarized evidence on long-term results after SG. Reviewers included one RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m². Mean duration of follow-up ranged from five to 11 years and mean proportion of patients followed for five years was 68.5%. Seventeen studies (n=1501 patients) reported five-year follow-up data; mean percent EWL was 58.4%. At five years, resolution of T2D was observed in 77.8% of patients who had SG; arterial hypertension, dyslipidemia, OSA, gastroesophageal reflux disease (GERD), and degenerative joint diseases also improved in most patients. Two studies reported weight loss after seven and eight years; percent EWL rates were 56.6% and 54.8%, respectively.

In 2009, Brethauer et al reviewed 36 studies (N=2570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers. Two RCTs, one 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=1749) on SG as primary procedure. Mean percentage of EWL was reported in 24 studies (N=1662) and was 55.4% overall (range, 33%-85%). Mean postoperative BMI was reported in 26 studies (N=1940) 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 three to 60 months. Ten studies included detailed postoperative comorbidity data (N=754); more than 70% of patients had improvement or remission of T2DM, 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 more 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=2570). All extracted studies reported mortality data with five deaths within 30 days of surgery (overall mortality rate 0.19%, two in the high-risk/staged group and three in the primary procedure group).

In a 2015 meta-analysis of 21 randomized and nonrandomized studies (total N=18,766 patients) comparing SG with LRYGB for morbid obesity, Zhang et al reported no significant difference in percent EWL from 0.5- to 1.5-year follow-ups. However, after 1.5 years, Roux-en-Y bypass was associated with higher percent EWL (2-year MD=5.77; 95% CI, 4.29 to 7.25; p<0.05). Adverse events were more frequent following Roux-en-Y bypass (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

In 2013, Trastulli et al conducted a systematic review of 15 RCTs (total N=1191 patients) that compared SG with other bariatric procedures. Reviewers reported mean complication rates with
SG of 12.1% (range, 10%-13.2%) compared with 20.9% with LAGB (range, 10%-26.4%). Percent EWL ranged from 49% to 81% with SG and from 62.1% to 94.4% with LAGB.

Randomized Controlled Trials
Himpens et al report on a randomized study comparing LAGB and laparoscopic isolated SG. Eighty subjects received surgery over a period of one year. Median BMI was 37 (range, 30-47) in the LAGB group versus 39 in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, gastroesophageal reflux disease (GERD), complications, and reoperations were recorded at one- and three-year follow-up. Median decrease in BMI in the gastric bypass group was 15.5 (range, 5-39) after one year and 18 (range, 0- 39) at three years after LAGB. One year after SG, decrease in BMI was 25 (range, 0-45) and 27.5 (range, 0- 48) after three years. Median EWL in the LAGB group was 41.4% after one year and 48% at three years. Median EWL after SG was 58% and 66% at one and three years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the differences were not significant; GERD appeared de novo in more SG than LAGB patients at one year, and the relationship reversed at three years; between group differences were not significant at either time point. Two SG patients required reoperation for complications. Late complications requiring reoperation after LAGB included pouch dilations treated by band removal (n=2) or conversion to Roux-en-Y gastric bypass (RYGB) (n=1), one gastric erosion treated by conversion to RYGB, and three disconnections of the system were reconnected. Four patients had reoperations for inefficacy; two gastric bypass patients underwent conversion to RYGB, and two SG patients had conversion to duodenal switch (DS). The authors note that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.

Karamanakos et al carried out a double-blind study to compare outcomes of laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic SG (LSG) on body weight, appetite, and fasting and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery. Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI was marked and comparable in each group. EWL was greater after LSG at six months (55.5% vs 50.2%, respectively; p=0.04) and 12 months (69.7% vs 60.5%, respectively; p=0.05). Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but was greater after LSG.

An RCT comparing short-term outcomes of laparoscopic sleeve gastrectomy with gastric bypass was published in 2013. The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to SG. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the SG group (p=0.29). Minor complications were more common in the gastric bypass group compared with SG (17.1% vs 7.4%, p=0.02), as was combined major and minor complications (26.5% vs 13.2%, p=0.01).

Section Summary: Sleeve Gastrectomy
Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least five years. A meta-analysis found that short-term weight loss was similar after SG or gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events.
Biliopancreatic Diversion (BPD) without Duodenal Switch

The available evidence was reviewed in the 2006 TEC Assessment, and outcomes of BPD, with or without DS, were compared with those of gastric bypass. One comparative trial and seven single-arm series suggested that weight loss outcomes at one year are in the same range as for gastric bypass. While these data are not sufficient to distinguish small differences in weight loss between the two procedures, these data do not support the hypothesis that BPD results in greater weight loss than open gastric bypass.

Complication rates are poorly reported in these trials. The data suggest that mortality is low (approximately 1%) and in the same range as for open gastric bypass. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data suggest that long-term nutritional and vitamin deficiencies occur at a high rate following BPD. Slater et al focused specifically on vitamin and calcium deficiencies following BPD. These authors reported high rates of vitamin and calcium abnormalities in their population over a four-year period. By year four, approximately half (48%) of the patients were found to have low calcium, and 63% had low levels of vitamin D. Other fat-soluble vitamins showed similar patterns of abnormalities. Low vitamin A was found in 69% of patients at 4 years, low vitamin K in 68%, and low zinc in 50%. Dolan et al reported similar data in a study that compared several technical variations of BPD. These authors reported low calcium levels in 12% to 34% of patients, low vitamin D in 22.2% to 70.6%, low vitamin A in 53% to 67%, and low vitamin K in 44% to 59%. In addition, this study reported high rates of iron deficiency (11% to 47%) and anemia (11%-40%).

Skroubis et al randomized 130 patients with a BMI of 35 to 50 to either RYGB or biliopancreatic diversion (BPD; without duodenal switch) using a variant of BPD that included Roux-en-Y gastrectomy in place of SG. All patients were followed up for at least two years. Weight loss outcomes were superior for the BPD group at every time period examined up to two years. The EWL at one year was 73.7% for RYGB and 83.1% for BPD (p<0.001); at three years, the EWL was 72.6% for RYGB and 83.1% for BPD (p<0.001). There were more early complications in the RYGB group, but this difference did not reach statistical significance (six complications vs one, respectively; p=0.12). Late complications also did not differ significantly between the RYGB and BPD groups (16 complications vs 22, respectively; p=0.46).

Numerous clinical series of BPD have been published, but, as with other procedures, high-quality trials that directly compare outcomes of this procedure with gastric bypass are lacking. The largest experience with BPD is reported by Scopinaro et al, who developed the procedure. In 1996, Scopinaro et al summarized their experience with 1217 patients. With follow-up of up to nine years, the authors reported a durable EWL of 75%, suggesting that weight loss is greater with this procedure compared with gastric restrictive procedures. In addition, most patients reported disappearance or improvement of such complications as obstructive sleep apnea, hypertension, hypercholesteremia, 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 four postoperative years. All patients are encouraged to maintain an oral calcium intake of 2g/d, with monthly vitamin D supplementation.

Section Summary: BPD without Duodenal Switch
A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without duodenal switch and gastric bypass. However, BPD without duodenal switch leads to complications, especially long-term nutritional and vitamin deficiencies.

Biliopancreatic Diversion (BPD) with Duodenal Switch
BPD may be performed with or without the DS procedure. In the DS procedure, a SG is performed, preserving the pyloric sphincter. 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.

In a 2009 evidence-based review of literature, Farrell et al summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at the mean of one-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (four studies, aggregate n=896), 67% for RYGB (seven studies, N=1627), and 42% for AGB (11 studies, N=4456). At mean follow-up of five years, EWL for BPD with or without DS was 73% (three studies, aggregate N=174), 58% for RYGB (three studies, N=176), and 55% for AGB (five studies, N=640). The authors note that “given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another.”

Prachand et al (2006) published the largest comparative series of 350 super-obese patients with BMI greater than 50 who underwent either RYGB (n=152) or Scopinaro BPD combined with the DeMeester duodenal switch (DS-BPD) (n=198). In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The DS-BPD patients differed from RYGB patients on weight and BMI; mean weight in pounds was 368.2±52.3 (range, 267.4-596.5) in DS BPD patients versus 346.3±55.2 (range, 239.8-504.9) in the RYGB group, and mean BMI was 58.8±6.7 (range, 50-96) in DS-BPD patients versus 56.4±6.8 (range, 49.5-84.2) in the RYGB group. At one year, data were reported for 143 DS-BPD patients and 81 RYGB patients. The EWL was greater for BPD versus RYGB (64.1% vs 55.9%, respectively; p<0.01), and the reduction in BMI was also greater for BPD versus RYGB (23.6 vs 19.4, respectively; p<0.001). Complications and data on resolution of comorbidities were not reported in this study. Strain et al published a smaller comparative study of 72 patients who underwent either RYGB (n=50) or BPD (n=22). Choice of surgery was per surgeon and/or patient, and the patient populations
differed in age and time since surgery. Weight loss at one year was greater for BPD, with a reduction in BMI of 23.3 for BPD compared with 16.5 forRYGB (p<0.001).

