



Medical Policies



Medical Policies - Surgery

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Bariatric Surgery

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Effective Date: 03-15-2017

Coverage:

NOTE: Check member's contract for benefit coverage and/or exclusions for bariatric surgery and complications related to bariatric surgery. Not all benefit contracts cover bariatric surgery or complications of non-covered surgery.

PATIENT SELECTION CRITERIA FOR COVERAGE

For a member to be considered eligible for benefit coverage of bariatric surgery to treat morbid obesity, the member must meet the following **two criteria**:

1. Diagnosis of morbid obesity, defined as a:

- Body mass index (BMI) equal to or greater than 40 kg/meter² (* see guidelines below for BMI calculation); OR
- BMI equal to or greater than 35kg/meters² with at least one (1) of the following clinically significant obesity-related diseases or complications that are not controlled by best practice medical management:
 - o Hypertension, OR
 - o Dyslipidemia, OR
 - o Diabetes mellitus, OR
 - o Coronary heart disease, OR
 - o Sleep apnea, OR
 - o Osteoarthritis; AND

2. Documentation from the requesting surgical program that:

- Growth is completed (generally, growth is considered completed by 18 years of age); AND
- Documentation from the surgeon attesting that the patient has been educated in and understands the post-operative regimen, which should include ALL of the following components:

1. Nutrition program, which may include a very low calorie diet or a recognized commercial diet-based weight loss program; AND
2. Behavior modification or behavioral health interventions; AND
3. Counseling and instruction on exercise and increased physical activity; AND
4. Ongoing support for lifestyle changes to make and maintain appropriate choices that will reduce health risk factors and improve overall health; AND

- Patient has completed an evaluation by a master's level or higher behavioral healthcare provider acting within the scope of their licensure under applicable state law, within the 12 months preceding the request for surgery. This evaluation should document:

2/1/2012: Document updated with literature review. The patient selection requirement for a pre-surgical weight loss program for at least six (6) months, occurring within the twenty-four (24) months prior to the proposed surgery **has been replaced** with "Documentation from the surgeon attesting that the patient has been educated in and understands the post-operative regimen".

Back to Top

1. The absence of significant psychopathology that would hinder the ability of an individual to understand the procedure and comply with medical/surgical recommendations, AND
2. The absence of any psychological comorbidity that could contribute to weight mismanagement or a diagnosed eating disorder, AND
3. The patient's willingness to comply with preoperative and postoperative treatment plans.

Contraindications for surgical treatment of obesity include:

- Patients with mental handicaps that render a patient unable to understand the rules of eating and exercise and therefore make them unable to participate effectively in the post-operative treatment program (e.g., a patient with malignant hyperphagia [Prader-Willi syndrome], which combines mental retardation/intellectual disability with an uncontrollable desire for food).
- Patients with portal hypertension, an excessive hazard with laparoscopic gastric surgery.
- Women who are pregnant or lactating.
- Patients with serious medical illness in whom caloric restriction could exacerbate the illness.

Bariatric Surgery in Patients with a BMI less than 35 kg/m²

Bariatric surgery **is considered experimental, investigational and/or unproven** for patients with a BMI less than 35 kg/m².

*** Guidelines on how to calculate BMI :**

Body Mass Index (BMI) can be calculated using pounds and inches with this equation:

$$\text{BMI} = [\text{Weight (lbs)} \div \text{Height (in}^2\text{)}] \times 703$$

Body Mass Index can also be calculated using kilograms and meters:

$$\text{BMI} = \text{Weight (Kg)} \div \text{Height (m}^2\text{)}$$

To convert pounds to kilograms, multiply pounds by 0.45.

To convert inches to centimeters, multiply inches by 2.54.

To convert feet to meters multiple feet by 0.30.

COVERAGE STATEMENTS FOR SPECIFIC BARIATRIC SURGICAL PROCEDURES

(Gastric Restrictive and Gastric Malabsorptive)

NOTE: For a member to be eligible for benefit coverage of any one of these procedures the member must meet the Patient Selection Criteria described above AND the member's contract or certificate of coverage must allow coverage of bariatric surgery.

- Gastric bypass using a Roux-en-Y anastomosis (up to and including 150 cm) **may be considered medically necessary** as an open or laparoscopic surgical treatment option for patients with morbid obesity who meet the eligibility criteria for surgery.

NOTE: This policy does not address Roux-en-Y gastric bypass performed primarily for the treatment of gastric reflux even though this condition may improve following a Roux-en-Y performed for the treatment of morbid obesity.

- Adjustable gastric banding (open or laparoscopic), consisting of an external adjustable band placed high around the stomach creating a small pouch and a small stoma, **may be considered medically necessary** as a surgical treatment option for patients with morbid obesity who meet the eligibility criteria for surgery.

NOTE: If the original adjustable gastric banding procedure was a covered benefit, it is not necessary to request documentation for refill and maintenance procedures.

- Sleeve gastrectomy (open or laparoscopic) **may be considered medically necessary** as a surgical treatment option for patients with morbid obesity who meet the eligibility criteria for surgery.

- Biliopancreatic bypass (Scopinaro procedure) WITH duodenal switch (open or laparoscopic) **may be considered medically necessary** as a surgical treatment option for morbidly obese patients with BMI of 50 kg/m² or greater who meet the other eligibility criteria for surgery.

Gastric bypass using a Roux-en-Y anastomosis, adjustable gastric banding, sleeve gastrectomy or biliopancreatic bypass (Scopinaro procedure) with duodenal switch **are considered experimental, investigational and/or unproven** for the treatment of any condition other than morbid obesity, including but not limited to metabolic syndrome, gastroesophageal reflux disease and sleep apnea.

The following procedures **are considered not medically necessary** as a treatment of morbid obesity:

- Vertical banded gastroplasty is no longer a standard of care.
- Biliopancreatic bypass with duodenal switch **is considered not medically necessary** as a treatment for patients with a BMI less than 50kg/m².

The following bariatric procedures **considered experimental, investigational and/or unproven** as a treatment of morbid obesity, include, but are not limited to:

- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch
- Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)
- Long-limb gastric bypass procedure (i.e., >150 cm)
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Laparoscopic gastric plication
- AspireAssist® device
- Endoscopic bariatric procedures, either as a primary procedure or as a revision procedure (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches). This includes, but is not limited to:
 - o Insertion of the StomaphyX™ device,
 - o Natural Orifice Transluminal Endoscopic Surgery (NOTES™),
 - o Transoral ROSE procedure (Restorative Obesity Surgery),
 - o Sclerotherapy of the stoma,
 - o Insertion of a gastric balloon,
 - o Endoscopic gastroplasty, or
 - o Use of an endoscopically placed duodenojejunal sleeve.

MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS

NOTE: Check member's contract for benefit coverage and/or exclusions for bariatric surgery and complications related to bariatric surgery.

- Reoperation related to previous bariatric surgery **may be considered medically necessary** for complications such as stricture, obstruction, or erosion except when the members benefit plan excludes coverage of such complications.

- Removal of an adjustable gastric band **may be considered medically necessary** for complications not resolved by band deflation, including but not limited to obstruction, erosion, aspiration pneumonia, GERD, night cough, Barrett's esophagus, persistent vomiting, or persistent pain except when the members benefit plan excludes coverage of such complications.

- Repeat/Revision of bariatric surgery: **may be considered medically necessary** only when specifically included as a benefit or covered service in the member's benefit plan, summary plan description or contract AND when **ALL** of the following criteria are met:

- o For the original bariatric procedure, the patient met all the screening criteria including BMI requirements; AND

- o The patient has been compliant with a prescribed nutrition and exercise program following the original surgery; AND

- o Technical surgical failure (e.g., dilatation of gastric pouch, gastrojejunal stoma, or gastrojejunostomy anastomosis; port leakage; or band slippage), has occurred that can only be addressed surgically; AND

- o The patient is requesting reinstitution of an acceptable bariatric surgical modality.

- New bariatric surgery following a previous different bariatric procedure: A Roux-en-Y procedure following a previously approved vertical banded gastroplasty or laparoscopic adjustable banded gastroplasty **is not eligible for coverage** for patients who have been substantially **noncompliant** with a prescribed nutrition and exercise program following the original procedure or when the member's benefit plan does not allow for coverage.
- Incidental procedures during a bariatric surgery: **Coverage is allowed** for gallbladder removal at the time of a covered gastric bypass surgical procedure, either for documented gallbladder disease or for prophylaxis.
- Repair of a hiatal hernia at the time of bariatric surgery **may be considered medically necessary** for patients who have a preoperatively-diagnosed symptomatic hiatal hernia.
- Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a preoperatively diagnosed hiatal hernia in patients who do not have indications for surgical repair, **is considered not medically necessary**.

