
Medical Policy



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(See policy history boxes for previous effective dates)

Title: Bariatric Surgery (Gastric Surgery for Morbid Obesity)

Description / Background

BARIATRIC SURGERY

Bariatric surgery is performed for the treatment of morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m² or a BMI greater than 35 kg/m² with associated complications including, but not limited to, diabetes, 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, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. 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 (GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY), are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

Guidelines on how to calculate BMI

The BMI calculation ($\text{BMI} = \text{weight}/\text{height}^2$) is made utilizing kilograms for the patient's weight and meters for height.

Note: To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to meters, multiply inches by 0.0254.

There are a number of online sites that will assist in calculating the patient's BMI by inserting the patient's statistics into the appropriate boxes. One such site is http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

The following list summarizes the different restrictive and malabsorptive procedures used in bariatric surgery.

- **Adjustable Gastric Banding (CPT code 43770)**

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

Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe. Two such devices are approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S. The first such device that received FDA approval was the LAP-BAND (original applicant, Allergan Inc., BioEnterics, Carpinteria, CA; sold to Apollo Endosurgery Inc., Austin, TX, in 2013). The labeled indications for this device are as follows:

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

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

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

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

- **Open Gastric Bypass (gastric restrictive procedure with gastric bypass, with short-limb Roux-en-Y gastroenterostomy) (CPT code 43846)**

The original gastric bypass surgeries were based on the observation that post-gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweet eaters.” Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there may be more metabolic complications compared with other gastric restrictive procedures, including iron deficiency anemia, vitamin 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 a laparoscopic technique.

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

- **Laparoscopic Gastric Bypass (CPT code 43644)**

This code essentially describes the same procedure as open gastric bypass but performed laparoscopically.

- **Mini Gastric Bypass (no specific CPT code)**

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

- **Sleeve Gastrectomy (CPT code 43775)**

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

- **Endoluminal (also called endosurgical, endoscopic, or natural orifice) bariatric procedures (no specific CPT code)**

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

- **Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure) (CPT code 43847)**

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

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

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

addition, there have been several case reports of liver failure resulting in death or liver transplant.

- **Biliopancreatic Bypass with Duodenal Switch (CPT code 43845)**

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

- **Single Anastomosis Duodeno-ileal Bypass with Sleeve Gastrectomy (SADI-S) (no specific CPT code)**

The SADI-S is a type of type of bariatric surgery with a single anastomosis. It has a restrictive component when reducing the greater curvature of the stomach, but specially a malabsorptive component, as the common channel is also reduced. The objective of this surgical technique is to lessen the intestinal loop where nutrients are absorbed.

- **Stomach Intestinal Pylorus-Sparing Surgery (SIPS) (No specific CPT code)**

SIPS is a type of weight-loss surgery. It was developed in 2013 by two U.S. surgeons. The SIPS is a modified version of the duodenal switch surgery. The SIPS involves the creation of a 300-cm common channel with a single-anastomosis duodenal enterostomy.

- **Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847)**

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

- **Laparoscopic Malabsorptive Procedure (CPT code 43645)**

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

- **Laparoscopic Gastric Plication (no specific CPT code)**

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

Weight Loss Outcomes

There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. Excess body weight is defined as actual weight minus “ideal weight” and “ideal weight” is based on 1983 Metropolitan Life Insurance Company height-weight tables for “medium frame”.

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 1 summarizes the variations in reporting weight loss outcomes.

Table 1. Weight Loss Outcomes

Outcome Measure	Definition	Clinical Significance
Decrease in weight	Absolute difference in weight pre- and post-treatment	Unclear relation to outcomes, especially in morbidly obese
Decrease in BMI	Absolute difference in BMI pre- and post-treatment	May be clinically significant if change in BMI clearly leads to change in risk category
Percent EBW loss	Amount of weight loss divided by EBW	Has anchor to help frame clinical significance; unclear threshold for clinical significance
Percent patients losing >50% of EBW	No. patients 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 Events, Nutritional Deficiencies)

Metabolic adverse events are of particular concern in malabsorptive procedures. Other long-term complications include anastomotic ulcers, esophagitis, and procedure-specific complications such as band erosion or migration for gastric-banding surgeries.

Improved Health Outcomes in Terms of Weight-Related Comorbidities

Aside from psychosocial concerns, which may be considerable, 1 motivation for bariatric surgery is to decrease the incidence of complications of obesity, such as diabetes, cardiovascular risk factors (i.e., increased cholesterol, hypertension), obstructive sleep apnea, or arthritis. Unfortunately, these final health outcomes are not consistently reported.