The largest case series of this procedure is by Marceau et al (2009), who reported their 15-year experience with duodenal switch in 1423 patients from 1992 to 2005. Follow-up evaluations were available for 97% of patients. Survival rate was 92%. After a mean of seven years (range, 2-15 years), 92% of patients with an initial BMI of 50 kg/m² or less obtained a BMI of less than 35 kg/m², and 83% of patients with BMI greater than 50 kg/m² achieved a BMI of less than 40 kg/m². Diabetes medication was discontinued in 92% and decreased in others. Use of continuous positive airway pressure was discontinued in 92% of patients, and the prevalence of cardiac risk index greater than five decreased by 86%. Operative mortality was 1%, the revision rate was 0.7%, and the reversal rate was 0.2%. Revision for failure to lose sufficient weight was needed in only 1.5% of patients. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage.

Section Summary: BPD with Duodenal Switch
Nonrandomized comparative studies have found significantly higher weight loss after BPB-DS compared with gastric bypass at one year. A large case series found sustained weight loss after seven years.

Gastric Bypass with Long Limb (>150cm)
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 adverse effects associated with BPB. However, there has been limited published evidence on outcomes from this procedure and a large degree of variability in the technical aspects of the procedure among the published literature. Murr et al 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 BPB, the authors reported similar weight loss but decreased metabolic or nutritional abnormalities, attributed in part to the increased length of the common segment, 100cm compared with 50cm used in BPB. Sugerman et al also attribute increasing the length of the common segment to decreasing metabolic morbidities.

The 2005 TEC Assessment reviewed studies that compared outcomes of standard or “short-”limb gastric bypass with outcomes of “long-”limb gastric bypass. There were six comparative studies, two or more in which different lengths of the Roux limb were compared. However, although the categorization of patients into “standard” versus “long-limb” is based on the length of the Roux (alimentary) limb, there is not a definite cutoff for long versus standard limbs. In these studies, there was variability in the lengths of the Roux limbs for both the standard gastric bypass and for the long-limb groups.

Most comparisons of weight loss do not reveal significant differences between short- and long limb gastric bypass. The strongest evidence in this category is from two RCTs. In both of these trials, there were no significant differences in weight loss between groups. Brolin et al compared three limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at one year, while the other two groups had similar decrease in BMI.
MacLean et al examined morbidly obese and superbese patients separately and reported a significant difference in favor of the long-limb gastric bypass group. However, this analysis compared the final BMI of the two groups and did not report the actual change in BMI or the initial BMI for each group.

AEs were poorly reported by these studies, with only three reporting data on AEs. Mason et al reported the percent of patients with “major post-op complications," which was 2.3% for standard gastric bypass and 1.2% for long-limb gastric bypass. There was no further breakdown of the types of major complications recorded and no statistical testing for this outcome. In the remaining two studies, the rates of short-term AEs reported by Inabnet et al were higher for standard gastric bypass, while the rates reported by Brolin et al were higher for the long-limb gastric bypass. Data on long-term complications were scant and did not reveal any apparent differences between short- and long-limb procedures.

Two-Stage Procedures
Bariatric surgeries that are performed in two stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50. The rationale for a two-stage procedure is that the risk of an extensive surgery is prohibitive in patients with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a SG, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a BPD, is performed.

The evidence on two-stage procedures consists of case-series of patients undergoing SG as the initial procedure. Many of these case series do not report on the second-stage operation, and in those that do; only a minority of patients undergoing the first stage actually proceed to the second-stage surgery. For example, Cottam et al reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned two-stage procedure. The incidence of major perioperative complications for laparoscopic SG was 13%. After one year, the mean EWL was 46%. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. The incidence of major complications following the second procedure was 8%. In a similar study, Alexandrou et al reported on 41 patients who underwent SG as the first stage of a planned two-stage procedure. After one-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, ten (24% of total) underwent the second-stage procedure. The remaining 18 patients (44% of total) were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo two-stage procedures are at risk for complications from both procedures. Silecchia et al described the complication rates in 87 patients undergoing a Stage I SG followed by a BPD in 27 patients. For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

This evidence does not indicate that a two-stage bariatric surgery procedure improves outcomes for patients with extreme levels of obesity. There is no evidence to suggest that weight loss is
improved or that complications are reduced, by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year such that a second procedure is no longer indicated. In addition, patients undergoing a two-stage procedure are at risk for complications from both procedures; therefore, it is possible that overall complications are increased by this approach.

Section Summary: Two-Stage Bariatric Surgery Procedures
There is a lack of evidence indicating whether 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. Case series have shown a relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages.

Laparoscopic Gastric Plication
Laparoscopic gastric plication is a bariatric surgery procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves two main steps, mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction, but specifics of the technique are not standardized.

In 2014, Ji et al reported a systematic review of studies reporting outcomes after laparoscopic gastric plication. The study included 14 publications, including one nonrandomized matched cohort analysis, ten uncontrolled case series, and three case reports, including a total of 1450 patients. The largest study, by Talebpour et al, included 800 patients who were enrolled over a 12-year period at a single institution where the technique was developed. Only three studies were identified that included more than 100 patients. The longest follow-up was to 120 months in the Talebpour et al study; other studies that reported a follow-up time had follow-up to 24 months (two studies), 18 months (two studies), or 12 months (nine studies). The mean preoperative BMI ranged from 31.2 to 44.5 kg/m². The mean percent EWL after the procedure was reported in nine studies (N=1407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from six to 24 months. One study reported weight loss in terms of percent decrease in BMI, with a reported decrease at six and 12 months of 66.4% and 60.2%, respectively. One study compared anterior plication and greater curvature plication and reported improved weight loss with greater curvature plication (percent EWL of 53.7% vs 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no mortality was reported and the rate of major postoperative complications requiring reoperation ranged from 0% to 15.4% (average, 3.7%), most commonly due to gastric obstruction or gastric preformation. Surgical techniques were not standardized. The authors conclude that laparoscopic gastric plication may be a promising treatment for obesity, but the currently available evidence is limited by small study size, a lack of randomized trials comparing the technique with established bariatric surgery techniques, and limited medium- to long-term follow-up data.

In a 2012 systematic review, Abdelbaki et al summarized outcomes from seven studies of laparoscopic gastric plication, two of which included more than 100 patients enrolled, for a total of 307 patients. At six-month follow-up, EWL ranged from 28.4% to 54% for the five studies, which reported weight loss outcomes. All studies reported some incidence of nausea and
vomiting, most of which was mild. Twenty patients (6.5 %) were readmitted, of whom 14 (4.6 %) patients required reoperation, most commonly for gastric obstruction (8/14 [57%]).

In 2013, Pattanshetti et al published results of a study that described the evolution of a laparoscopic adjustable gastric banded plication procedure, a hybrid procedure involving both adjustable gastric banding and greater curvature plication which was developed by the authors. Eighty patients were included, with mean BMI 38.05 (±4.73) kg/m². At 6, 12, 18, and 24 months, mean percent EWL was 42.6% (±13.7%), 56.4% (±19.9%), 57.6% (±19.9%), and 65.8% (±17.3%), respectively. Five postoperative complications developed that required reoperation.

Section Summary: Laparoscopic Gastric Plication
There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication to other bariatric surgery procedures. A 2014 systematic review identified only one small comparative study, which was not randomized.

Single Anastomosis Duodenoileal Bypass with Sleeve Gastrectomy
No controlled trials of single anastomosis duodenoileal bypass with sleeve gastrectomy were identified. Some case series have reported on weight loss and other clinical outcomes up to five years postsurgery. One larger series was published in 2015 and reported on 97 patients with obesity and T2D. The authors reported that control of diabetes, defined as an HbA1c less than 6.0%, was achieved between 70% and 84% of patients at different time points. Remission rates were higher for patients on oral therapy than those on insulin, and were higher in patients with a shorter duration of diabetes.

Section Summary: Single Anastomosis Duodenoileal Bypass with SG
No published controlled trials have evaluated single anastomosis duodenoileal bypass with SG. There are a few case series, the largest of which had fewer than 100 patients.

Duodenojejunal Sleeve
The EndoBarrier® (GI Dynamics Inc., Lexington, MA) is a fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and extends 80cm into the small bowel, usually terminating in the proximal jejunum. A systematic review of the effect of EndoBarrier® on weight loss and diabetes control outcomes was published in 2015. It included five small RCTs (total N=235 patients; range, 18-77 patients), with follow-up ranging from 12 to 24 weeks. Comparators were diet and/or other lifestyle modifications, and two studies had sham controls. All studies were judged to be at high risk of bias using the Cochrane risk of bias tool.