Description:

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

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

When conservative measures fail, some patients may consider surgical approaches. A 1991 National Institutes of Health Consensus Conference defined surgical candidates as "those patients with a BMI of greater than 40 kg/m², or greater than 35 kg/m² in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes." (1)

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

The following summarizes the different types of bariatric surgery procedures.

Vertical-Banded Gastroplasty

Vertical-banded gastroplasty (VGB) was formerly one of the most common gastric restrictive procedures performed in the United States, but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter 2 requiring reoperation. Dilation of the stoma is a common reason for weight regain. VGB may be performed using an open or laparoscopic approach.

Adjustable Gastric Banding

Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two banding devices are approved by the Food and Drug Administration (FDA) for marketing in the United States. The first to receive FDA approval was the LAP-BAND (original applicant, Allergan, BioEnterics, Carpinteria, CA; now Apollo Endosurgery, Austin, TX). The labeled indications for this device are as follows:

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

In 2011, FDA-labelled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m² with at least 1 obesity-related comorbid condition.

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

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

Open Gastric Bypass

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 gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant "dumping syndrome," in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in "sweets eaters." Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the "blind" bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

Laparoscopic Gastric Bypass

Introduced in 2005, laparoscopic gastric bypass is the laparoscopic version of the open gastric bypass described above.

Mini-Gastric Bypass

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.

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) seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high risk patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., biliopancreatic diversion).

Endoluminal Bariatric Procedures

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

Biliopancreatic Bypass Procedure

The biliopancreatic bypass (BPB) procedure (also known as the Scopinaro procedure), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, 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.
[Back to Top](#)
- 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 BPB, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, several case reports have noted liver failure resulting in death or liver transplant.

Biliopancreatic Bypass With Duodenal Switch

The duodenal switch procedure was introduced in 2005. The duodenal switch procedure is a variant of the BPB previously described. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the BPB, 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 BPB, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment. A new procedure, the single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) is a simplified duodenal switch. (80)

Long-Limb Gastric Bypass (i.e., >150 cm)

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

Laparoscopic Malabsorptive Procedure

This describes any of the malabsorptive/restrictive procedures done by laparoscopy.

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 2 main steps mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction but technique specifics are not standardized.

AspireAssist® Device

The AspireAssist® device is intended to assist in weight loss in obese patients by enabling removal of a portion of stomach contents through a gastrostomy tube. Lifestyle therapy is used in conjunction with AspireAssist® to help develop healthier eating habits and reduce caloric intake in patients. The AspireAssist® system consists of a tube that connects the inside of the stomach to the Skin-Port outside of the abdomen. After eating, the patient attaches an external connector and tubing to the skin-port, opens the port valve, and drains the food. (131)

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

Several gastric bands for use in bariatric surgery have been approved by FDA through the premarket approval process and are summarized in Table 1 (FDA Product Code: LTI).

Table 1: FDA-Approved Gastric Band Devices

Device	Manufacturer	Original PMA Date	Labeled Indications

REALIZE Adjustable Gastric Band (Curved Adjustable Gastric Band)	Ethicon Endosurgery Inc., Somerville, NJ, and Cincinnati, OH)	Nov 2007	Intended for use in weight reduction for morbidly obese patients and is indicated for individuals with a BMI of at least 40 kg/m ² , or a BMI of at least 35 kg/m ² with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. 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.
LAP-BAND Adjustable Gastric Band	Apollo Endosurgery Inc., Austin TX (Original applicant: Allergan Inc.)	Jun 2001	Indicated for use in weight reduction for severely obese patients with a BMI of at least 40 kg/m ² or a BMI of at least 30 kg/m ² with ≥1 severe comorbid conditions, or those who are ≥100 lb 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.

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

Other Devices

On June 14, 2016, the U.S. Food and Drug Administration approved through the premarket approval application (PMA) process the AspireAssist® device (Aspire Bariatrics, Inc., King of Prussia, PA). The AspireAssist® is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a Body Mass Index (BMI) of 35.0-55.0 kg/m² who have failed to achieve and maintain weight loss with non-surgery weight loss therapy. It is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring.

Rationale:

Patient Selection Criteria for Coverage

A requirement that a candidate for bariatric surgery complete a formal, medically supervised weight loss programs of specified duration has been a fixture of HCSC bariatric surgery medical policy for some time. The rationale for this requirement was founded on review and interpretation of available evidence in the scientific medical literature, primarily national consensus guidelines. However, HCSC has decided to modify this requirement based on a current review of the bariatric surgery scientific literature related to required pre-surgery weight loss programs, and including consideration of input from bariatric surgeons and their professional societies. **The HCSC policy will no longer require documentation that a morbidly obese member must have completed a pre-surgery weight loss program of specified duration as one of the criteria for benefit coverage of bariatric surgery.** This change does not mean, however, that HCSC no longer believes that successful bariatric surgery requires multi-disciplinary support from the member's bariatric surgery program and a life-long commitment to life-style changes.

Definition of Outcomes

Outcomes of bariatric surgeries are 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 with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. Outcomes for specific surgeries may widely differ among institutions or surgeons, perhaps due to small variations in surgical technique, length and frequency of follow-up, or patient selection criteria. However, during the 1970s and 1980s, both vertical-banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These 2 procedures were the focus of the 1991 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 (BPP). (1)

A 2003 Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessment summarized studies comparing open gastric bypass and VBG. (2) 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 more than 80% of all bariatric surgery procedures performed in 2002. (3) 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 BPP with or without duodenal switch (DS). The following outcomes are considered relevant for bariatric surgery: weight loss, durability, short-term complications, reoperation rate, long-term complications, and improved health outcomes.

Weight Loss

There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. These 2 methods are generally preferred over the absolute amount of weight loss, because they reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 2 summarizes the variation in reporting weight loss outcomes.

Table 2. Weight Loss Outcomes

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

BMI: body mass index; EBW: excess body weight.

Durability of Weight Loss

Weight change (i.e., gain or loss) at yearly intervals is often reported. Weight loss at 1 year is considered the minimum length of time for evaluating these procedures; weight loss at 3 to 5 years is considered an intermediate time period for evaluating weight loss; and weight loss at 5 to 10 years or more is considered to represent long-term weight loss following bariatric surgery.

Short-Term Complications (Operative and Perioperative Complications <30 Days)

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (e.g., pneumonia, myocardial infarction).

Reoperation Rate

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

Long-Term Complications (Metabolic Adverse 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 surgeries.

Improved Health Outcomes in Terms of Weight-Related Comorbidities

Aside from psychosocial concerns, which may be considerable, one motivation for bariatric surgery is to decrease the incidence of complications of obesity, such as diabetes, cardiovascular risk factors (i.e., increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

Bariatric Surgery in Adults With Morbid Obesity

There is a vast literature 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. Some comparative trials, including randomized and nonrandomized designs, compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedures. The emphasis for this evidence review will be on comparative trials of bariatric surgery and nonsurgical therapy or of 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 comparisons of bariatric surgery and conservative treatments for weight loss. (4) 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 started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34 kg/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 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. A total of 2010 people chose surgery and 2037 people 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 surgeon chose the surgical procedure offered. Most 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. Patients are followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

[Back to Top](#)

Many publications from this trial have reported on methods, weight loss, and clinical outcomes. (5-9) The following general conclusions can be drawn from the SOS study:

- Weight loss is greater with bariatric surgery than with conservative treatment. At 10 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 reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors (e.g., hypertension, 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 improves 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 (RYGBP) or laparoscopic adjustable gastric banding (LAGB) with follow-up through 3 years postprocedure. (10) The study enrolled 2458 subjects, with median a BMI 45.9 kg/m² (interquartile range [IQR], 41.7-51.5). For their first bariatric surgical procedure, 1738 participants underwent RYGBP, 610 LAGB, 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 (AGB) patients with available data at 3 years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years postsurgery, 67.5% and 28.5% of RYGBP and AGB patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of RYGBP and AGB patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the RYGBP patients and 17.5% (95% CI, 13.8% to 21.9%) of LAGB patients.

Systematic Reviews

Numerous systematic reviews have assessed the efficacy of bariatric surgery compared with conservative therapy, some of which are older and do not include the full range of available studies. (11, 12)

In 2014, Colquitt et al. updated 2003 and 2009 Cochrane reviews of bariatric surgery for obesity. (13) The authors identified 22 randomized trials that compared bariatric surgery with nonsurgical obesity management or that compared different bariatric surgery procedures, with 1798 participants (sample size range, 15-250 participants). All 7 RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at 1- to 2-year follow-ups. However, the authors noted that AE rates and reoperation rates were poorly reported across trials, and long-term follow-up (beyond 1-2 years) is limited.