Regulatory Status

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

Several gastric bands for use in bariatric surgery have received FDA-approval through the premarket approval process and are summarized in Table 2 (FDA Product Code: LTI):

Table 2: FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
AspireAssist System®	Aspire Bariatrics	June 2016	For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults >22 y, with a BME of 35.0 to 55.0 kg/m ² and no contraindications to the procedure who have failed to achieve and maintain weight loss therapy
ORBERA® intragastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30-40 kg/m ²) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
ReShape®	ReShape	Jul 2015	For use in obese adults (BMI, 30-40 kg/m ²) and ≥1 comorbid

Integrated Dual Balloon System	Medical		conditions who have failed weight reduction with diet and exercise, and have no contraindications, Maximum placement time is 6 mo. Balloon delivered transorally and inflated with saline.
REALIZE® Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/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. Indicated for use only in morbidly obese adults who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs)
LAP-BAND® Adjustable Gastric Banding System	Apollo Endosurgery	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m ² or a BMI of at least 30 kg/m ² with ≥1 comorbid conditions who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).

BMI: body mass index; FDA: food and drug administration; PMA: premarket approval.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intragastric balloons in response to reports of 2 types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. A second set of adverse reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of 5 unanticipated deaths occurring from 2016 through the time of the letter, due to intragastric balloons. The FDA recommended close monitoring of patients receiving these devices.

Medical Policy Statement

The safety and effectiveness of laparoscopic and open gastric restrictive procedures including but not limited to gastric-band, Roux-en-Y, gastric bypass, sleeve gastrectomy and biliopancreatic diversion have been established. They may be considered useful therapeutic options when specified criteria are met.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

NOTE: Please check WebDENIS for BCBSM-specific plan criteria
Please check BCN benefit page at the end of the policy for BCN- specific plan criteria.

Inclusions:

The surgical procedures for severe obesity, including sleeve gastrectomy, are considered established treatment options if all the following criteria are met:

- The patient has a BMI >40 or a BMI of >35 with one or more co-morbid conditions including, but not limited to:

- Degenerative joint disease (including degenerative disc disease)
- Hypertension
- Hyperlipidemia, coronary artery disease
- Presence of other atherosclerotic diseases
- Type II diabetes mellitus
- Sleep apnea
- Congestive heart failure.
- Bariatric surgery may be indicated for patients 18 to 60 years of age. Requests for bariatric surgery for patients less than 18 years of age should include documentation that the primary care physician has addressed the risk of surgery on future growth, the patient's maturity level and the patient's ability to understand the procedure and comply with postoperative instructions, as well as the adequacy of family support. Patients above 60 years of age may be considered if it is documented in the medical record that the patient's physiologic age and co-morbid condition(s) result in a positive risk/benefit ratio.
- The patient has been clinically evaluated by an MD or DO (or their authorized delegate (e.g., physician assistant, etc.)). The physician has documented failure of non-surgical management including a structured, professionally supervised (physician or non-physician) weight loss program for a minimum of:
 - Six full, consecutive months (180 days) within the last four years prior to the recommendation for bariatric surgery (for **BCBSM** patients) OR
 - Six full, consecutive months (180 days) within the last two years prior to the recommendation for bariatric surgery (for **BCN** patients).
 - The six full consecutive month (180 days) weight loss program listed above is waived for super morbidly obese individuals who have a BMI ≥ 50 . Documentation should include periodic weights, dietary therapy and physical exercise, as well as behavioral therapy, counseling and pharmacotherapy, as indicated.
- Documentation that the PCP and the patient have a good understanding of the risks involved and reasonable expectations that the patient will be compliant with all post-surgical requirements.
- A psychological evaluation must be performed as a pre-surgical assessment by a contracted mental health professional in order to establish the patient's emotional stability, ability to comprehend the risk of surgery and to give informed consent, and ability to cope with expected post-surgical lifestyle changes and limitations. Such psychological consultations may include one unit total of psychological testing for purposes of personality assessment (e.g., the MMPI-2 or adolescent version, the MMPI-A).
- The physician needs to be aware and follow-up with individuals who have had gastric surgery for any long-term complications.
- In cases where a revision of the original procedure is planned because of failure due to anatomic or technical reasons (e.g., obstruction, staple dehiscence, etc.), or excessive weight loss of 20% or more *below* ideal body weight, the revision is determined to be medically appropriate without consideration of the initial preoperative criteria. The medical records should include documentation of:
 - The date and type of the previous procedure
 - The factor(s) that precipitated the failure and/or the nature of the complications from the previous procedure that mandate (necessitate) the takedown
- If the indication for the revision is a weight gain OR a failure of the patient to lose a desired amount of weight DUE TO PATIENT NON-ADHERENCE, then the patient must re-qualify for the subsequent procedure and meet all of the initial preoperative criteria.