Combined results demonstrated that the EndoBarrier® group had 12.6% greater EWL (95% CI, 9.0% to 16.2%) compared to medical therapy. For diabetes control outcomes, trends toward greater improvement in the EndoBarrier® group were not statistically significant. Mean difference in HbA1c level was -0.8% (95% CI, -1.8% to 0.3%) and the relative risk of reducing or discontinuing diabetic medications was 3.28 (95% CI, 0.54 to 10.73).

The largest single trial was a multicenter RCT published in 2014, which included 77 patients with BMI greater than 30 kg/m² and T2D. Patients were treated for six months with EndoBarrier® or medical therapy. At six months, the EndoBarrier® was removed and patients
were followed for an additional six months. Thirty-eight patients were randomized to the EndoBarrier® group and 31 (82%) of 38 completed 12 months of treatment. Thirty-nine patients were randomized to medical treatment and 35 (90%) of 39 completed 12 months of treatment. At six months, the decrease in BMI was significantly greater in the EndoBarrier® group than in the medical therapy group (3.3 kg/m² vs 1.8 kg/m², p<0.05), and at 12 months the difference in BMI was of marginal statistical significance (2.2 kg/m² vs 1.3 kg/m², p=0.06), respectively. HbA1c level was significantly lower in the EndoBarrier® group at six months (7.0% vs 7.9%, p<0.05), but at 12 months the difference between groups did not differ significantly (7.3% vs 8.0%, p=0.95).

Section Summary: Duodenojejunal Sleeve
A systematic review of evidence on a duodenojejunal sleeve included five RCTs and found significantly greater short-term weight loss (12-24 weeks) with duodenojejunal sleeves compared with medical therapy. There was no significant difference in symptom reduction associated with diabetes. All RCTs had small sample sizes and were judged by the systematic reviewers to be at high risk of bias.

Intragastric Balloon Devices
Intragastric balloons are placed in the stomach via endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2015, two gastric balloon devices have FDA approval; both are designed to stay in the stomach for no more than six months. The ReShape Duo is a saline-inflated dual-balloon system and the OBERA Intragastric Balloon System (previously marketed outside of the United States as BioEnterics) is a saline-inflated silicone balloon.

Systematic Reviews
Several systematic reviews of RCTs evaluating IGB devices for the treatment of obesity have been published; none was limited to FDA-approved devices. Most recently, in 2017, Saber et al identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention. IGB was compared with sham in 15 trials, behavioral modification in four trials, and pharmacotherapy in one trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between three and six months. In a meta-analysis of seven RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group compared with the control group (mean effect size [ES], 1.59 kg/m²; 95% CI, -0.84 to 4.03 kg/m²; p<0.001). Findings on other outcomes were similar. A meta-analysis of four studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%; p=0.02). In addition, a meta-analysis of six studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg; p=0.003).

Although the review was not limited to FDA-approved devices, older devices were air-filled and newer devices, including the two approved by FDA in 2015, are fluid-filled. Sufficient data were available to conduct a sensitivity analysis of three month efficacy data. A meta-analysis of four studies did not find a significant difference in weight loss with air-filled IGB devices or a control intervention at three months (ES= 0.26; 95% CI, -0.12 to 0.64; p=0.19). In contrast, a meta-analysis of eight studies of fluid-filled devices found significantly better outcomes with the IGB than with control (ES=0.25; 95% CI, 0.05 to 0.45; p=0.02).
Randomized Controlled Trials

Pivotal trials on both FDA-approved devices have been published. In 2015, Ponce et al published a multicenter sham-controlled double-blinded trial evaluating the ReShape Duo intragastric balloon. A total of 326 patients were randomized to six months of treatment with an IGB plus lifestyle therapy (n=187) or a sham device plus lifestyle therapy (n=126). Patients in the control group were given the option of active IGB treatment at six months. Key eligibility criteria were age 21 to 60 years, baseline BMI between 30 and 40 kg/m², one or more obesity-related comorbidities, and failure to lose sufficient weight in the past 36 months in a medically supervised weight loss program. A total of 176 IGB and 126 control patients (90% of the randomized population) completed the initial six month treatment and were included in the primary end point analysis. After six months, 77 patients in the control group opted to receive an IGB; these patients were also included in the IGB safety analysis.

Coprimary effectiveness outcomes, assessed at six months, were mean percent EWL and having at least 35% of patients in the IGB group achieving at least a 25% EWL. Both primary effectiveness outcomes were met. In the intention-to-treat (ITT) analysis, the mean percent EWL at six months was 25.1 in the IGB group and 11.3 in the control group (p=0.004). The proportion of patients who achieved at least a 25% EWL was 48.8%, with a lower confidence bound of 41.6%. Most adverse events were anticipated accommodative symptoms (eg, nausea, vomiting, abdominal pain), which generally resolved after three to seven days; they were severe in 1% to 2% of patients and were successfully treated. Most device-related serious adverse events (75% [21/28]) were emergency department visits for treatment of accommodate symptoms. There were no deaths, intestinal obstructions, gastric perforations, or device migrations.

In 2017, Courcoulas et al published a multicenter, pivotal RCT evaluating the Obera IGB in the United States (as noted, the device has been used in other countries). A total of 317 patients were randomized and initiated six months of treatment with an IGB plus lifestyle therapy (n=137) or lifestyle therapy only (n=136). Patients were followed for an additional six months. Key eligibility criteria were age 18 to 65 years, baseline BMI between 30 and 40 kg/m², a history of obesity for at least two years, and having failed previous weight loss attempts. Nineteen patients in the IGB group and 121 in the control group completed the six-month treatment period.

Coprimary effectiveness outcomes, assessed at nine months, were mean percent EWL and difference in mean weight loss. Mean percent EWL at nine months was 26.4% in the IGB group and 10.1% in the control group (difference, 16.2%; 95% CI, 12.3% to 20.2%; p<0.001). Mean weight loss at nine months was -8.8 kg (-19.4 lb) in the IGB group and -3.2 kg (-7.1 lb) in the control group (p<0.001). There were also significant between-group differences in mean weight loss and mean percent EWL at six and 12 months.

As in the trial on the Reshape Duo device, most adverse events in the Obera pivotal trial were anticipated accommodative symptoms. A total of 139 (87%) patients reported nausea, 121 (76%) reported vomiting, and 92 (58%) reported abdominal pain. Fewer than 5% of these adverse events were serious; most were mild or moderate. Thirty patients in the device group had the IGB removed before month six because of an adverse event (n=15) or patient request (n=15). There were no deaths and nine serious adverse events unrelated to device accommodation;
among others, they included one case of gastric outlet obstruction and one case of gastric perforation with sepsis.

The Courcoulas et al pivotal trial was not blinded or sham-controlled; however, a double-blind sham-controlled RCT evaluating the BioEnterics gastric balloon (previous called the Obera device) was published by Genco et al in 2006. This crossover trial included 32 obese patients ages 25 to 50 years with a mean BMI of 47.3 kg/m². Patients received, in random order, three months of an IGB and three months of sham. (Both groups underwent upper gastrointestinal endoscopy, but no device was placed in the sham group.) Patients who initially received the IGB had a mean BMI reduction of 5.8 kg/m² after three months; after crossover to sham, they had a mean additional BMI reduction of 1.1 kg/m². Patients initially in the sham group had an initial mean BMI reduction of 0.4 kg/m²; after crossover to an active device, they had a mean BMI reduction of 5.1 kg/m². The between-group difference in BMI reductions was statistically significant (p<0.001). Findings on other outcomes (mean percent EWL, mean weight loss) were similar.

Case Series
A case series of patients treated with an IGB with up to 60-month follow-up was published by Kotzampassi et al in 2012. A total of 500 patients were treated with the BioEnterics IGB. Twenty-six patients did not complete the initial six months of treatment and another 77 patients did not comply with dietary restrictions and did not have satisfactory weight loss at six months. Among 352 patients with data available, BMI was 44.5 kg/m² at baseline, 35.7 kg/m² at device removal, 38.8 kg/m² 12 months after device removal, and 40.1 kg/m² 24 months after device removal. Mean percent EWL was 43.9% at device removal, 27.7% 12 months after device removal, and 17% 24 months after device removal. Among the 195 patients with available five-year data, mean baseline BMI was 43.3 kg/m², mean BMI at device removal was 33.8 kg/m², and mean BMI at five years was 40.1 kg/m². Mean percent EWL at five years was 13.0%. Overall, patients who initially complied with six months of IGB device use and lost weight, slowly gained weight over time but weighed less at final follow-up than at baseline.