Gloy et al. conducted a systematic review and meta-analysis of RCTs comparing current bariatric surgery techniques with nonsurgical treatment for patients with BMI of 30 kg/m² or more. (14) 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 2 diabetes (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 (8%) of 261 patients required reoperations (5/124 after AGB, 4/69 after RYGBP, 1/49 after sleeve gastrectomy [SG], 1/19 after BPD). Similar to the Colquitt meta-analysis, no studies reported longer term follow-up (>2 years) and heterogeneity between studies was high.

Chang et al. published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery. (15) The authors included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean presurgery BMI was 45.62 kg/m², 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, and 10% for observational studies (95% CI, 7% to 13%). At 1-year follow-up, mean change in BMI was -13.53 kg/m² (95% CI, -15.51 to -11.55) in RCTs and -11.79 kg/m² (95% CI, -13.89 to -9.69) in observational studies. Decreases in BMI were generally sustained over 2 to 4 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. (16-31)

Puzziferri et al. conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies with 7971 patients. (32) At follow-up, which ranged from 2 to 5 years postprocedure, the mean sample size-weighted percentage of excess weight loss (EWL) was higher for gastric bypass (65.7%) than for gastric banding (45.0%). The authors noted that few studies reported sufficient long-term results 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 Surgery Procedures

Vertical-Banded Gastroplasty (VBG)

VBG is a purely restrictive procedure that has been replaced by LAGB or SG. Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50%. (33, 34)

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. (35) The percentage of patients with greater than 50% EWL at 3-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 across groups. A second, smaller RCT by Sugerman et al. randomized 40 patients to receive a VBG or a gastric bypass procedure. (36) After 9 months, the gastric bypass patients had significantly greater weight loss that persisted at 3-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight.

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). (2) All 8 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 more than 50% EWL for those undergoing gastric bypass compared with VBG. Comparison of AEs was more difficult, because the data did not allow rigorous assessment. Nevertheless, the data suggested that the mortality rate for both surgeries was low overall. Serious perioperative AEs were also infrequently reported, but were 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 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 followed for a minimum of 2 years. (37) 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. conducted a systematic review of studies reporting greater than 10-year follow-up for VBG, which included 3 studies with extractable data. (38) Mean EWL was 61.4% (SD=13.5%) from baseline to follow-up in the 3 studies, but the authors note a lack of long-term evidence related to outcomes following VBG.

Gastric Bypass With Short Limb (<150 cm)

The body of literature on improved weight loss has been instrumental in establishing gastric bypass as the reference procedure to which other procedures are compared. Practice patterns in the United States indicate surgeons have adopted this approach, with gastric bypass now comprising most of the bariatric procedures performed.

Many clinical series reporting results of open gastric bypass have been published, as have numerous systematic reviews of this evidence. Griffen summarized the experience of more than 10,000 gastric bypass operations from a number of bariatric surgeons. (39) Results showed that approximately 85% were able to reduce their weight to levels below 150% of their ideal weight. In about 5000 patients who were followed for 10 years, 80% were maintained this result. Pories et al. reported on 608 patients who underwent a gastric bypass procedure and were followed up for 1 to 14 years. (40) One unique feature of this report is that only 3% of patients were lost to follow-up. Average weight loss was 75% of excess weight at 1 year, declining to 50% by the eighth year. The authors observed an immediate drop in both blood glucose and exogenous insulin requirements after surgery. Long-term observation of 298 patients with preoperative diabetes or impaired glucose intolerance revealed that 91% had normal values for blood glucose and hemoglobin A1c (HbA1c) after surgery. The incidence of hypertension declined from 58% before surgery to 14% after gastric bypass.

Comparative trials summarized in the 2003 BCBSA TEC Assessment (2) consistently reported favorable outcomes for open gastric bypass when compared with VBG, including 2 RCTs. Some nonrandomized trials that compared open gastric bypass with procedures other than VBG were also summarized in the TEC Assessment. (2) While there are fewer trials for these other procedures, comparisons of open gastric bypass to gastric banding, horizontal gastropasty, and silastic ring gastropasty all reported that weight loss was superior with open gastric bypass.

Metabolic abnormalities are seen more frequently in gastric bypass patients than in 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 BCBSA TEC Assessment focused on laparoscopic gastric bypass, which intends to reproduce the open procedure via minimally invasive techniques. (41) This is a technically complex surgery that requires a dedicated team and a relatively high degree of skill and experience in laparoscopic technique. This Assessment reviewed 7 comparative trials of open gastric bypass and laparoscopic gastric bypass, including 3 RCTs. In addition, 18 large clinical series of laparoscopic gastric bypass were included.

The 2005 BCBSA TEC Assessment concluded that weight loss at 1 year is similar for laparoscopic and open gastric bypass approaches. (41) Longer follow-up periods have been less well-reported but appear to be similar for both approaches. While comparisons of complication rates are less certain, some patterns are evident and consistent across the data examined. The profile of AEs differs between the 2 approaches, with each having advantages and disadvantages. Laparoscopic gastric bypass offers a less invasive procedure associated with decreased hospital stay and earlier return to usual activities. 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 frequent with laparoscopic gastric bypass. On the other hand, anastomotic problems, gastrointestinal tract bleeding, and bowel obstruction appear to be higher with the laparoscopic approach, though not markedly higher. Given these data, the overall the benefit-risk profile for these 2 approaches appears to be similar.

The mini-gastric bypass has primarily been advocated by 1 surgeon. In 2001, Rutledge published his experience with 1274 patients who underwent this procedure. (42) Mean operating time was 36 minutes, and mean hospital stay was 1.5 days. Mean EWL was 51% at 6 months, 68% at 12 months, and 77% at 2 years. The overall complication rate reported was 5.2%. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis, which diverts the biliary juices away from the stomach.

Laparoscopic Adjustable Gastric Banding (LAGB)

Adjustable gastric banding, using an externally adjustable band placed around the stomach, has been extensively used in Europe. One such device, the LAP-BAND, has received approval from the U.S. Food and Drug Administration (FDA) in the United States. The procedure is designed to mimic the VBG but be an easier, reversible, and flexible surgery. Similar to all gastric surgeries, the literature is dominated by large case series from individual surgeons who report their individual results. Most published series are from outside the United States.

The data presented as part of the FDA-approval process for the LAP-BAND are summarized in the package insert and represent one of the most rigorously performed clinical series of this procedure in the United States. (43) In a group of 299 patients, the mean EWL was 36.2% at 3 years, which contrasts with a 40% to 60% EWL reported in other series of VBG and 50% for gastric bypass. One challenge of VBG is dilation of the pouch, which may prompt surgical revision. The LAP-BAND procedure is intended to address this complication, because any pouch dilation can be altered by percutaneous adjustment of the inflatable band. The incidences of band adjustment or how this maneuver affects weight loss are not provided in the package insert. For example, although a 24% incidence rate of band slippage or pouch dilation was reported, it was not reported whether this complication was resolved with gastric band adjustment. There was a 9% incidence of surgical revision procedures and an additional 24% of patients had their entire LAP-BAND systems explanted, most commonly due to band slippage or pouch dilation but also due to erosion, infection, or gastrointestinal disorders.

A 2006 BCBSA TEC Assessment updated the evidence on LAGB, and compared outcomes with gastric bypass. (44) This Assessment concluded that, for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass or LAGB as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (e.g., extent of weight loss and frequency and timing of potential complications) of the 2 procedures to optimize choice 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 1 year is lower for LAGB than for open gastric bypass. The percentage of EWL at 1 year is approximately 40%, compared with 60% or higher for open gastric bypass. At time points beyond 1 year, some comparative studies have reported that the difference in weight loss between LAGB and open gastric bypass narrows, but other studies do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss shrinks after 1 to 2 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 with bands 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 open gastric bypass or LAGB. Death is extremely rare, and serious perioperative complications probably occur at rates 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 50% lower (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

[Back to Top](#)

studies due to incomplete follow-up and lack of systematic surveillance. The rates of long-term complications reported in some studies raise concern about the impact of these events on the overall benefit-risk profile for LAGB.

In comparing LAGB with open gastric bypass, there are tradeoffs 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, benefits defined by the amount of weight lost are lower for LAGB. The patterns of long-term complications also differ between the 2 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.

Sleeve Gastrectomy (SG)

SG may be performed as a stand-alone procedure or in combination with a malabsorptive procedure, such as the biliopancreatic diversion (BPD) with DS. It has also been proposed as the first step in a 2- stage procedure, with gastric bypass or BPD as the second stage.

In 2009, Brethauer et al. reviewed 36 studies (total N=2570 patients) for a systematic review of SG as a staged and primary procedure, the largest trials coming from European centers. (45) Two RCTs, 1 nonrandomized, matched cohort analysis, and 33 case series were examined. Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (N=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 kg/m². Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost; all had significant reductions from baseline. Follow-up periods were 3 to 60 months. Ten studies included detailed postoperative comorbidity data (n=754); more than 70% of patients with improved control or remission of T2D, and significant reductions were seen in hypertension and hyperlipidemia, sleep apnea, and joint pain. Rates 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 5 deaths within 30 days of surgery (overall mortality rate, 0.19%; 2 in the high-risk/staged group, 3 in the primary procedure group). The authors noted that long-term follow-up is limited.