Exclusions:

The following surgical procedures are considered experimental/investigational because their safety and/or effectiveness have not been proven:

- Gastric bypass using a Billroth II type of anastomosis , also known as mini gastric bypass
 - Biliopancreatic bypass without duodenal switch
 - Long-limb gastric bypass procedure (i.e., >150 cm)
 - Stomach stapling
 - Endoscopic/endoluminal procedures (including but not limited to insertion of the StomaphyX™ device, insertion of a gastric balloon, endoscopic gastroplasty, or use of an endoscopically placed duodenojejunal sleeve) as a primary bariatric procedure or as a revision procedure, (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches).
 - Any bariatric surgery for patients with type 2 diabetes who have a BMI of less than 35.
 - Laparoscopic gastric plication
 - Vagus nerve blocking (see separate policy, “Vagus Nerve Blocking for Morbid Obesity.”)
 - Single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S)
 - Stomach intestine pylorus sparing surgery (SIPS)
 - Bariatric surgery for pre-adolescents
 - Intragastric balloons
 - Aspiration therapy device
-

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

43644	43645	43770	43771	43772	43773
43774	43775	43842	43843	43845	43846
43847	43848	43886	43887	43888	43999
44130	96101	96102	96103	S2083	

Other codes (investigational, not medically necessary, etc.):

43999*

**When used to indicate any of the following procedures:*

- *Loop gastric bypass gastroplasty - also known as mini-gastric bypass*
 - *Stomach stapling*
 - *SADI-S*
 - *SIPS*
 - *Endoscopic procedures to treat weight gain after bariatric surgery*
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Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of

life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Overview: Bariatric Surgery In Adults With Morbid Obesity

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

Randomized controlled trials (RCTs) of bariatric surgery have been performed but are limited and insufficient to draw conclusions about the comparison of bariatric surgery with conservative treatments for weight loss.² RCTs are difficult in bariatric surgery because many experts consider it inappropriate or unethical to randomize patients to bariatric surgery. In addition, the majority of patients and clinicians have strong feelings about their preference for treatment, which results in a select population that might agree to randomization and therefore, limited generalizability. As a result, the literature that is most important in determining the efficacy of bariatric surgery is from nonrandomized studies.

Swedish Obese Subjects Trial

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/m² at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients were self-selected into treatment, and there were baseline differences between groups, primarily reflecting weight that is more excess and a higher incidence of co-morbidities

in the surgery group. There were a total of 2,010 people who chose surgery and 2,037 individuals who chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each individual surgeon chose the surgical procedure offered. Most of the procedures were vertical-banded gastroplasty (VBG) (over 70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. The patients are followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

There have been many publications from this trial reporting on methods, weight loss, and clinical outcomes.³⁻⁷ The following general conclusions can be drawn from the SOS study:

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

Longitudinal Assessment of Bariatric Surgery Consortium

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding with follow-up through 3 years post procedure.⁸ The study enrolled 2458 subjects, with median BMI 45.9 (interquartile range [IQR], 41.7-51.5). For their first bariatric surgical procedure, 1738 participants underwent Roux-en-Y gastric bypass, 610 laparoscopic adjustable gastric banding, and 110 other procedures. At 3-year follow-up, for 1533 Roux-en-Y patients with available data, percentage of baseline weight lost was 31.5% (IQR, 24.6%-38.4%). For the 439 adjustable gastric banding patients with available data at 3 years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years post surgery, 67.5% and 28.5% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the Roux-en-Y gastric bypass patients and 17.5% (95% CI, 13.8% to 21.9%) of laparoscopic adjustable gastric banding patients.

Systematic reviews

Numerous systematic reviews have been published on the efficacy of bariatric surgery compared with conservative therapy or compared different types of bariatric surgery techniques, some of which are older and do not include the full range of available studies.^{9,10}

Kang et al (2017) conducted a systematic review with a network meta-analysis that compared the 3 most common types of bariatric surgery techniques: RYGB, SG, and LAGB.¹¹ The literature search, conducted through July 2016, identified 11 RCTs for inclusion (8 RYGB vs.