Section Summary: Intragastric Balloon Devices
There are RCTs on the two FDA-approved devices, a case series with long-term follow-up on one of these devices, and systematic reviews on various IGB devices. RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or lifestyle therapy alone. There are some adverse events, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events can be severe. One RCT followed patients for an additional six months after IGB removal and found sustained weight loss. A large case series with follow-up up to five years has suggested that patients regain weight over time. Additional long-term follow-up data are needed.

Aspiration Therapy Device
Aspiration therapy involves an FDA-approved device (AspireAssist) that allows patients to drain a portion of the stomach contents after meals via an implanted tube connected to an external skin port. One RCT has been published. The trial, by Thompson et al (2016), randomized 207 participants to 52 weeks of AspireAssist therapy plus lifestyle counseling (n=127) or lifestyle counseling alone (n=70). Participants were between 21 and 65 years of age, with a BMI ranging
from 35 to 55 kg/m². Coprimary outcomes were mean EWL at 52 weeks and the proportion of patients with 25% or more EWL at 52 weeks. Investigators did a modified ITT analysis including all patients in the AspireAssist group who attempted tube placement (n=111) and all patients in the lifestyle counseling group who attended at least one therapy session (n=60). Mean EWL at 52 weeks was 31.5% in the AspireAssist group and 9.8% in the lifestyle counseling group. The difference between groups was 21.7% (95% CI, 15.3% to 28.1%), which was greater than the 10% difference needed to meet the a priori definition of success. The proportion of patients with 25% or more EWL at 52 weeks was 58.6% in the AspireAssist group and 22% in the lifestyle counseling group (p<0.001). Bulimia or binge eating disorder were exclusion criteria and, during the study, there was no evidence that patients developed bulimia or that devices were overused (ie, used >3 times a day). Most of the adverse events (≈90%) in the AspireAssist group were associated with placement of a percutaneous endoscopic gastric tube. All five serious adverse events occurred in the AspireAssist group (mild peritonitis, severe abdominal pain and one case of product malfunction). Durability of a treatment effect beyond one year was not reported.

In addition to the RCT, a 2016 case series by Noren and Forssell evaluated AspireAssist use by 25 obese patients. Patients had one year of aspiration therapy and also participated in a cognitive-behavioral therapy weight loss program for the initial three months. Patients were instructed to aspirate three times a day after meals. Twenty (80%) patients completed the one-year intervention period. Mean baseline weight was 107.4 kg. In a per protocol analysis, the mean EWL was 54.5% at 12 months. Data on 15 (60%) patients were available at 24 months; mean EWL was 61.5%.

Section Summary: Aspiration Therapy Device
The evidence consists of one RCT with one-year follow-up and a small case series with up to two years of follow-up. The RCT found significantly greater weight loss (measured several ways) with aspiration therapy compared with lifestyle therapy at one year. The case series followed only 15 patients more than one year; at two years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on aspiration therapy remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, and nutrition.

Primary Obesity Surgery, Endoluminal
The “POSE” (primary obesity surgery, endoluminal) procedure is an endoscopic gastroplasty procedure that uses tissue anchors to reduce the stomach’s size and ability to stretch to accommodate a meal. The procedure uses the g-Cath EZ™ Suture Anchor Delivery Catheter (USGI Medical Inc., San Clemente, CA) to create a durable fold in the stomach. In 2013, Espinos et al reported results from a prospective, single-center cohort study of the POSE procedure in patients with obesity that refused surgical therapy. Forty-five patients who had a technically successful POSE procedure were included. Over six months of follow-up, patients had a mean percent EWL of 49.4%, with a mean BMI decrease of 5.8. Randomized studies are ongoing in the United States, including an industry-sponsored randomized, blinded, sham controlled trial, the USGI Medical ESSENTIAL Study for Weight Loss.
Mini-Gastric Bypass
The “mini-gastric bypass” is a laparoscopic procedure forming a large and elongated gastric pouch and a loop gastric bypass with distal diversion (200 cm or up to ½ of small bowel) to reduce food absorption. Currently, data is very limited on this procedure. The mini-gastric bypass has primarily been advocated by one surgeon. In 2001, Rutledge published his experience with 1274 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 EWL was 51% at six months, 68% at 12 months, and 77% at two 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.

Gastric Electrical Stimulation
The Gastric Electrical Stimulation procedure uses electrodes to stimulate the stomach. This procedure when used for the treatment of obesity is also considered investigational and is addressed in medical policy #148 Gastric Electrical Stimulation.

There are several procedures which are currently considered to be outdated and are rarely performed today. These include the jejunoileal bypass, gastric wrapping, the Garren-Edwards gastric bubble, and the loop gastric bypass.

Revision Bariatric Surgery
A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of comorbidities with somewhat higher complication rates than for primary surgery. In 2015, Sudan et al reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database. The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) There were a total of 449,473 bariatric operations in the database of which 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3 %) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective operations and 8750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1%), AGB (N=153,142, 36.5%), SG (N=42,178, 10%), and BPD±DS (N=4,260, 1%), with the rest classified as miscellaneous. AGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Rouxen- Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs 1.8±4.9, p<0.001) and for conversions (2.86±4.58 vs 1.8±4.9, p<0.001). The mean percent EBWL at one year was 43.5 % after primary operation, 39.3 % after conversions, and 35.9 % after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions compared with primary operations (0.31% vs 0.17%, p<0.001), but not for corrections compared
with primary operations (0.24% vs 0.17%, p=NS). One-year serious adverse event (SAE) rates were higher for conversions compared with primary operations (3.61% vs 1.87%, p<0.001), but not for corrections compared with primary operations (1.9% vs 1.87%, p=NS). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

As part of the American Society for Metabolic and Bariatric Surgery Revision Task Force, Brethauer et al (2014) conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews. The review is primarily descriptive, but the authors make the following conclusions:

“The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.”

Endoscopic Revision Procedures
While bariatric surgery revision/correction can be conducted using standard operative approaches, novel endoscopic procedures are being publicized as an option for these patients. Some of these procedures use devices that are also being evaluated for endoscopic treatment of gastroesophageal reflux (see medical policy #023 Tranesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease (GERD)). The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate). Reported trials that used one of the suturing devices had fewer than ten patients. For example, Herron reported on a feasibility study in animals. Thompson reported on a pilot study with changes in anastomotic diameter and weight loss in eight patients who had weight regain and dilated gastrojejunal anastomoses after RYGB. No comparative trials were identified; comparative trials are important because of the known association between an intervention and short-term weight loss.

The StomaphyX™ device is one device used in this approach. This device was cleared by the FDA through the 510(k) process. It was determined to be equivalent to the EndoCinch™ system which has 510(k) marketing clearance for endoscopic suturing for gastrointestinal surgery. In 2014, Eid et al reported results from a single-center RCT of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after RYGBP at least two years earlier. Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after one-year follow-up was completed by 45 patients in the StomaphX group and 29 patients in the sham control group after preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphX patients. The primary efficacy end point (reduction in pre-Roux-en-Y gastric bypass excess weight by ≥15%, excess BMI loss, and BMI
<35, at 12 months postprocedure) was achieved by 10/45 (22.2%) of the StomaphyX group and one of 29 (3.4%) of the sham control group (p<0.01).

A survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons indicates different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. 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. A systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by ASMBS’s Emerging Technology and Procedures Committee concluded, “The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available.”

Section Summary: Revision Bariatric Surgery
For surgical revision of bariatric surgery after failed treatment, evidence from nonrandomized studies suggests that revisions are associated with improvements in weight similar to those seen in primary surgery. However, the published scientific literature on use of devices and procedures in patients who regain weight after bariatric surgery is very limited.

Bariatric Surgery as a Treatment for T2DM
Current indications for bariatric surgery view poorly or uncontrolled diabetes mellitus as a comorbidity whose presence supports the medical necessity of surgery for patients with BMI of 35 to 40. There also is growing interest in gastrointestinal surgery to treat patients with T2D in patients with lower BMI. There are numerous small RCTs that have been published comparing bariatric surgery with medical treatment and several meta-analyses of these RCTs. This section will focus on RCTs and systematic reviews of RCTs of bariatric surgery versus medical therapy.

T2D and BMI 30 to 34.9 kg/m²
In 2016, Wu et al published a meta-analysis of studies comparing bariatric surgery and nonsurgical interventions for patients with T2D. Eight RCTs with 619 patients were included. RCTs addressed RYGBP (six studies), LAGB (three studies), LSG (one study), and BPD (one study). Mean BMI across studies was 29 kg/m² or higher; in six of eight studies, mean BMI was 35 kg/m² or higher. One study had five-year follow-up and the others had one to three years of follow-up. The study with five-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m². All eight studies reported remission of T2D as an efficacy end point. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR=5.76; 95% CI, 3.15 to 10.55; p<0.001).