More recent systematic reviews have summarized the evidence for SG. Trastulli et al. conducted a systematic review of 15 RCTs (total N=1191 patients) that compared SG with other bariatric procedures. (46) The authors 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 62.1% to 94.4% with LAGB.

Li et al. conducted a meta-analysis of RCTs comparing SG with laparoscopic Roux-en-Y gastric bypass (LRYGB) for morbid obesity or T2D that included 5 trials (total N=396 patients). (47) LRYGB was associated with higher rates of T2D remission and greater EWL, but higher rates of complications. In a separate 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. (48) However, after 1.5 years, Roux-en-Y bypass was associated with higher percent EWL (mean difference at 2 years, 5.77; 95% CI, 4.29 to 7.25; p<0.05). AEs were more frequent following Roux-en-Y bypass (odds ratio [OR] for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

Himpens et al. report on a randomized study comparing LAGB and laparoscopic isolated SG. Eighty subjects received surgery over 1 year. (49) Median baseline BMI was 37 kg/m² (range, 30-47 kg/m²) in the LAGB group and 39 kg/m² (range, 30-53 kg/m²) in the SG group.

Outcomes of weight loss, feeling of hunger, sweet-eating, gastroesophageal reflux disease (GERD), complications, and reoperations were recorded at 1- and 3-year follow-ups. Median decrease in BMI in the gastric bypass group was 15.5 kg/m² (range, 5-39 kg/m²) after 1 year and 18 kg/m² (range, 0-39 kg/m²) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m² (range, 0-45 kg/m²) and 27.5 kg/m² (range, 0-48 kg/m²) after 3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported loss

[Back to Top](#)

of craving for sweets, but the differences were not statistically significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relation reversed at 3 years; between-group differences were not statistically significant at either time point. Two SG patients required reoperation for complications. Seven late complications required reoperation after LAGB including pouch dilations treated by band removal (n=2) or conversion to RYGBP (RYGB) (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 disconnections of the system that required reconnection. Four patients had reoperations for lack of efficacy; 2 LAGB patients underwent conversion to RYGB, and 2 SG patients underwent conversion to DS. The authors noted that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group. (49) Karamanakos et al. carried out a double-blind study to compare outcomes of LRYGB and laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery. (50) Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI were marked and comparable in each group. EWL was greater after LSG at 6 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 decreased more after LSG.

An RCT comparing short-term outcomes of LSG with gastric bypass was published in 2012. (51) The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to SG. The rate of major complications (no deaths in either group) 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 than in the SG group (17.1% vs 7.4%, $p=0.02$), as were combined major and minor complications (26.5% vs 13.2%, $p=0.01$).

Several publications have compared SG with other bariatric procedures. In a comparative study from France, Chouillard et al. analyzed with 200 patients who had undergone SG or RYGB between 2005 and 2008. (52) Patients in each group were matched for age, sex, and BMI. The postoperative complications, percentage of EWL, and the resolution of comorbidities in each group were compared at 6, 12, and 18 months postoperatively. Overall mortality rates were similar, however, the morbidity rate was significantly higher in the RYGB group (20.5%) than in the SG group (6.5%; $p<0.05$). The overall remission of T2D was significantly higher in the RYGB group. However, the percentage of EWL at 6, 12, and 18 months, as well as the resolution of nondiabetic comorbidities, were comparable in both groups. The authors concluded that in this study, compared with SG, RYGB was associated with a greater short-term morbidity rate and RYGB could be associated with better diabetes control. They also noted that additional studies were needed to evaluate the comparative efficacy of SG and RYGB for the treatment of morbid obesity and its comorbidities.

Leyba et al. reported on a series of 117 patients from Venezuela who were treated with SG or RYGB. (53) From January 2008 to December 2008, 117 obese patients who met criteria for bariatric surgery were assigned by patient choice after informed consent to a LRYGB procedure (n=75) or to an LSG procedure. Both groups were comparable by age, sex, BMI, and comorbidities. Mean operative time of LSG was 82 minutes, while for LRYGB was 98 minutes ($p<0.05$). Differences in hospital length of stay, major complications, improvement in comorbidities, and EWL were not significant ($p>0.05$). One year postsurgery, average EWL was 86% in LRYGB and 78.8% in LSG ($p>0.05$). The authors concluded that in the short term, both techniques were comparable for safety and effectiveness.

In a comparative study from India, Lakdawala et al. compared 50 patients who underwent LSG and LRYGB from 2007 to 2008. (54) Groups were matched by age, sex, and BMI. Patients were evaluated at 6 months and 1 year postoperatively. Resolution of most comorbidities, such as T2D, hypertension, dyslipidemia, sleep apnea, joint pain, and percentage of EWL, in both groups was comparable at 6 months and 1 year. Early resolution of T2D was better in the LRYGB group; outcomes were comparable at 1 year. There was increased incidence of GERD in SG patients. Chiu et al. reported a systematic review on the effect of SG on symptoms of GERD. (55) A total of 15 reports were retrieved; 2 reports analyzed GERD as a primary outcome, and 13 included GERD as a secondary study outcome. Of the 15 studies, 4 showed an increase in GERD after SG, 7 found reduced GERD prevalence after SG, 3 included only the postoperative prevalence of GERD, and 1 did not include data on prevalence of GERD. The authors concluded that the studies showed differing outcomes and that studies objectively evaluating GERD after SG are needed.

A small number of clinical series have also reported on SG as the initial procedure of a 2-stage operation. This approach has been attempted mostly in patients with “super” obesity (BMI >50 kg/m²), in whom a more complex initial surgery may be associated with higher risk. Weight loss following SG may reduce the risk of these patients undergoing a more complex malabsorptive procedure in the future. Available series to date have reported only on very small numbers of patients. For example, Mognol et al. (N=10) and Regan et al. (N=7). (56, 57) The published data on outcomes following completion of both stages of the 2- stage surgery are also limited to case reports and case series with very small numbers of patients.

Biliopancreatic Bypass (BPB)

Skroubis et al. randomized 130 patients with a BMI of 35 to 50 kg/m² to RYGB or BPD (without DS) using a variant of BPB that included Roux-en-Y gastrectomy in place of SG. (58) All patients were followed for at least 2 years. Weight loss outcomes were superior for the BPD group at every interval examined up to 2 years. EWL at 1 year was 73.7% for RYGB and 83.1% for BPD (p<0.001); at 3 years, 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 was not statistically significant (6 complications vs 1, respectively; p=0.12). Late complications also did not differ significantly between the RYGB and BPD groups (16 complications vs 22 complications, respectively; p=0.46).

Numerous clinical series of BPB have been published, but, as with other procedures, high-quality trials that directly comparing outcomes of this procedure with gastric bypass are lacking. The largest experience with BPB (total N=1217 patients) is reported by Scopinaro et al., who developed the procedure. (59) With follow-up of up to 9 years, the authors reported a durable EWL of 75%, suggesting that weight loss is greater with this procedure than with gastric restrictive procedures. In addition, most patients reported disappearance or improvement of complications such 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 protein malnutrition, 4% of patients underwent reoperation to elongate the common limb (thus increasing protein absorption) or to have the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity and, presumably, patient eating habits, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients are encouraged to maintain an oral calcium intake of 2 g/d, with monthly vitamin D supplementation.

The available evidence was reviewed in the 2006 BCBSA TEC Assessment, and outcomes of BPB, with or without DS, were compared with those of gastric bypass. (44) One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 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 2 procedures, these data do not support the hypothesis that BPB 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 BPB. Slater et al. focused specifically on vitamin and calcium deficiencies following BPB. (60) These authors reported high rates of vitamin and calcium abnormalities in their population over a 4-year period. By year 4, 48% of patients had 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 BPB. (61) 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%-47%) and anemia (11%-40%). The rates of nutritional deficiencies and the consequences of these deficiencies require further investigation.

Biliopancreatic Bypass with Duodenal Switch (BPD With DS)

BPD may be performed with or without the DS procedure. In the DS procedure, an SG is performed, preserving the pyloric sphincter. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and to decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum.

The largest case series of this procedure is by Marceau et al., who reported their 15-year experience with DS in 1423 patients from 1992 to 2005. (62) Follow-up evaluations were available for 97% of patients. Survival rate was 92%. After a mean of 7 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 5 was 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%. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage.

In a 2009 evidence-based review of literature, Farrell et al. summarized data on BPD with or without DS, RYGB (proximal), and AGB, and reported that at a mean 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies; n=896 patients), 67% for RYGB (7 studies; n=1627 patients), and 42% for AGB (11 studies; n=4456 patients). (63) At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies; n=174 patients), 58% for RYGB (3 studies; n=176 patients), and 55% for AGB (5 studies; n=640 patients). The authors noted that "given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for 1 procedure over another."