SG; 2 RYGB vs. LAGB; 1 SG vs. LAGB). Quality of the trials was assessed using the Jadad score, based on allocation concealment, blinding, intention-to-treat analysis, power calculation, and funding. Most trials had a Jadad score of 3 (scale range, 1-5). A meta-analysis for the outcome of BMI reduction showed that there was no difference between SG and RYGB (6 trials): 0.7 (95% CI, -1.6 to 3.1). A meta-analysis of RYGB and LAGB (2 trials) and a single trial of SG and LAGB showed that LAGB was not as effective as RYGB or SG: 5.8 (95% CI, 2.3 to 9.1) and 5.1 (95% CI, 0.9 to 8.9), respectively. Meta-analyses for the outcome of percent EWL showed the same pattern, no difference comparing SG and RYGB (5 trials; -4.0; 95% CI, -14.0 to 8.2), and both SG and RYGB more effective compared with LAGB (2 trials; 22.0; 95% CI, 6.5 to 34.0; 1 trial; 26.0; 95% CI, 6.4 to 41.0; respectively).

In 2014, Colquitt et al published an update to a Cochrane review of bariatric surgery for obesity, which was originally published in 2003 and most recently updated in 2009.¹² The authors identified 22 randomized trials that compared bariatric surgery with nonsurgical obesity management or that compared different bariatric surgery procedures, with 1798 participants, with sample sizes from 15 to 250. All 7 RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at 1- to 2-year follow-up. However, the authors note 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 (2013) conducted a systematic review and meta-analysis of RCTs comparing current bariatric surgery techniques with nonsurgical treatment for patients with BMI of 30 or more.¹³

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 mellitus (T2DM) was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of remission with T2DM, 22.1; 95% CI, 3.2 to 154.3; $p < 0.000$); similarly remission of metabolic syndrome was more likely for bariatric surgery patients (RR=2.4; 95% CI, 1.6 to 3.6; $p < 0.001$). After bariatric surgery, 21 of 261 (8%) patients required reoperations (5/124 after adjustable gastric banding, 4/69 after Roux-en-Y gastric bypass, 1/49 after sleeve gastrectomy, 1/19 after BPD). Similar to the Colquitt et al meta-analysis, no studies reported longer-term follow-up (beyond 2 years) and heterogeneity between studies was high.

Chang et al (2014) published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery.¹⁴ The authors included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean presurgery BMI was 45.62, and among the studies that provided information about obesity-related comorbidities, 26.2% of patients had T2DM, 47.39% had hypertension, 27.97% had dyslipidemia, 7.15% had cardiovascular disease, and 25.30% had sleep apnea. Perioperative complications were relatively low, with a perioperative mortality rate in RCTs of 0.08% (95% CI, 0.01% to 0.24%) and in observational studies of 0.22% (95% CI, 0.14% to 0.31%). Complication rates were 17% (95% CI, 11% to 23%) for RCTs, compared with 10% for observational studies (10% [95% CI, 7% to 13%]). At 1-year follow-up, mean change in BMI was -13.53 (95% CI, -15.51 to -11.55) in RCTs and -11.79 (95% CI, -13.89 to -9.69) in observational studies. Decreases in BMI were generally sustained over 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, T2DM, hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease.¹⁵⁻³⁰

Puzziferi et al (2014) conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies with 7971 patients.³¹ At follow-up, which ranged from 2 to 5 years post procedure, the mean sample size–weighted percentage of excess weight loss was higher for gastric bypass than for gastric banding (65.7% vs. 45.0%). The authors note that few studies report long-term results with enough follow-up to minimize bias.

Section Summary: Bariatric Surgery in Adults With Morbid Obesity

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

EVIDENCE FOR SPECIFIC TYPES OF BARIATRIC SURGERY PROCEDURES

Gastric Bypass

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 have indicated surgeons have adopted this approach, with gastric bypass now comprising most of the bariatric procedures performed.

Comparative trials summarized in the 2003 TEC Assessment³² consistently report favorable outcomes for open gastric bypass when compared with vertical-banded gastroplasty, including 2 RCTs. Some nonrandomized trials that compare open gastric bypass with procedures other than VBG were also summarized in the 2003 TEC Assessment. While there are fewer trials for these other procedures, comparisons of open gastric bypass to gastric banding, horizontal gastroplasty, and silastic ring gastroplasty all reported that weight loss was superior with open gastric bypass. Metabolic abnormalities are seen more frequently in gastric bypass patients compared to those receiving a VBG. Anemia, iron deficiency, vitamin B12-deficiency, and red blood cell folate-deficiency are commonly seen. Marginal ulcerations are also seen in gastric bypasses, particularly in those whose gastric pouches are too large and include acid-secreting parietal cells.

A 2005 TEC Assessment focused on the issue of laparoscopic gastric bypass, which intends to reproduce the open procedure via minimally invasive techniques.³³ This is a technically complex operation that requires a dedicated team and a relatively high degree of skill and experience in laparoscopic surgery. This Assessment reviewed 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 in the review.