Another diabetes-related outcome (mean reduction in HbA₁c levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD = -1.29; 95% CI, -1.70 to -0.87). In addition, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD = -5.80; 95% CI, -6.95 to -4.64; p<0.001).

Since publication of the Wu meta-analysis, five-year follow-up has been reported for the Schauer et al RCT, which is shown in Table 3. When the Wu et al meta-analysis was published, only three-year findings of the Schauer study were available. The study included patients with T2D
who had BMI 27-43 kg/m². The RCTs evaluating bariatric surgery in patients with T2D, including the five-year follow-up of the Schauer study, are summarized in Table 3.

Observational studies evaluating patients undergoing bariatric surgery in patients with T2D with follow-up to three or more years are shown in Table 4.

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m². Eleven comparative trials of medical therapy versus bariatric surgery were included, with five RCTs and six nonrandomized comparative studies identified. Follow-up was between one and three years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR=14.1; 95% CI, 6.7 to 29.9; p<0.001). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD = -5.5 kg/m²; 95% CI, -6.7 to -4.3 kg/m², p<0.001), a lower HbA1c level (MD = -1.4%; 95% CI, -1.9% to -0.9%; p<0.001), lower rates of hypertension (OR=0.25; 95% CI, 0.12 to 0.50; p<0.001), and lower rates of dyslipidemia (OR=0.21; 95% CI, 0.10 to 0.44; p<0.001).

Also in 2015, Rao et al published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m² or less who underwent RYGBP. Nine articles were included (total N=343 patients). After 12 months, patients with T2D had a significant decrease in BMI (weighted mean difference [WMD], -7.42; 95% CI, -8.87 to -5.97; p<0.001) and improvements in HbA1c levels (WMD = -2.76; 95% CI, -3.41 to -2.11; p<0.000). Reviewers reported that longer term follow-up would be needed.

Previously, a 2012 TEC Assessment evaluated bariatric surgery in diabetic patients with a BMI less than 35 kg/m². The evidence consisted mainly of case series. The Assessment identified only observational studies. Based on the data, the Assessment concluded that gastric bypass met TEC criteria as a treatment for diabetes in patients with a BMI less than 35 kg/m² but that other procedures did not meet the TEC criteria for this indication:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with a BMI less than 35 kg/m². There was only one randomized trial comparing two bariatric procedures. Therefore, studies were categorized by procedure type and presented as case series, regardless of the underlying study type.
- Nine studies reported diabetes remission rates and other outcomes in subjects undergoing gastric bypass. Diabetes remission rates varied between 48% and 100% at follow-up times of one year and beyond. One study was a randomized clinical trial of gastric bypass versus SG; in it, diabetes remission associated with gastric bypass was 93% versus 47% for SG at one year.
- Two studies reported outcomes of SG. Diabetes remission rates were 55% and 47% at one year.
- One study reported outcomes of ileal interposition. The diabetes remission rate at a mean follow-up time of 39.1 months was 78.3%.
- Two studies reported outcomes of gastric banding. The outcomes reported were not considered to be rigorous, because the only measure of diabetes outcome was withdrawal.
of diabetes medication. Reported remission rates were 27.5% and 50% at variable follow-up times.

- One study of BPD reported a remission rate of 67% for subjects with a BMI between 30 and 35 kg/m² and 27% for subjects with a BMI between 25 and 30 kg/m² at 12-month follow-up.
- One study reported outcomes of duodenojejunal exclusion. Subjects in this study had more severe diabetes than subjects enrolled in other studies; 100% were on insulin treatment and the duration of diabetes was between five and 15 years. The diabetes remission rate was 17% at 6 months.

Section Summary: T2D and With BMI 30 to 34.9 kg/m²

Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/m². The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have one to three years of follow-up; one RCT, which included patients with BMI between 30 and 34.9 kg/m², had five-year follow-up data.
Table 3: RCTs\textsuperscript{a} Comparing Bariatric Surgery in Patients with T2D to Control

<table>
<thead>
<tr>
<th>Study (Country)</th>
<th>N</th>
<th>BMI Range, kg/m\textsuperscript{2}</th>
<th>Patients With BMI ≤35 kg/m\textsuperscript{2}</th>
<th>Length of FU, years</th>
<th>Definition Diabetes Remission</th>
<th>Diabetes Remission Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dixon et al (2008) (US)</td>
<td>60</td>
<td>30-40</td>
<td>22%</td>
<td>2</td>
<td>% achieving FBS&lt;126mg/dL, HbA\textsubscript{1c}&lt;6.2% (off meds)</td>
<td>22/30 (93%)</td>
</tr>
<tr>
<td>Ikramuddin et al (2015) (U.S)</td>
<td>120</td>
<td>30-40</td>
<td>59%</td>
<td>2</td>
<td>% achieving all 3 ADA goals: HbA\textsubscript{1c}&lt;7.0%, LDL&lt;2.59 mmol/L, SBP&lt;130 mm Hg</td>
<td>26/60 (43%)</td>
</tr>
<tr>
<td>Liang et al (2013) (China)</td>
<td>108</td>
<td>&gt;28\textsuperscript{g}</td>
<td>1</td>
<td>T2D remission\textsuperscript{b}</td>
<td>28/31 (90%)</td>
<td></td>
</tr>
<tr>
<td>Courcoulas et al (2015) (U.S)</td>
<td>61</td>
<td>30-40</td>
<td>43%</td>
<td>3</td>
<td>Partial: HbA\textsubscript{1c}&lt;6.5%, Full: HbA\textsubscript{1c}&lt;5.7% (off meds)</td>
<td>8/20 (40%)</td>
</tr>
<tr>
<td>Schauer et al (2017) (U.S)</td>
<td>150</td>
<td>27-43</td>
<td>37%</td>
<td>5</td>
<td>% HbA\textsubscript{1c}&lt;6.0% (% meds)</td>
<td>14/49 (29%)</td>
</tr>
<tr>
<td>Mingrone et al</td>
<td>60</td>
<td>35+</td>
<td>0%</td>
<td>5</td>
<td>%HbA\textsubscript{1c}&lt;6.5% (% meds)</td>
<td>8/19 (42%)</td>
</tr>
<tr>
<td>Wentworth et al (2014) (Italy)</td>
<td>51</td>
<td>25-30</td>
<td>100%</td>
<td>2</td>
<td>&lt;125mg/dL or 200mg/dL or 2-h OGTT (off meds x2 d)</td>
<td>Surgery (LAGB)</td>
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<td><strong>12/23 (52%)</strong></td>
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</table>

<table>
<thead>
<tr>
<th>Halperin et al (2014) (U.S.)</th>
<th>43</th>
<th>30-42</th>
<th>30%</th>
<th>1</th>
<th>% HbA1c&lt;6.5%</th>
<th>Surgery (RYGB)</th>
<th>Control (HILL/A1C-S)</th>
</tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>11/19 (58%)</strong></td>
<td></td>
<td><strong>3/19 (16%)</strong></td>
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</tbody>
</table>


*All RCTs in this table are in the Wu et al (2016) meta-analysis; 7 of the 8 (except Mingrone et al) are in the Muller-Stich et al (2015) meta-analysis; the Rao et al (2015) meta-analysis and the TEC Assessment did not include RCTs. No additional RCTs comparing bariatric surgery to nonsurgical treatment in patients with T2D were identified.

*Used secondary outcome. Primary outcome was change in left ventricular mass index.

*Unadjusted (RYGB vs control).

*Unadjusted (LSG vs control).

*RYGB vs control.

*LSG vs control.

*WHO Asia-Pacific Obesity Classification.