Prachand et al. published the largest comparative series of 350 super-obese patients with BMI greater than 50 pounds who underwent RYGB (n=152) or Scopinaro BPD combined with the DeMeester DS (DS- BPD) (n=198). (64) 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 pounds) in DS-BPD patients versus 346.3±55.2 (range, 239.8-504.9 pounds) in the RYGB group, and mean BMI was 58.8±6.7 pounds (range, 50-96 pounds) in DS-BPD patients versus 56.4±6.8 (range, 49.5-84.2 pounds) in the RYGB group. At 1 year, data were reported for 143 DS-BPD patients and 81 RYGB patients. 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 RYGB (n=50) or BPD (n=22). Choice of surgery was per surgeon and/or patient, and the patient populations differed by age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 23.3 pounds for BPD compared with 16.5 pounds for RYGB (p<0.001). (65)

Gastric Bypass With Long Limb (>150 cm)

As discussed in the Description section, the degree of malabsorption associated with long-limb gastric bypass will vary with the length of the alimentary and biliary limbs. These modifications have been developed to decrease the adverse metabolic 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. Murr et al. reported on 26 patients who underwent a "very very long- limb Roux-en-Y gastric bypass." (66) In comparison to a case series of 11 patients who underwent BPB, the authors reported similar weight loss but fewer metabolic or nutritional abnormalities attributed, in part, to the increased length of the common segment (100 cm vs 50 cm used in BPB). Sugerman et al. also attribute increasing the length of the common segment to fewer metabolic morbidities. (67)

The 2005 BCBSA TEC Assessment reviewed 6 comparative studies that compared outcomes of standard ("short- limb" gastric bypass) with outcomes of "long-limb" gastric bypass. Although the categorization of patients into "standard" and "long-limb" is based on the length of the Roux (alimentary) limb, there is no definitive cutoff for long versus standard limbs. In these studies, there was variability in the lengths of the Roux limbs for both the standard and the long-limb gastric bypass groups.

Most comparisons of weight loss have not revealed significant differences between short- and long-limb gastric bypass. The strongest evidence in this category derives from 2 RCTs, (68, 69) neither of which found significant differences in weight loss between groups. Brolin et al. compared 3 limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at 1 year. (70) MacLean et al. examined morbidly obese and super-obese patients separately and reported a significant difference in favor of the long-limb gastric bypass group. (71) However, this analysis only assessed final BMI of the 2 groups and did not report the actual change in BMI or the initial BMI for each group.

AEs were poorly reported by these studies. Mason et al. reported the percentage of patients with “major post-op complications,” which was 2.3% for standard gastric bypass and 1.2% for long-limb gastric bypass. (72) There was no further breakdown by types of major complications recorded and no statistical testing for this outcome. In 2 other studies, the rates of short-term AEs reported by Inabnet et al. (69) were higher for standard gastric bypass, while the rates reported by Brolin et al. (70) were higher for the long-limb gastric bypass. Data on long-term complications are scant and do not reveal differences between short- and long-limb procedures.

Two-Stage Procedures

Bariatric surgeries performed in 2 stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50 kg/m². The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients who are extremely obese. Therefore, procedure with low risk (usually an SG) is performed first. After the patient loses some weight, thus lowering the surgical risk, a second more extensive procedure (e.g., BPD) is performed.

The evidence on 2-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 surgery, and in those that do; only a minority of patients undergoing first stage surgery proceed to second-stage surgery. For example, Cottam et al. reported on 126 patients with a mean BMI of 65 kg/m² who underwent LSG as the first portion of a planned 2-stage procedure. (73) The incidence of major perioperative complications for LSG was 13%. After 1 year, mean EWL was 46%. A total of 36 (29%) patients 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 2-stage procedure. (74) After 1-year follow-up, 12 (29%) patients achieved a BMI of less than 35 kg/m² and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 (44% of total) patients were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al. described the complication rates in 87 patients who underwent a stage I SG followed by a BPD in 27 patients. (75) For the first stage, 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, 29.6% had major complications, including bleeding, duodenoileal stenosis, and rhabdomyolysis.

This evidence does not indicate whether a 2-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 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.

Laparoscopic Gastric Plication

[Back to top](#)

Laparoscopic gastric plication is a bariatric procedure that involves laparoscopic placement of sutures over the greater curvature (laparoscopic greater curvature plication) or anterior gastric region (laparoscopic anterior curvature plication) to create a tube-like stomach. The procedure involves 2 main steps-mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction-but specific techniques are not standardized.

In 2015, Ji et al. reported a systematic review of 14 studies reporting outcomes after laparoscopic gastric plication. (76) The review included 1 nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports (total N=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. (77) Only 3 studies identified included more than 100 patients. The longest follow-up was to 120 months in the Talebpour study; other studies that provided follow-up reported to 24 months (2 studies), 18 months (2 studies), or 12 months (9 studies). Mean preoperative BMI ranged from 31.2 to 44.5 kg/m². Mean percent EWL after the procedure was reported in 9 studies (n=1407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from 6 to 24 months. One study reported weight loss in terms of percent decrease in BMI, with a reported decrease at 6 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, 53.7% vs 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no deaths were 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 reviewers concluded that laparoscopic gastric plication may be a promising treatment for obesity, but the currently available evidence is limited by small study size, 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 7 studies of laparoscopic gastric plication, 2 of which enrolled more than 100 patients (total N=307 patients). (78) At 6-month follow-up, EWL ranged from 28.4% to 54% for the 5 studies that reported weight loss outcomes. All studies reported some incidence of nausea and vomiting, most of which was mild. Twenty (6.5%) patients 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 LAGB plication procedure, a hybrid procedure involving both AGB and greater curvature plication developed by the authors. (79) Eighty patients were included, with a baseline mean BMI of 38.05 (± 4.73) kg/m². At 6, 12, 18, and 24 months postsurgery, mean percent EWL was 42.6% ($\pm 13.7\%$), 56.4% ($\pm 19.9\%$), 57.6% ($\pm 19.9\%$), and 65.8% ($\pm 17.3\%$), respectively. Five postoperative complications required reoperation.

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 5 years postsurgery. One larger series was published in 2015 and reported on 97 patients with obesity and T2D. (80) 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.

AspireAssist®

Sullivan et al. reported on a pilot study to evaluate the use of an endoscopic aspiration therapy for obesity. Eighteen obese subjects were randomly assigned to groups that underwent aspiration therapy for 1 year plus lifestyle therapy (n=11; mean body mass index, 42.6 $\pm$ 1.4 kg/m (2) or lifestyle therapy only (n=7; mean body mass index, 43.4 $\pm$ 2.0 kg/m (2)). Ten of the 11 subjects who underwent aspiration therapy and 4 of the 7 subjects who underwent lifestyle therapy completed the first year of the study. After 1 year, subjects in the aspiration therapy group lost 18.6% $\pm$ 2.3% of their body weight (49.0% $\pm$ 7.7% of excess weight loss [EWL]) and those in the lifestyle therapy group lost 5.9% $\pm$ 5.0% (14.9% $\pm$ 12.2% of EWL) (P < .04).

Conclusions reached by the authors from the pilot study included: aspiration therapy appears to be a safe and effective long-term weight loss therapy for obesity. (129)

The PATHWAY pivotal trial, is reported in the U.S. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data (SSED). This trial was a prospective, randomized, multi-center, controlled, open-label, 52-week clinical study. The data collected included 111 treatment and 60 control patients at 10 investigational sites. The *Effectiveness Conclusions* noted in the SSED included the following:

The first co-primary endpoint specified that AspireAssist® (AT) Treatment Group would achieve a mean percent excess weight loss (%EWL) that was significantly greater than the Control Group by a superiority margin of 10.0 at 52 weeks. The average %EWL at 52 weeks was 31.5% for the AT Treatment Group and 9.8% for the Control Group, resulting in an average difference between the AT Treatment Group and Control Group of 21.7% (95% CI: [15.3, 28.1%]).

The second co-primary endpoint specified that significantly greater than 50% of subjects in the AT Treatment Group would achieve greater than 25% EWL at 52 weeks. This endpoint was not met. The study demonstrated that 56.8% (95% CI: [49.0, 64.5%]) of subjects in the AT Treatment Group had achieved 25% EWL. (130)

Endoluminal Bariatric Surgery Procedures

A variety of endoluminal devices and techniques have been investigated as an alternative to other open or laparoscopic bariatric surgery procedures for primary obesity surgery, many of which are early in their development and do not have FDA approval as of the 2014 update. A brief summary of the evidence related to more common techniques follows.