This TEC Assessment concluded that weight loss at 1 year is similar between laparoscopic and open gastric bypass approaches.³² Weight loss at longer follow-up periods has been less well-reported but appears to be similar as well. While comparisons of complication rates are

less certain, certain patterns are evident and relatively consistent across the data examined. The profile of AEs differs between the two approaches, with each having its advantages and disadvantages. Laparoscopic gastric bypass offers a less-invasive procedure that is associated with decreased hospital stay and earlier return to usual activities. The mortality may be lower with the laparoscopic approach, although both procedures have mortality rates less than 1%. Postoperative wound infections and incisional hernias are also less common with laparoscopic gastric bypass. On the other hand, anastomotic problems, gastrointestinal tract bleeding, and bowel obstruction appear to be higher with the laparoscopic approach, but not markedly higher. Given these data, it is not possible to say that one procedure is superior to the other, and overall the benefit/risk ratio for these two approaches appears to be more similar than different.

In 2016, Yan et al published a systematic review of RCTs comparing gastric bypass and medical treatment in obese patients (i.e., BMI ≥ 30 kg/m²) with T2D.³⁴ The primary study outcome was remission of T2D, which was reported in 5 of the 6 studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment (odds ratio [OR], 76.37; 95% CI, 20.70 to 271.73; $p < 0.001$). In addition, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD = -6.54 kg/m²; 95% CI, -9.28 to -3.80 kg/m²; $p < 0.001$).

Section Summary: Gastric Bypass

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

Laparoscopic Adjustable Gastric Banding

A 2006 TEC Assessment updated the evidence on LAGB, and compared outcomes to those of gastric bypass.³⁵ This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the two procedures to allow the optimal choice to be made based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at 1 year is less for LAGB compared with GBY. The percentage of excess weight lost (EWL) at 1 year is in the range of approximately 40%, compared to 60% or higher for GBY. At time points longer than 1 year, some of the comparative studies report that the difference in weight loss between LAGB and GBY lessens, but others do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss between the procedures begins to lessen after 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 who have their band removed or deflated are excluded from analysis.

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

The reported rates of long-term AEs vary considerably. In the comparative trials, re-operations are reported in approximately 25% of patients, while in the single-arm studies, the composite rate for re-operations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the range of rates for band slippage is 1–36%, and the range for port access problems is 2–20%. 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 under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. A recent publication by Ibrahim et al (2017) reviewed 25,042 Medicare beneficiaries who underwent a laparoscopic gastric band surgery; 18.5% (n=4636) patients underwent one or more reoperation(s). Reoperation was prompted by the need for band removal (41.8%), band and port replacement (28.6%), and other requirements.³⁶ The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ratio for LAGB.

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

A 2012 systematic review by Chakravarty et al comparing LAGB with other bariatric surgery procedures had a conclusion similar to the TEC Assessment.³⁷ Reviewers included 5 RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (e.g., gastric bypass or sleeve gastrectomy [SG]). However, the short-term complication rate was lower with LAGB and no difference was found in quality of life after LAGB versus other procedures.

Section Summary: Laparoscopic Adjustable Gastric Banding

Systematic reviews of the literature have concluded that LAGB is a reasonable alternative to gastric bypass; there is less weight loss with LAGB; however, is associated with fewer serious adverse events.

SLEEVE GASTRECTOMY

Systematic Reviews

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

Osland et al (2017) published a systematic review and meta-analysis of RCTs comparing laparoscopic vertical SG with RYGB (see Table 1).³⁸ The literature search, conducted from 2000 to November 2015, identified 9 RCTs for inclusion (total N=865 patients). Four trials were included in meta-analyses comparing percent EWL between the 2 groups. Results at both 6- and 12-month follow-ups showed that the procedures are comparable (see Table 2).

A 2016 systematic review by Juodeikis and Brimas summarized evidence on long-term results after SG (see Table 3).³⁹ Reviewers included 1 RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m². Mean duration of follow-up ranged from 5 to 11 years and mean proportion of patients followed for 5 years was 68.5%. Seventeen studies (n=1501 patients) reported 5-year follow-up data; . At 5 years, resolution of T2D arterial hypertension, dyslipidemia, OSA, gastroesophageal reflux disease (GERD), and degenerative joint diseases also improved in most patients (see Table 4). Two studies reported weight loss after 7 and 8 years; percent EWL rates were 56.6% and 54.8%, respectively.

In a 2015 meta-analysis of 21 randomized and nonrandomized studies (total N=18,766 patients) comparing SG with LRYGB for morbid obesity, Zhang et al reported no significant difference in percent EWL from 0.5 to 1.5 year follow-ups (see Tables 3 and 4).⁴⁰ However, after 1.5 years, Roux-en-Y bypass was associated with higher percent EWL (2-year MD=5.77; 95% CI, 4.29 to 7.25; p<0.05). Adverse events were more frequent following Roux-en-Y bypass (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

In 2013, Trastulli et al conducted a systematic review of randomized trials that compared SG with other bariatric procedures (see Table 3).⁴¹ Summary statistics were provided; meta-analyses were not conducted (see Table 4). 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 compared with 62.1% to 94.4% with LAGB.