*Through February 2017
### Table 4: Observational Studies on Bariatric Surgery in Patients with Type 2 Diabetes with Follow-Up ≥3 Years

<table>
<thead>
<tr>
<th>Study (Country)</th>
<th>N</th>
<th>BMI Range, kg/m²</th>
<th>Patients With BMI ≤35 kg/m²</th>
<th>Length of FU</th>
<th>Interv</th>
<th>Mean HbA₁c Base</th>
<th>Mean BMI Base</th>
<th>Diabetes Remission Rate</th>
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<tr>
<td><strong>Group I</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Scopinaro et al (2014)</td>
<td>20 treated; 27 matched diabetic controls</td>
<td>30-34.9</td>
<td>100%</td>
<td>3 y</td>
<td>RYGB</td>
<td>9.5%</td>
<td>7.0%&lt;sup&gt;a&lt;/sup&gt;</td>
<td>32.9</td>
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</tr>
<tr>
<td>Lanzarini et al (2013)</td>
<td>31</td>
<td>30-35</td>
<td>100%</td>
<td>30 mo&lt;sup&gt;c&lt;/sup&gt;</td>
<td>RYGB</td>
<td>7.9%</td>
<td>5.5%&lt;sup&gt;a&lt;/sup&gt;</td>
<td>33.1</td>
</tr>
<tr>
<td>Boza et al (2011) (Chile)</td>
<td>30</td>
<td>&lt;35</td>
<td>100%</td>
<td>2 y</td>
<td>RYGB</td>
<td>8.1%</td>
<td>≈6.2%&lt;sup&gt;ab&lt;/sup&gt;</td>
<td>33.5</td>
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<tr>
<td>DePaula et al (2012) (Brazil)</td>
<td>202</td>
<td>&lt;35</td>
<td>100%</td>
<td>39 mo&lt;sup&gt;c&lt;/sup&gt;</td>
<td>SG</td>
<td>8.7%</td>
<td>6.1%&lt;sup&gt;a&lt;/sup&gt;</td>
<td>29.7</td>
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<tr>
<td><strong>Group II</strong></td>
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<tr>
<td>Lee et al (2008) (Taiwan)</td>
<td>544 bypass</td>
<td>32-77</td>
<td>Not reported</td>
<td>3 y</td>
<td>Bypass</td>
<td>6.2%</td>
<td>4.8%</td>
<td>41.3</td>
</tr>
<tr>
<td></td>
<td>116 LAGB</td>
<td>Not reported</td>
<td>LAGB</td>
<td>5.9%</td>
<td>5.2%</td>
<td>41.9</td>
<td>32.7</td>
<td></td>
</tr>
</tbody>
</table>

Group I is defined as poor control optimal medical management (may include insulin). Group II is defined as adequate control with medication (may include insulin). Base: baseline; BMI: body mass index; Bypass: mini-gastric bypass; FU: follow-up; HbA₁c: hemoglobin A₁c; Interv: intervention; LAGB: laparoscopic adjustable gastric banding; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

<sup>a</sup>p<0.05 (follow-up vs baseline).

<sup>b</sup>Estimated from figure.

<sup>c</sup>Mean.
Bariatric Surgery in Nondiabetic Patients with BMI Less Than 35 kg/m²
A 2012 TEC Assessment evaluated laparoscopic gastric banding in nondiabetic individuals with a BMI less than 35. This Assessment was prompted by FDA approval of LAP-BAND™ for this indication in 2011. The TEC Assessment concluded that LAGB does not meet the TEC criteria in these patients and made the following summary statements:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There is only one small RCT, which has methodologic limitations, one nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence is sufficient to determine that weight loss following LAGB is greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities is lacking. The limited evidence is not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities can be assumed.
- There is very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following is uncertain, and this uncertainty is one of the main reasons why it is difficult to determine whether the benefit of LAGB outweighs the risk for this population. While the short-term safety of LAGB has been well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

Section Summary: Bariatric Surgery in Nondiabetic Patients with a BMI Less Than 35 kg/m²
There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery
Hiatal hernia is associated with obesity and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of hiatal hernia has been associated with complications after laparoscopic adjustable gastric banding, although other studies report no differences in perioperative complications after laparoscopic adjustable gastric banding in patients with GERD and/or hiatal hernia and those without GERD and/or hiatal hernia. Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management of hiatal hernia that recommends that, during operations for RYGBP, SG, and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate [Further research is likely to alter confidence in the estimate of impact and may change the estimate]).

There is limited evidence about whether the repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery, consisting primarily of cohort studies comparing
outcomes for patients with hiatal hernia who underwent repair during bariatric surgery to patients without hiatal hernia.

Gulkarov et al (2008) reported results of a prospective cohort study comparing outcomes for patients who underwent laparoscopic adjustable gastric banding with or without concurrent hiatal hernia repair (N=1298 with adjustable gastric banding alone; N=520 with concurrent hiatal hernia repair). The authors report that initially hiatal hernias were diagnosed based on preoperative esophagram and upper endoscopy, but this was discontinued after these studies were shown to have poor predictive value for small-to-medium size hernias; subsequent patients were diagnosed at the time of operation. It is not specified how many patients were diagnosed with each method, and how many of those had symptoms before gastric banding. Fewer patients who underwent concurrent hiatal hernia repair required reoperation for a complication (3.5% vs 7.9% in the adjustable gastric banding alone group; p<0.001). Hiatal hernia repair added an average of 14 minutes to operative time. Weight loss outcomes did not differ significantly between the groups.

Santonicola et al (2014) evaluated the effects of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on GERD in obese patients. The study included 78 patients who underwent sleeve gastrectomy with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia identified who underwent SG only. The prevalence of typical GERD symptoms did not improve from baseline to follow-up in patients who underwent concomitant hiatal hernia repair (38.4% presurgery vs 30.8% postsurgery, p=0.3). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% presurgery vs 19.6% postsurgery, p=0.003).

Reynoso et al (2011) reported outcomes after primary and revisional laparoscopic adjustable gastric banding in patients with hiatal hernia treated at a single hospital system. Of 1637 patients with hiatal hernia undergoing primary gastric banding, 190 (11.6%) underwent concurrent hiatal hernia repair; of 181 patients undergoing revision gastric banding, 15 (8.3%) underwent concurrent hiatal hernia repair. For primary procedures, there were no significant differences in mortality, morbidity, length of stay, and 30-day readmission rates for patients who underwent adjustable gastric banding with and without hiatal hernia repair. However, it appears that this comparison is for patients without hiatal hernia compared with patients with hiatal hernia who also underwent hiatal hernia repair.

Ardestani et al (2014) analyzed data from the Bariatric Outcomes Longitudinal Database to compare outcomes for patients with and without hiatal hernia repair at the time of laparoscopic adjustable gastric banding. Of 41,611 patients who underwent laparoscopic adjustable gastric banding from 2007 to 2010, 8120 (19.5%) had concomitant hiatal hernia repair. Those with hiatal hernia repair were more likely to have GERD preoperatively (49% vs 40% in the non-hiatal hernia repair group; p<0.001). Perioperative outcomes were similar between groups. Of those with GERD preoperatively, rates of improvement in GERD symptoms did not differ significantly 1 year postprocedure (53% in the hiatal hernia repair group vs 52% in the non-hiatal hernia repair group; p=0.4). Although the hiatal hernia repair added minimal time (mean, four minutes) to surgery, the authors conclude that many repairs may involve small hernias with limited clinical effect.
In general, studies report that the addition of hiatal hernia repair at the time of bariatric surgery is safe and feasible. In a small case series of 21 patients, Frezza et al (2008) described the feasibility of crural repair at the time of laparoscopic adjustable gastric banding for patients with hiatal hernia. Al-Haddad et al used data from the U.S. Nationwide Inpatient Sample to evaluate the surgical risk associated with hiatal hernia repair at the time of bariatric surgery. For laparoscopic RYGBP, there were 206,559 and 9060 patients who underwent the procedure alone or with concomitant hiatal hernia repair, respectively. For laparoscopic AGB, there were 52,901 and 9893 patients who underwent the procedure alone or with hiatal hernia repair, respectively. The authors reported no evidence of increased risk of perioperative adverse events associated with the concomitant hiatal hernia repair. However, patients who underwent a concomitant hiatal hernia repair were less likely to have prolonged length of stay (PLOS), with an average treatment effect on the treated (ATT) of hiatal hernia repair of -0.124 (95% CI, -0.15 to -0.088) for PLOS for patients who underwent Roux-en-Y gastric bypass and an ATT of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for PLOS for patients who underwent laparoscopic adjustable gastric banding.

Section Summary: Hiatal Hernia Repair in Conjunction with Bariatric Surgery
Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. However, the evidence related to whether hiatal hernia repair improves outcomes after bariatric surgery is limited, particularly for hiatal hernias that are incidentally diagnosed at the time of surgery. No studies were identified that compared outcomes after bariatric surgery with or without hiatal hernia repair in a population of patients with known hiatal hernia. For patients with a preoperative diagnosis of hiatal hernia, symptoms related to the hernia, and indications for surgical repair it is reasonable to undertake this at the time of bariatric surgery. For other patients, it is uncertain whether repair of a hiatal hernia at the time of bariatric surgery improves outcomes.

Presurgical Preparatory Regimen
- The patient should be committed to the appropriate work up for consideration for a surgical procedure and also for the continuing long-term post-operative medical management.
- The patient is willing to lose weight prior to surgery to make surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restrictions which will occur post-surgery.
- An individual’s understanding with the procedure and the ability to comply with lifelong follow-up and lifestyle changes, “e.g., as exemplified by compliance with previous medical care” are necessary for the success of the procedure.
- Modifications to improve dietary and exercise habits may reduce surgical risks and improve surgical outcomes.