Duodenojejunal Sleeve

Several endoscopically placed sleeves designed to block absorption from the proximal small intestine have been investigated to treat obesity and T2D, although no devices currently have FDA approval. The most evidence found is related to the EndoBarrier® (GI Dynamics, Lexington, MA), which is a fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and extends 80 cm 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. (81) It included 5 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 2 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. (82) Patients were treated for 6 months with EndoBarrier® or medical therapy. At 6 months, the EndoBarrier® was removed and patients were followed for an additional 6 months. (38) 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 6 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 6 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).

Gastric Balloon

Intragastric balloons are placed in the stomach using endoscope or swallowing to act as space-occupying devices to induce satiety. No gastric balloons currently have FDA approval, but devices under investigation include the following. The ReShape Duo™ (ReShape Medical, San Clemente, CA) is a saline-inflated dual-balloon system designed to remain in the stomach for 6 months. The BioEnterics® Intragastric Balloon System (Allergan, Irvine, CA) is a saline-inflated silicone balloon that is inserted endoscopically and designed to remain in the stomach for 6 months. The Obalon Balloon (Obalon Therapeutics, Carlsbad, CA) is a swallowable balloon that is inflated with gas and subsequently removed endoscopically. A 2011 review of endoluminal procedures for obesity reported that studies have demonstrated weight loss with gastric balloons in the short- and mid-term ranges, but long-term weight loss, especially following balloon removal, has been equivocal. (83) Randomized trials of gastric balloons for obesity are underway.

Primary Obesity Surgery, Endoluminal Procedure

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, 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 who refused surgical therapy. (84) Forty-five patients who had a technically successful POSE procedure were included. Over 6 months of follow-up, patients had a mean percent EWL of 49.4%, with a mean BMI decrease of 5.8 kg/m². Randomized studies are ongoing in the United States, including an industry-sponsored, blinded, sham-controlled randomized trial, the USGI Medical ESSENTIAL Study for Weight Loss (NCT01958385).

Section Summary: Evidence for Specific Types of Bariatric Surgery Procedures

The evidence on the comparative efficacy of different bariatric surgery approaches mostly consists of low-quality evidence, with a lack of long-term, high-quality RCTs. Compared with gastric bypass, the evidence is sufficient to conclude that LAGB is associated with fewer short-term complications and less medium- to long-term weight loss. The evidence is also sufficient to conclude that SG has similar or fewer short-term complications, with less medium- to long-term weight loss than for gastric bypass. The evidence on other types of bariatric surgery procedures is insufficient to form conclusions on their impact on health outcomes. For BPB, the weight loss is similar or greater than gastric bypass, but the complications rates, especially nutritional complications, may also be higher. The evidence base for other types of procedures is insufficient to form conclusions.

Revision Bariatric Surgery

There are a number of reasons why patients treated with accepted forms of bariatric surgery may not lose weight or may regain weight initially lost. These reasons include issues of adherence (compliance), as well as technical (structural) issues. Some patients who regain weight after bariatric surgery (e.g., RYGB) have enlarged gastric stoma and/or enlarged gastric pouches. Correction of these abnormalities has been reported to result in successful weight loss. However, some have questioned whether the association with enlarged stoma is as important as it is for enlarged pouches. (85)

Revision Surgical Procedures

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 (BOLD). (86) The BOLD is a large, multi-institutional bariatric surgery-specific database to which data were 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. Reoperations were further divided into corrective surgeries (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.) Of 449,473 bariatric operations in the database, 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 RYGBP (n=204,705 [49.1%]), AGB (n=153,142 [36.5%]), SG (n=42,178 [10%]), and BPD plus DS (n=4260 [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 RYGBP). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 days vs 1.8±4.9 days, p<0.001) and for conversions (2.86±4.58 days vs 1.8±4.9 days, p<0.001). Mean percent EWL at 1 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 than the 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 AE 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 concluded 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 (ASMBS) Revision Task Force, Brethauer et al. conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews. (87) The review is primarily descriptive, but the authors made 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."

A sample of outcomes reported in retrospective series of revision surgeries follows. Mognol et al. reported on conversion of AGB to Roux-en-Y in 70 patients. (88) Indications for conversion were insufficient weight loss or weight regain after band deflation for gastric pouch dilatation in 34 (49%) patients, inadequate weight loss in 17 (25%) patients, symptomatic proximal gastric pouch dilatation in 15 (20%) patients, intragastric band migration in 3 (5%) patients, and psychological band intolerance in 1 patient. Median EWL was 70%. Sixty percent of patients achieved a BMI of less than 33 kg/m² at a mean follow-up of 18 months. The early complication rate was 14.3% (10/70). Late major complications occurred in 6 (8.6%) patients. Brolin and Cody, reporting on a series of 151 revision surgeries, observed that "Weight loss after revision of pure restrictive operations is significantly better than after revision of operations with malabsorptive components. Improvement of comorbidities in the great majority of patients justifies revision of all types of bariatric operations for unsatisfactory weight loss." (89) Bueter et al. reported that of 172 patients who underwent AGB placement between May 1997 and June 2006, 41 had 1 or more revision procedures. (90) There were no deaths following the reoperations. Band replacement (n=18), band repositioning (n=7), conversion to SG (n=2), and RYGBP (n=2), or band removal without any further substitution (n=12) were performed as first reoperation. Seven patients had a second reoperation. Median follow-up since reoperation was 56 months (range, 7-113 months). Percent EWL of patients was 59.4% (n=5) after RYGBP, 45.1% (n=18) after rebanding, and 33.4% (n=2) after SG. Comorbidities were further reduced or even resolved after reoperation.

Endoscopic Revision Procedures

While bariatric surgery revision/correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices that are also being evaluated for endoscopic treatment of GERD. The published data on 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). (91) Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron et al. reported on a feasibility study in animals. (92) Thompson et al. reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who had weight regain and dilated gastrojejunal anastomoses after RYGB. (93) 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, which has been used in this approach, was cleared by 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 tract surgery. In 2014, Elcidi et al. reported results from a single-center RCT of the StomaphyX device compared with a sham procedure for revisions in patients with prior weight loss after RYGBP at least 2 years earlier. (94) Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphyX patients. The primary efficacy end point

(reduction in pre-RYGBP excess weight by $\geq 15\%$, excess BMI loss, and BMI $< 35 \text{ kg/m}^2$, at 12 months postprocedure) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group ($p < 0.01$).

A survey of ASMBS members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. (95) 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.” (96)

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 endoscopic devices and procedures in patients who regain weight after bariatric surgery is very limited. These endoscopic procedures are considered experimental, investigational and/or unproven.

Bariatric Surgery as a Treatment for Type 2 Diabetes (T2D)

Current indications for bariatric surgery view poorly or uncontrolled diabetes as a comorbidity whose presence supports the medical necessity of surgery for patients with BMI of 35 to 40 kg/m^2 . There also is growing interest in gastrointestinal surgery to treat patients with T2D in patients with lower BMI. This section focuses on RCTs and systematic reviews of RCTs comparing bariatric surgery with medical therapy.

Morbidly Obese Patients

Randomized Controlled Trials

Stampede was an unblinded RCT of 150 patients with a BMI between 27 kg/m^2 and 43 kg/m^2 and uncontrolled diabetes. (97) About two-thirds of patients in this trial had a BMI greater than 35 kg/m^2 . Patients were randomized to 1 of 3 arms: medical treatment, RYGBP, or SG. Patients were followed for 1 year; the primary outcome measure was remission of diabetes, defined as an HbA1c level of 6.0% or less. There was improvement in glycemic control for all groups. Starting from a baseline HbA1c level of 9.2%, the final levels were 7.5% for the medical group, 6.6% in the SG group ($p = 0.003$ vs medical therapy), and 6.4% in the gastric bypass group ($p < 0.001$ vs medical therapy). The primary end point was reached by 12% of patients in the medical therapy group, 37% in the SG group ($p = 0.008$ vs medical therapy), and 42% in the gastric bypass group ($p = 0.002$ vs medical therapy). The use of antidiabetic medications increased in the medical therapy group and decreased in both surgical groups. All patients in the gastric bypass group who achieved the primary end point did so without medications, while 28% of patients in the SG group who reached the primary end point required continued medication use.

Three-year follow-up from the Stampede trial was published in 2014. (98) At 36 months, follow-up was available for 91% of subjects. The primary outcome (remission of diabetes) was met by 5% of patients in the medical therapy group, compared with 38% of those in the gastric bypass group ($p < 0.001$) and 24% of those in the SG group ($p = 0.01$). Compared with medical therapy patients, patients in the gastric bypass and SG groups required fewer diabetes medications: 2.6 ± 1.1 in the medical therapy group compared with 0.48 ± 0.80 in the gastric bypass group ($p < 0.001$) and 1.02 ± 1.01 in the SG group ($p < 0.001$).