In 2009, Brethauer et al reviewed 36 studies (n=2570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers (see Table 3).⁴² Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (n=1,749) on SG as primary procedure. Mean percentage of excess weight loss (% EWL) was reported in 24 studies (n=1,662) and was 55.4% overall (range, 33–85%). Mean postoperative BMI was reported in 26 studies (n=1940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with greater than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies reporting detailed complication data (n=2,570). All extracted studies reported mortality data with 5 deaths within 30 days of surgery (overall mortality rate 0.19%, 2 in the high-risk/staged group and 3 in the primary procedure group).

Table 3. Systematic Review Characteristics for Sleeve Gastrectomy

Study	Dates	Studies	Participants	Design	Duration
Osland et al (2017) ³⁸	2000-Nov 2017	9	• SG=437 • RYGB=428	RCTs	3 mo to 5 y

Juodeikis et al (2016) ³⁹	Through May 2016	20	1626	• 1 RCT • 19 retrospective	5 to 11 y
Zhang et al (2015) ⁴⁰	Through Oct 2013	21	18,766	• 8 RCTs • 13 nonrandomized comparative studies	1 to 5 y
Trastulli et al (2013) ⁴¹	Through Nov 2012	15	1191	RCTs	6 mo to 3 y
Brethauer et al (2009) ⁴²	1996-20009	36	2570	• 2 RCTs • 1 cohort • 33 case series	3 mo to 5 y

NR: not reported; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy

Table 4. Systematic Review Results for Sleeve Gastrectomy

Study	Percent EWL (95% CI)	Comorbidities (95% CI)
Osland et al (2017) ³⁸	Mean difference, SG and RYGB • 6 mo (3 trials): 0.5 (-5.0 to 6.0)	Not reported
Juodeikis et al (2016) ³⁹	Mean rates for SG: • 5 y (17 trials): 58.4% • 7 y (2 trials): 56.6% • 11 y (1 trial): 62.5%	Remission/improvement: • Type 2 diabetes: 77.8% • Hypertension: 68.0% • Dyslipidemia: 65.9% • Sleep apnea: 75.8%
Zhang et al (2015) ⁴⁰	Mean difference, RYGB and SG: • 6 mo (9 studies): 0.2 (-2.5 to 2.9) • 12 mo (15 studies): 2.9 (-0.2 to 6.0) • 4 y (3 studies): 2.7 (0.2 to 5.2)	Mean difference resolution, RYGB and SG: • Type 2 diabetes (10 studies): 3.3 (2.0 to 5.5) • Hypertension (10 studies): 1.3 (0.7 to 2.4) • Dyslipidemia (5 studies): 1.5 (0.8 to 2.6) • Sleep apnea (7 studies): 1.5 (0.8 to 2.6)
Trastulli et al (2013) ⁴¹	Mean by procedure: • SG: 49% to 81% • LGB: 62% to 94% • LAGB: 29% to 48%	Type 2 diabetes: • SG, 67% to 100% • LGB, 80% to 100%
Brethauer et al (2009) ⁴²	Mean rate overall for SG: • 55% (range, 33%-85%)	Remission/improvement • Type 2 diabetes: >70% • Significant reductions also seen in hypertension, hyperlipidemia, and sleep apnea

CI: confidence interval; EWL: excess body weight loss; LAGB: laparoscopic adjustable gastric banding; LGB: laparoscopic gastric bypass; RCT: randomized controlled trial; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

Randomized Controlled Trials

An RCT comparing short-term outcomes of laparoscopic sleeve gastrectomy with gastric bypass was published in 2013.⁴³ The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to sleeve gastrectomy. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the sleeve gastrectomy group ($p=0.29$). Minor complications were more common in the gastric bypass group compared to sleeve gastrectomy (17.1% versus 7.4%, $p=0.02$), as was combined major and minor complications (26.5% versus 13.2%, $p=0.01$).

Karamanakos et al (2008) carried out a double-blind RCT to compare outcomes of laparoscopic RYGB 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.⁴⁴ 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 than

laparoscopic RYGB at 6 months (55.5% vs. 50.2%; $p=0.04$) and 12 months (69.7% vs. 60.5%; $p=0.05$), all respectively. Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but decreased more after LSG.