Obesity makes many types of surgery more technically difficult to perform. Weight loss prior to surgery may make the procedure easier to perform. In addition, weight reduction may reduce the size of the liver making surgical access to the stomach easier. In contrast, the liver enlarges and becomes increasingly infiltrated with fat when weight is gained prior to surgery. A fatty liver is more likely to suffer injury during the surgical procedure. The patient who is able to comply
with pre-surgical interventions is likely to show a better compliance with the post-operative care and severe dietary restrictions which will be imposed post-operatively.

**Rationale for Nutrition and Exercise Program Prior to Surgery**

Effective weight control involves multiple techniques and strategies including dietary therapy, physical activity, behavioral therapy, pharmacotherapy, and surgery as well as combinations of these strategies. Physical activity should be an integral part of weight loss therapy and weight maintenance. The NIH Consensus Conference (1998) has stated the patient should begin a nutrition and exercise program prior to surgery: “An integrated program must be in place to provide guidance on diet, physical activity and behavioral and social support both prior to and after surgery”. This statement documents that the initial goal of medical therapy is a 10% reduction in weight and that a reasonable duration for medical therapy is six months. The rationale for this initial goal is that a moderate weight loss, i.e., 10% of the initial body weight, can significantly decrease the severity of obesity-associated risk factors.

The combination of a reduced calorie diet and increased physical activity can result in substantial improvements in blood pressure, glucose tolerance, lipid profile and cardiorespiratory fitness. The purpose of the pre-operative nutrition program prior to obesity surgery is to test patient motivation, to reduce perioperative morbidity, to accustom patients to the restriction of food intake after surgery, and to increase total weight loss (van de Weijgert, et al, 1999; Jung and Cusciheri, 2000; Pekkarinen, et al, 1997; Martin, et al, 1995). The medical literature indicates that even super obese patients with a BMI >50 may benefit from initiating a nutritional and exercise program prior to surgery. Obesity in and of itself increases the likelihood of pulmonary complications and wound infections. Even relatively moderate weight loss prior to surgery can result in substantial improvements in pulmonary function, glucose tolerance, blood pressure and other physiological parameters (Anderson, et al, 1992; Hakala, et al, 1995; Kansanen, et al, 1998 and Pekkarinen, et al, 1998).

**Requirement that Morbid Obesity be Present for a Defined Period of Time Prior to Surgery**

According to the guidelines of the American Association of Clinical Endocrinologists and the American College of Endocrinology (1998), “Surgical treatment of obesity may be considered only in carefully selected patients where…obesity has been present for at least five years”. Obesity surgery should not be indicated for persons with transient increases in weight (Collazo-Clavell, 1999). Patients who gain weight to meet certain criteria or who are unwilling to participate in serious, medically supervised nutritional attempts at weight loss should not be considered surgical candidates.

**Requirement for Physician Supervision**

Physicians should document their assessment of the patient, what health interventions are prescribed and their assessment of the patient’s progress. There is established evidence that medical supervision of a nutrition and exercise program increases the likelihood of success (Blackburn, 1993). It is recommended by the American Medical Association Council on Scientific Affairs, “Any person considering a weight loss program first consult a physician for a physical exam and objective evaluation of the proposed weight loss program as it relates to the individual’s physical condition”… Various health organizations recommend that physicians

Smoking Cessation
The NIH also recommends all smokers should quit smoking due to the high risk smoking adds to all patients. It is of particular importance for high-risk management in obese patients since these patients already have reduced pulmonary capacity. These patients become a high priority for risk reduction by smoking cessation. Smoking and obesity together have been shown to compound cardiovascular risks. Smoking is a risk factor for post-operative pulmonary complications as has been demonstrated repeatedly since the first report in 1944. Smoking increases risks even among those without chronic lung disease. The relative risk of pulmonary complications among smokers as compared with non-smokers ranges from 1.4 to 4.3. The risk declines only after 8 weeks of pre-operative cessation (Smetana et al, New England Journal of Medicine). Warner, et al, prospectively studied 200 smokers preparing for coronary bypass surgery and found a lower risk of pulmonary complications among those who have stopped smoking at least eight weeks before surgery than among current smokers.

Summary of Evidence
Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous different surgical techniques available. These different techniques have heterogenous mechanisms of action, with varying degrees of gastric restriction that creates a small gastric pouch, malabsorption of nutrients, and metabolic changes that result from gastric and intestinal surgery.

Adults with Morbid Obesity
For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass: there is less weight loss with LAGB, but the procedure is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
For individuals who are adults with morbid obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG or gastric bypass. Long-term weight loss was greater after gastric bypass but SG is associated with fewer AEs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

For individuals who are adults with morbid obesity who receive BPD without duodenal switch, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without duodenal switch or gastric bypass. However, there are concerns about complications associated with BPD without duodenal switch, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2014 systematic review identified only 1 small comparative study (unrandomized) comparing laparoscopic gastric plication with other bariatric surgery procedures. Additional comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive single anastomosis duodenoileal bypass with SG, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. No controlled trials were published evaluating single anastomosis duodenoileal bypass with SG. There are a few case series, the largest of which had fewer than 100 patients. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of single anastomosis duodenoileal bypass with SG. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes 1 RCT and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related
mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at 1 year. One small case series reported on 15 patients at 2 years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism and nutrition and long-term durability of treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Adults with T2D
For individuals who are diabetic and not morbidly obese who receive gastric bypass, sleeve gastrectomy, biliopancreatic diversion, or adjustable gastric banding, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/m². The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most of the RCTs in this population have 1 to 3 years of follow-up; 1 RCT that included patients with BMI between 30 and 34.9 kg/m² had 5 year follow-up data. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

Practice Guidelines and Position Statements
American Association of Clinical Endocrinologists et al
In 2017, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm. The document states: “Bariatric surgery should be considered for adult patients with a BMI [body mass index] of 35 kg/m² or more and comorbidities, especially if therapeutic goals have not been reached using other modalities.”
In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity. The guidelines addressed nine broad clinical questions with 123 recommendations. The authors noted that the 2013 guidelines specifically on bariatric surgery (see below) were considered adequate in the current form. With regard to bariatric surgery for these guidelines, the following recommendations were added to those in the 2013 guideline:

- **Recommendation 35:** “Patients with obesity (BMI ≥30 kg/m²) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion.” (Grade B; BEL 1 [best evidence level], downgraded due to evidence gaps)
- **Recommendation 121.** “Patients with a BMI of ≥35 kg/m² and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m² with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.
  - BMI ≥35 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD [cardiovascular disease] risk (Grade A; BEL 1).
  - BMI ≥30 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk (Grade B; BEL 2).
  - BMI ≥30 kg/m² and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk (Grade C; BEL 3).”
- **Recommendation 122.** “Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone (Grade D).”
- **Recommendation 62:** “Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett’s esophagus.” (intermediate recommendation, intermediate evidence). This recommendation also states, “Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux” (strong recommendation; strong evidence).

Joint Guidelines were published by the American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMBS) in 2013. Recommendations on the following questions are summarized below.
“Which patients should be offered bariatric surgery?”
- Patients with a BMI $\geq 40$ kg/m$^2$ without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for 1 of the procedures.
- Patients with a BMI $\geq 35$ kg/m$^2$ and one or more severe obesity-related comorbidities.
- Patients with BMI of 30 to 34.9 kg/m$^2$ with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.
- There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.

“Which bariatric surgical procedure should be offered?”
- The best choice for any bariatric procedure (type of procedure and type of approach) depends on the individualized goals of therapy (e.g., weight loss and/or metabolic [glycemic] control), available local-regional expertise (surgeon and institution), patient preferences, and personalized risk stratification. At this time, there is still insufficient evidence to generalize in favor of one bariatric surgical procedure for the severely obese population.

American College of Cardiology et al
In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published guidelines on the management of obesity and overweight in adults. The guidelines make the following recommendations related to bariatric surgery:
- For adults with a BMI $>40$ kg/m$^2$ or BMI $>35$ kg/m$^2$ with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment (with or without pharmacotherapy) with sufficient weight loss to achieve targeted health outcome goals, advise that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation (NHLBI Grade A (strong); AHA/ACC class of recommendation: IIa; AHA/ACC level of evidence: A).
- For individuals with a BMI $<35$ kg/m$^2$, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.