A ~~Second RCT~~ published in 2012 compared bariatric surgery to medical therapy. (99) This trial randomized 60 patients to 1 of 3 arms: medical therapy, RYGBP, and BPD. Patients were followed for at least 1 year, with the primary end point being remission of diabetes, defined as a fasting glucose less than 100, HbA1c level less than 6.5%, and termination of diabetes medications. There was a significant decrease in HbA1c levels for all groups. HbA1c levels decreased by 8.9% in the medical group, by 25% in the gastric bypass group, and by 43% in

the BPD group; the differences between the medical and surgical groups were statistically significant. At 2-year follow-up, remission was achieved in 0% of the medical therapy group, 75% in the gastric bypass group, and 95% in the BPD group.

Two RCTs comparing bariatric surgery with medical therapy enrolled diabetic patients with a BMI between 30 kg/m² and 40 kg/m². Ikramuddin et al. performed an unblinded RCT of gastric bypass versus intensive medical therapy on 120 patients with T2D for at least 6 months and an HbA1c level of at least 8.1%. (100) Patients were followed for 12 months; the primary end point was a composite of HbA1c level less than 7.0%, low-density lipoprotein cholesterol less than 100 mg/dL, and systolic blood pressure less than 130 mm Hg. Twenty-eight patients in the surgery group achieved the primary outcome compared with 11 patients in the medical therapy group (OR=4.8; 95% CI, 1.9 to 11.7). The percentage of patients achieving HbA1c levels less than 7.0% was 75% in the surgery group compared with 32% of patients in the medical therapy group (OR=6.0; 95% CI, 2.6 to 13.9). There were 22 serious complications in the surgery group, including 4 perioperative complications, compared with 15 serious complications in the medical group.

Dixon et al. conducted an RCT designed to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI between 30 kg/m² and 40 kg/m². (101) (Results were not reported separately for patients with BMI <35 or >35 kg/m², and 47/60 patients had BMI >35 kg/m².) Sixty patients were enrolled, with 30 randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the 2-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and 4 (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 kg/m² as ideal weight) versus 4.3% in the conventional group. Mean HbA1c levels were less than 6.2% at baseline in 2 surgically and 4 conventionally treated patients versus 24 and 6 patients, respectively, at 2 years. At baseline, 2 surgically treated and 4 conventionally treated patients were using no pharmacotherapy versus 26 and 8, respectively, at 2 years. One surgical patient developed a wound infection, and 2 developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band.

One RCT identified compared RYGBP to SG in patients with BMI of 35 kg/m² or more and T2D. (102) Forty-one patients were randomized, 37 of whom completed the protocol (19 in the RYGBP group, 18 in the SG group). At 12-month follow-up, the mean percent change in weight from baseline was 25.9 (5.4) in the Roux-en-Y bypass group and 28.4 (5.9) in the SG group (p=non-significant [NS]). Mean absolute improvement in HbA1c levels from baseline to 12 months were 1.57%±1.35% in the RYGBP group and 2.27%±2.22% in the SG group (p=NS).

The remaining evidence currently consists of small case series and case reports with short follow-up from non-U.S. centers employing procedures considered experimental, investigational and/or unproven in this policy. For example, Lee et al. retrospectively identified 44 patients with T2D and a BMI less than 35 kg/m², 114 patients with a BMI between 35 kg/m² and 45 kg/m², and 43 patients with a BMI greater than 45 kg/m² in a large series of patients who underwent laparoscopic mini-gastric bypass. (103) One year postsurgery, fasting plasma glucose levels returned to normal in 89.5% of patients with BMI less than 35 kg/m² and in 98% of those with a BMI greater than 35 kg/m². The treatment goals of an HbA1c level less than 7%, low-density lipoprotein level less than 150 mg/dL, and triglyceride level less than 150 mg/dL, was met by 76.5% of patients with a BMI less than 35 kg/m² and by 92.4% of those with a BMI greater than 35 kg/m².

Diabetic Patients Without Morbid Obesity

Systematic Reviews

Muller-Stich et al. published a systematic review of bariatric surgery in patients with diabetes with a BMI greater than 35 kg/m². (104) Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified. 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 (mean difference, -5.5 kg/m²); a lower HbA1c level (mean difference, 1.4%; 95% CI, 0.9% to 1.9%; 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).

[Back to Top](#)

A meta-analysis published in 2014 included 4 RCTs comparing laparoscopic gastric bypass with SG in diabetic patients. (105) The main outcomes were several measures of diabetes control and cardiovascular risk factors. For most outcomes, there was a trend toward greater improvement for the gastric bypass group, but the differences were not statistically significant. For example, the gastric bypass group had a larger decrease in HbA1c levels (0.41%) than the SG group, but the difference was not statistically significant (95% CI, -0.09% to 0.91%). There was also a similar difference between groups in BMI (mean difference, 0.85 kg/m²; 95% CI, -0.13 to 1.58). However, there were significant differences in favor of gastric bypass on reduction in cardiovascular risk factors (e.g., blood pressure, lipid levels).

Randomized Controlled Trials

A 2012 BCBSA TEC Assessment evaluated bariatric surgery in diabetic patients with a BMI less than 35 kg/m². (106) The evidence consisted mainly of case series. This Assessment made the following conclusions:

- 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 1 randomized trial comparing 2 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 1 year and beyond. One of the studies was a randomized clinical trial of gastric bypass versus SG; in this study, diabetes remission associated with gastric bypass was 93% versus 47% for SG at 1 year.
- Two studies reported outcomes of SG. The diabetes remission rates were 55% and 47% at 1 year.
- One study selected 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. The 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 kg/m² and 35 kg/m² and 27% for subjects with a BMI between 25 kg/m² and 30 kg/m² at 12-month follow-up.
- One study reported outcomes of duodenal-jejunal 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 5 and 15 years. The diabetes remission rate was 17% at 6 months.

The BCBSA TEC Assessment concluded that gastric bypass met the 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.

Since the publication of the 2012 BCBSA TEC Assessment, 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 had RYGBP. (107) 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). The authors reported that longer term follow-up is needed.

DePaula et al. reported on 39 patients with a BMI less than 35 kg/m² who underwent 1 of 2 laparoscopic procedures comprising different combinations of ileal interposition into the proximal jejunum using a sleeve or diverted SG. (108) Mean BMI was 30.1 kg/m² (range, 23.4-34.9 kg/m²). All had T2D for at least 3 years (mean duration, 9.3 years; range, 3-22 years) and evidence of stable treatment with oral hypoglycemic agents or insulin for at least 12 months. Mean follow-up was 7 months (range, 4-16 months). Mean postoperative BMI was 24.9 kg/m² (range, 18.9-31.7 kg/m²). Adequate glycemic control was achieved for 86.9% of patients, and 13.1% had improvement. Four major complications occurred within 30 days of surgery, and mortality was 2.6%. Scopinaro et al. reported outcomes at mean follow-up of 13 years (range,

10-18 years) on 7 patients with a BMI less than 35 kg/m² who underwent BPD. (6) In all patients, serum glucose levels were normalized at 1, 2, and 3 years. In 5 patients, a slight increase above 123 mg/dL was observed at or around 5 years. The values were maintained at all subsequent follow-ups with no value higher than 160 mg being recorded. The other 2 patients had full resolution of diabetes at all follow-up times. Serum cholesterol and triglyceride values fell to normal 1 year after BPD and remained within the normal range. Blood pressure normalized in 6 cases and improved in 1. No patient had excessive weight loss at any postoperative time. Kakoulidis et al. investigated the role of SG for patients with a BMI ranging from 30 to 35 kg/m². Fifteen of the 79 patients in the study had T2D. (109) At follow-up of 6 months or more, diabetes had resolved in 2 patients and improved in one.

Section Summary: Bariatric Surgery as a Treatment for T2D

Several small RCTs and systematic reviews of available trials have concluded that bariatric surgery is more efficacious than medical therapy as a treatment for T2D. Remission rates of diabetes at 1 to 2 years have been 50% or higher following bariatric surgery, compared with rates of approximately 10% with medical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Long-term outcomes of bariatric surgery are currently not available. Patient selection criteria for bariatric surgery in diabetic patients are also lacking.

Bariatric Surgery in Nondiabetic Patients With a BMI Less Than 35 kg/m²

A 2012 BCBSA TEC Assessment evaluated laparoscopic gastric banding in individuals without diabetes who had a BMI less than 35 kg/m². (110) This Assessment was prompted by FDA approval of LAP-BAND™ for this indication in 2011. The TEC Assessment concluded that LAGB did not meet 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 1 small RCT, which has methodologic limitations, 1 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 was sufficient to determine that weight loss following LAGB is greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities can be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB were uncertain, and this uncertainty has been 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.