Himpens et al (2006) reported on a randomized trial comparing LAGB and laparoscopic isolated SG in 80 patients and reported 3 year follow-up.⁴⁵ Median baseline BMI was 37 kg/m² (range, 30-47 kg/m²) in the LAGB groups and 39 kg/m² (range, 30-53 kg/m²) in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, 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 of craving for sweets, but the difference was 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 RYGB ($n=1$), 1 gastric erosion treated by conversion to RYGB, and 3 system disconnections that required reconnection. Four patients had reoperations for lack of efficacy (2 LAGB patients underwent conversion to RYGB, 2 SG patients underwent conversion to duodenal switch). 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.

Section Summary: Sleeve Gastrectomy

Systematic reviews of RCTs and observational studies, evaluating SG alone and comparing SG with RYGB, have found that SG results in substantial weight loss, comparable to RYGB, and that this weight loss is durable for at least 5 years. A meta-analysis found that short-term weight loss was similar after SG or gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events.

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 decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum.

Systematic Review

In a 2009 evidence-based review of literature, Farrell et al summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at the mean of 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies, aggregate $n=896$), 67% for RYGB (7 studies, $n=1,627$), and 42% for AGB (11 studies, $n=4,456$). At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies, aggregate $n=174$), 58% for RYGB (3 studies, $n=176$), and 55% for AGB (5 studies, $n=640$). The authors note that “given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another.”⁴⁶

Non-randomized Comparative Studies

Skogar et al (2017) published results from a retrospective mail survey of patients undergoing BPD/DS (n=113) or RYGB (n=98) (see Table 5).⁴⁷ Reduction in BMI was statistically larger in patients receiving BPD/DS compared with patients receiving RYGB (see Table 6). Both groups experienced significant reductions in diabetes and sleep apnea. Significant reductions in dyslipidemia were only seen in the group receiving BPD/DS. The overall complication rate was lower for patients undergoing RYGB.

Strain et al published a smaller comparative study of 72 patients who underwent either RYGB (n=50) or BPD (n=22) (see Table 5). Choice of surgery was per surgeon and/or patient, and the patient populations differed in age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 23.3 for BPD compared to 16.5 for RYGB ($p<0.001$).⁴⁷

Prachand et al published the largest comparative series of 350 super-obese patients with BMI greater than 50 who underwent either RYGB (n=152) or Scopinaro BD combined with the DeMeester duodenal switch (DS-BPD) (n=198) (see Table 5).⁴⁹ In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The DS-BPD patients differed from RYGB patients on weight and BMI; mean weight in pounds was 368.2 ± 52.3 (range, 267.4–596.5) in DS-BPD patients versus 346.3 ± 55.2 (range, 239.8–504.9) in the RYGB group, and mean BMI was 58.8 ± 6.7 (range, 50–96) in DS-BPD patients versus 56.4 ± 6.8 (range, 49.5–84.2) in the RYGB group. At 1 year, data were reported for 143 DS-BPD patients and 81 RYGB patients (see Table 6). The EWL was greater for BPD versus RYGB (64.1% vs. 55.9%, respectively; $p<0.01$), and the reduction in BMI was also greater for BPD versus RYGB (23.6 vs. 19.4, respectively; $p<0.001$). Complications and data on resolution of comorbidities were not reported in this study.

Table 5. Nonrandomized Comparative Study Characteristics for BPD/DS

Author	Country	Dates	Participants	Follow-up
Skogar et al (2017) ⁴⁷	Sweden	2003-2012	• BPD/DS: 113 • RYGB: 98	4 y
Strain et al (2007) ⁴⁸	United States	2002-2005	• BPD/DS: 22 • RYGB: 50	• BPD/DS: 19 mo • RYGB: 15 mo
Prachand et al (2006) ⁴⁹	United States	2002-2005	• BPD/DS: 198 • RYGB: 152	3 y

BPD/DS: biliopancreatic diversion with duodenal switch; RYGB: Roux-En-Y gastric bypass.

Table 6. Nonrandomized Comparative Study Results for BPD/DS

Study	Mean Reduction in BMI (SD)		P ^a	Percent Achieving $\geq 50\%$ EBWL		
	Presurgery, kg/m ²	Post-surgery, kg/m ²		1 Year	2 Years	3 Years
Skogar et al (2017) ⁴⁷						
BPD/DS	56 (6.7)	31 (5.5)			NR	
RYGB	52 (4.0)	36 (7.1)	<0.01		NR	
Strain et al (2007) ⁴⁸						
BPD/DS	54 (11.9)	30 (6.1)			NR	
RYGB	48 (6.3)	31 (5.0)	<0.001		NR	