Institute for Clinical Systems Improvement
In 2013, the Institute for Clinical Systems Improvement (ICSI) published health care guidelines on the prevention and management of obesity in adults.110 The following were current indications for bariatric surgery:
- BMI $>40$ kg/m$^2$
- BMI $>35$ kg/m$^2$ with significant comorbidity (diabetes, hypertension, dyslipidemia, sleep apnea, cardiovascular disease, gastroesophageal reflux, and pseudotumor cerebri)
- Need for significant weight loss prior to solid organ transplantation, abdominal wall hernia repair, or joint replacement
- Medical management to exclude untreated endocrinopathies, stabilize hypertension or type 2 DM, and demonstrate patient compliance
• Psychological stability, as determined by an experienced practitioner

American Society for Metabolic & Bariatric Surgery
In 2016, ASBMS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES]). The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

• There is level 1 data from RCTs on the “efficacy [and] safety of intragastric balloon therapy for obesity … [and] lower-level evidence [suggesting] that weight loss can be maintained … for some finite time into the future.”
• It is difficult to separate the effect from the intragastric “balloon alone from those of supervised diet and lifestyle changes…..” This has been addressed in recent FDA pivotal trials. “In general, any obesity treatment, including intragastric balloon therapy, would benefit from a multidisciplinary team…..”
• “…serious complications are rare. Early postoperative tolerance challenges … can be managed with pharmacotherapy in the majority of patients…..”

In 2012, ASMBS updated its 2009 position on sleeve gastrectomy. This updated statement provided the following conclusions:

• Substantial comparative and long-term data have been published in the peer-reviewed literature demonstrating durable weight loss, improved medical comorbidities, long-term patient satisfaction, and improved quality of life after SG.
• ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach.
• Based on the current published literature, SG has a risk/benefit profile that lies between the laparoscopic adjustable gastric band and the laparoscopic Roux-en-Y gastric bypass. As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this could be managed effectively with re-intervention. Informed consent for SG used as a primary procedure should be consistent with consent provided for other bariatric procedures and should include the risk of long-term weight gain.
• Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature.

Society of American Gastrointestinal and Endoscopic Surgeons
In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery. These guidelines state, “During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired” (moderate quality evidence, weak recommendation).

U.S. Preventive Services Task Force Recommendations
Bariatric surgery is not a preventive service.
Proprietary Information of Blue Cross and Blue Shield of Alabama
An Independent Licensee of the Blue Cross and Blue Shield Association
Medical Policy #053
Benefit Application:
Coverage for bariatric surgery is subject to member’s specific benefits and to the bariatric procedures covered by Blue Cross and Blue Shield of Alabama medical policy. Group specific policy will supersede this policy when applicable.

Benefits will only be provided for one surgical procedure in a lifetime. Benefits will not be provided for subsequent surgery for complications related to a covered surgical procedure for obesity (morbid) if the complications arise from noncompliance with medical recommendations regarding patient activity and lifestyle following the procedure. Once per lifetime coverage limits on bariatric surgical procedure(s) may cause a repeat procedure such as a conversion of a laparoscopic adjustable band to a Roux-en-Y to be non-covered.

ITS: Home Policy provisions apply

FEP contracts: Per FEP, gastric restrictive procedures, gastric malabsorptive procedures, and combination restrictive and malabsorptive procedures to treat morbid obesity, a condition in which an individual has a body mass index (BMI) of 40 or more, or an individual with a BMI of 35 or more with comorbidities who has failed conservative treatment. Eligible members must be 18 years of age or over. Benefits are also available for diagnostic studies and a psychological examination performed prior to the procedure to determine if the patient is a candidate for the procedure.

International Paper, for select groups, will cover the biliopancreatic diversion (Bypass) with Duodenal Switch when diagnosed as morbidly obese and criteria for gastric restrictive surgery are met. Please verify benefits.

Tyco International has special benefit consideration. Please verify benefits. Effective for dates of service on or after July 1, 2008, only the Regence Blue Shield Medical Policy #58 will be used in making benefit determinations for Boeing TMP members.

LGB Groups please verify benefits for special language.

XO Communications, LLC, please verify benefits for special language effective January 1, 2009.

Current Coding:
CPT codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
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<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
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<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
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<td>Code</td>
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<tr>
<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)</td>
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<td>43771</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only</td>
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<td>43772</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only</td>
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<td>43773</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only</td>
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<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components</td>
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<tr>
<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy) (effective on and after 01/01/2010)</td>
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<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty</td>
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<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical banded gastroplasty</td>
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<tr>
<td>43845</td>
<td>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)</td>
</tr>
<tr>
<td>43846</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (less than 100cm) Roux-en-Y gastroenterostomy</td>
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<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption</td>
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<td>43848</td>
<td>Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)</td>
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<tr>
<td>43886</td>
<td>Gastric restrictive procedure, open; revision of subcutaneous port component only</td>
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<tr>
<td>43887</td>
<td>; removal of subcutaneous port component only</td>
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<tr>
<td>43888</td>
<td>; removal and replacement of subcutaneous port component only</td>
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<tr>
<td>90791</td>
<td>Psychiatric diagnostic evaluation (effective on and after 01/01/2013)</td>
</tr>
<tr>
<td>90792</td>
<td>; with medical services (effective on and after 01/01/2013)</td>
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<tr>
<td>96150</td>
<td>Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health-oriented questionnaires), each 15 minutes face-to-face with the patient; initial assessment</td>
</tr>
</tbody>
</table>

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

**HCPCS:**

<table>
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<tr>
<th>Code</th>
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<tr>
<td>S2083</td>
<td>Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline</td>
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</table>
Previous Coding:

90801  Psychiatric diagnostic interview examination  
(deleted effective 01/01/2013)

96100  Psychological testing (includes psychodiagnostic assessment of  
personality, psychopathology, emotionality, intellectual abilities, e.g.,  
Wais-r, Rorschach, MMPI) with interpretation and report, per hour  
(deleted 01/01/2006)

S2082  Laparoscopy, surgical; gastric restrictive procedure, adjustable gastric  
band includes placement of subcutaneous port (deleted 01/01/2006)

S2085  Laparoscopy, gastric restrictive procedure with gastric bypass for  
morbid obesity, with short limb (less than 100 cm) Roux-en-Y  
gastroenterostomy (deleted 01/01/2005)

References:

1. Aasheim ET. Vitamin status after bariatric surgery: a randomized study of gastric bypass  
4. Agency for Healthcare Research and Quality (AHRQ). Bariatric surgery utilization and  
5. Aikenhead A, Lobstein T, Knai C. Review of current guidelines on adolescent bariatric  
6. Alexandrou A, Felekouras E, Giamnopulos A, et al. What is the Actual Fate of Super-  
Morbid_Obese Patients Who Undergo Laparoscopic Sleeve Gastrectomy as the First Step  
1628.
adjustable gastric banding and laparoscopic Roux-en Y gastric bypass: a national database  
position statement on intragastric balloon therapy endorsed by the Society of  
467.
9. American Association of Clinical Endocrinologists (AACE), American College of  
Endocrinology (ACE). AACE/ACE position statement on the prevention, diagnosis, and  
10. American Society for Bariatric Surgery. Rationale for the surgical treatment of morbid  
11. American Society for Bariatric Surgery. Brief history and summary of bariatric surgery:  
28. Blue Cross and Blue Shield Association Bariatric Surgery Network Q & A. Available at www.bcbsal.org/providers/pdfs/Q&ABariatricNetworkFinal/pdf.
30. Blue Cross and Blue Shield Association (BCBSA) technology Evaluation Center (TEC). Laparoscopic Adjustable Gastric Banding in Patient with Body Mass Index Less than 35 kg/m² with Weight-Related Comorbidity. TEC Assessments 2012. 2012; 27(3).
38. BMI calculation: www.intmed.mcw.edu/clinical/body.html


166. Mun EC, Tavakkolizadeh A. Surgical management of severe obesity. www.uptodate.com


Policy History:
Medical Policy Administration Committee, June 2002
Available for comment June 17-July 31, 2002
Medical Policy Group, November 2003 (1)
Medical Review Committee, December 2003
Medical Policy Administration Committee, December 2003
Available for comment October 12-December 29, 2004
Medical Policy Group, November 2005 (1)
Medical Policy Administration Committee, November 2005
Available for comment December 16, 2005-January 30, 2006
Medical Policy Group, May 2006 (1)
Medical Policy Administration Committee, May 2006
Available for comment May 5-June 19, 2006
Medical Policy Group, June 2006 (1)
Available for comment June 21 through August 4, 2016
Medical Policy Group, June 2016 (3): Added AspireAssist device to procedures considered investigational; updated Key Words
Medical Policy Group, August 2016 (3): in response to comments, clarified the policy statement related to concomitant hiatal hernia repair to read as follows: Repair of a hiatal hernia at the time of bariatric surgery meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage. No other changes made.
Medical Policy Panel, April 2017
Medical Policy Group, May 2017 (3): 2017 Updates to Key Points & References; no changes in policy statements

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.
Body Mass Index Table

To use the table, find the appropriate height in the left-hand column labeled Height. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.

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