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 LAGB, (111) although other studies report no differences in perioperative complications after LAGB in patients with GERD and/or hiatal hernia and those without GERD and/or hiatal hernia. (112) 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 recommending that, during operations for RYGBP, SG, and the placement of AGS, 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]). (113)

There is limited evidence whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists 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. reported results of a prospective cohort study comparing outcomes for patients who underwent LAGB with or without concurrent hiatal hernia repair (n=1298 with AGB alone; n=520 with concurrent hiatal hernia repair). (114) 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 was not specified how many patients were diagnosed with each method or 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 AGB 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. evaluated the effects of LSG with or without hiatal hernia repair on GERD in obese patients. (115) The study included 78 patients who underwent SG with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia 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. reported outcomes after primary and revisional LAGB in patients with hiatal hernia treated at a single hospital system. (116) 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 AGB with and without hiatal hernia repair. However, this compares patients with hiatal hernia undergoing repair to patients without hiatal hernia. The more relevant comparison would be comparing repair versus no repair in patients who have hiatal hernia.

Ardestani et al. analyzed data from the BOLD to compare outcomes for patients with and without hiatal hernia repair at the time of LAGB. (117) Of 41,611 patients who had LAGB 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 at 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, 4 minutes) to surgery, the authors concluded that many repairs may have involved 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. described the feasibility of crural repair at the time of LAGB for patients with hiatal hernia. (118) 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. (119) For laparoscopic RYGBP, there were 206,559 and 9060 patients who underwent the procedure alone or with concomitant hiatal hernia repair, respectively. For LAGB, 52,901 and 9893 patients, respectively, underwent the procedure alone or with hiatal hernia repair. The authors reported no evidence of increased risk of perioperative AEs 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 -1.124 (95% CI, -0.15 to -0.088) for PLOS for patients who underwent RYGBP and an ATT of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for PLOS for patients who underwent LAGB.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery

Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. 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 procedure 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.

Ongoing and Unpublished Clinical Trials

There are a large number of ongoing and unpublished trials of bariatric surgery. A search of ClinicalTrials.gov in January 2016 using the key words “bariatric surgery” and limited to intervention trials returned 441 studies. Restricting this set of studies to open studies resulted in 177 ongoing trials. These trials are being conducted in various patient populations and with different types of bariatric procedures and different comparators.

Summary of Evidence

The evidence for gastric bypass, laparoscopic gastric banding, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch in individuals who are adults with morbid obesity includes randomized controlled trials (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 a very large body of literature on bariatric surgery, but few high-quality RCTs and no RCTs that report on long-term clinical outcomes compared to medical therapy. The available evidence, largely from nonrandomized comparative studies and case series, supports the conclusion that bariatric surgery results in greater weight loss and improvements in weight-related comorbidity than nonsurgical treatments. Gastric bypass, performed by either the open or laparoscopic approach, improves health outcomes of morbidly obese patients by leading to substantial weight loss with relatively low rates of adverse events. There is also sufficient evidence that laparoscopic gastric banding, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch improve outcomes. For these procedures compared with gastric bypass, there is a tradeoff in terms of the amount of weight loss, short-term complications, and long-term complications. An informed choice between patients and surgeons should be made after a thorough consideration of the risks and benefits of each procedure. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for other bariatric surgery procedures in individuals who are adults with morbid obesity 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 less evidence on other types of bariatric surgery. Although some comparative studies exist, the evidence is insufficient to determine whether other procedures have a favorable risk-benefit profile compared with the criterion standard procedure, gastric bypass. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for any bariatric surgery procedure in individuals who are not diabetic and not morbidly obese 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 do not have diabetes or morbid obesity. A few small RCTs and case series report loss of weight and improvements in comorbidities for this population. However, the evidence does not allow 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.](#)

Joint guidelines were published by the American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery (ASMBS) in 2013. (120) Recommendations on the following questions are summarized below.

“Which patients should be offered bariatric surgery?”

- “Patients with a BMI ≥ 40 kg/m² 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 ≥ 35 kg/m² and 1 or more severe obesity-related comorbidities....”

- “Patients with BMI of 30-34.9 kg/m² 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. (121) The guidelines make the following recommendations related to bariatric surgery:

- “Advise adults with a BMI ≥ 40 kg/m² or BMI ≥ 35 kg/m² 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 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 COR [class of recommendation]: IIa; AHA/ACC LOE [level of evidence]: A”
- “For individuals with a BMI < 35 kg/m², there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation)”

American Society for Metabolic & Bariatric Surgery

In 2012, ASMBS updated its 2009 position on sleeve gastrectomy. (122) In 2009, the statement accepted sleeve gastrectomy as an approved bariatric surgical procedure primarily because of its potential value as a first-stage surgery for high-risk patients. (123) ASMBS cited the need for long-term data to confirm the effectiveness of the procedure as a stand-alone intervention. The 2012 update provides the following conclusions:

“Substantial comparative and long-term data have now been published in the peer-reviewed studies demonstrating durable weight loss, improved medical co-morbidities, long-term patient satisfaction, and improved quality of life after SG.

The 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.

From the current published data, SG has a risk/benefit profile that lies between LAGB and the laparoscopic RYGB [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 reintervention. 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.”

In 2009, the ASMBS Emerging Technologies and Clinical Issues Committee issued a position statement on emerging endosurgical interventions for treating obesity. (124) The committee stated that “use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of ASMBS and designed to evaluate the risk and efficacy of the intervention.”

The committee called for trials to generate data for risk-benefit analysis, assessments of disability, durability, and resource utilization and noted that dramatic reduction in risk might allow for acceptance of interventions not providing durable benefits comparable to currently accepted bariatric procedures.

National Institutes of Health

Recommendations from the National Institutes of Health (NIH) have emphasized the importance of a multidisciplinary approach to bariatric surgery patients, including such ancillary services as nutritional and psychological support. (1) NIH also recommended that bariatric surgery programs provide lifelong follow-up for treated patients. However, no regulatory mechanisms ensure that these resources are present in all programs.

Society of American Gastrointestinal and Endoscopic Surgeons

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias incidentally detected at the time of bariatric surgery. (113) 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).

Contract:

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coding:

CODING:

Disclaimer for coding information on Medical Policies

Procedure and diagnosis codes on Medical Policy documents are included only as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, device or diagnosis codes in a Medical Policy document has **no** relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a medical policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT/HCPCS/ICD-9/ICD-10 Codes
The following codes may be applicable to this Medical policy and may not be all inclusive.
CPT Codes
00797, 43236, 43633, 43644, 43645, 43770, 43771, 43772, 43773, 43774, 43775, 43842, 43843, 43845, 43846, 43847, 43848, 43886, 43887, 43888, 43999
HCPCS Codes
S2083
ICD-9 Diagnosis Codes
Refer to the ICD-9-CM manual Back to top
ICD-9 Procedure Codes
Refer to the ICD-9-CM manual
ICD-10 Diagnosis Codes
Refer to the ICD-10-CM manual

ICD-10 Procedure Codes
Refer to the ICD-10-CM manual

Medicare Coverage:

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The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

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[Back to Top](#)

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Policy History:

Date	Reason
3/15/2017	Document updated with literature review. The following changes were made to Coverage:1) The words include, but are not limited to, have been added to the following sentence: The following bariatric procedures considered experimental, investigational and/or unproven as a treatment of morbid obesity. 2) The following has been added to the experimental, investigational and/or unproven procedure list: Single anastomosis duodenoileal bypass with sleeve gastrectomy and AspireAssist® device. 3) The following statements have been added to the MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS section: Reoperation related to previous bariatric surgery may be considered medically necessary for complications such as stricture, obstruction, or erosion except when the members benefit plan excludes coverage of such complications, and Removal of an adjustable gastric band may be considered medically necessary for complications not resolved by band deflation, including but not limited to obstruction, erosion, aspiration pneumonia, GERD, night cough, Barrett’s esophagus, persistent vomiting, or persistent pain except when the members benefit plan excludes coverage of such complications. 4) Or when the member’s benefit plan does not allow for coverage, has been added to the following coverage statement: New bariatric surgery following a previous different bariatric procedure: A Roux-en-Y procedure following a previously approved vertical banded gastroplasty or laparoscopic adjustable banded gastroplasty is not eligible for coverage for patients who have been substantially noncompliant with a prescribed nutrition and exercise program following the original procedure or when the member’s benefit plan does not allow for coverage. 5) Examples have been changed in the technical failure statement in the MISCELLANEOUS PROCEDURE COVERAGE STATEMENTS section. Previously examples were: break down of gastric pouch, slippage, breakage or erosion of gastric band, bowel obstruction, staple line failure, etc.
Back to Top	

2/1/2012: Document updated with literature review. The patient selection requirement for a pre-surgical weight loss program for at least six (6) months, occurring within the twenty-four (24) months prior to the proposed surgery **has been replaced** with “Documentation from the surgeon attesting that the patient has been educated in and understands the post-operative regimen”.