Change in BMI						
Prachand et al (2006) ⁴⁹						
BPD/DS	59 (6.7)	27.8		83.9	89.2	84.2
RYGB	56 (6.8)	18.9	<0.01	70.4 ^b	79.3	59.3 ^b

BMI: body mass index; BPD/DS: biliopancreatic diversion with duodenal switch; EBWL: excess body weight loss; RYGB: Roux-en-Y gastric bypass

^a Between groups, difference in change

^b p<0.05

Case Series

In 2017, Strain et al reported on the nutrient status of 190 patients receiving BPD/DS after 9 years of follow-up.⁵⁰ At baseline, the patients had a mean age of 43 years and mean BMI of 53 kg/m². All patients reported taking some supplements. Deficiencies in protein, iron, and calcium developed by year 3 and continued through the study. Zinc deficiencies developed by year 5. Folate levels increased during the study, probably due to the efficacy of the supplement. The authors warned that interventions need to be implemented to improve nutrient status in patients receiving BPD/DS.

The largest case series of this procedure is by Marceau et al (2009), who reported their 15-year experience with DS in 1423 patients from 1992–2005.⁵¹ Follow-up evaluation was 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 equal to or less than 50 obtained BMI less than 35, and 83% of patients with BMI greater than 50 achieved a BMI of less than 40. Diabetes medication was discontinued in 92% and decreased in others. The use of continuous positive airway pressure (CPAP) 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.

Section Summary: BPD With Duodenal Switch

Nonrandomized comparative studies have found significantly higher weight loss after BPD-DS compared with gastric bypass at 1 year. A large case series found sustained weight loss after 7 years.

BPD Without Duodenal Switch

The available evidence on BPD-DS was reviewed in the 2006 TEC Assessment, and BPD outcomes, with or without DS, were compared with those of gastric bypass.³⁵ One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 year were in the same range as for gastric bypass. While these data were not sufficient to distinguish small differences in weight loss between the 2 procedures, they did not support the hypothesis that BPD resulted in greater weight loss than open gastric bypass.

Complication rates have been poorly reported in these trials. The data have suggested that mortality is low (≈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 have suggested that long-term nutritional and vitamin deficiencies occur at a high rate following BPD. Slater et al (2004) focused specifically on vitamin and calcium deficiencies following BPD.⁵² They 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 (2004) reported similar data in a study that compared several technical variations of BPB.⁵³ They 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%).

Skroubis et al (2006) randomized 130 patients with a BMI of 35 to 50 kg/m² to RYGB or BPB without duodenal switch using a variant of BPB that included Roux-en-Y gastrectomy in place of SG.⁵⁴ 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 group (16 complications) and BPD groups (22 complications; $p=0.46$).

Numerous clinical series of BPB have been published, but, as with other procedures, high-quality trials that directly compare outcomes of this procedure with gastric bypass are lacking. In 1996, Scopinaro et al summarized their experience with 1,217 patients.⁵⁵ With follow-up of up to 9 years, the authors reported a durable excess weight loss of 75%, suggesting that weight loss is greater with this procedure compared to gastric restrictive procedures. In addition, the vast majority of patients reported disappearance or improvement of such complications as obstructive sleep apnea, hypertension, hypercholesteremia, and diabetes. The authors considered protein malnutrition the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity, and presumably, eating habits of the patients, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients are encouraged to maintain an oral calcium intake of 2 g/day, with monthly vitamin D supplementation.

Section Summary: BPD Without Duodenal Switch

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

Vertical-Banded Gastroplasty (VBG)

VBG is one of the early types of bariatric surgery developed in the 1980s. This is a purely restrictive procedure that has been largely replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there is a high

rate of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. The overall rates of revisions and reoperations at up to 10 years may be as high as 50%.^{56,57}

Systematic Review

Hsieh et al (2014) conducted a systematic review of studies reporting greater than 10-year follow-up for VBG, which included 3 studies with extractable data.⁵⁸ Mean EWL was 61.4% from baseline to follow-up in the 3 studies, but reviewers noted a lack of long-term evidence related to outcomes following VBG.

A number of other nonrandomized, comparative studies of open gastric bypass versus vertical-banded gastroplasty were included in the 2003 TEC Assessment (n=8 studies, 3,470 patients).³² All 8 of these studies reported greater amounts of weight loss with open gastric bypass. These studies reported a 44–70% improvement in total weight loss, a 28–43% improvement in the percent excess weight loss (EWL), and 19–36% more patients with greater than 50% EWL for those undergoing gastric bypass compared with vertical-banded gastroplasty. Comparison of adverse events was more difficult, as the data in these studies did not allow rigorous comparison of adverse events. Nevertheless, the data suggested that the mortality rate for both operations was low overall. Serious perioperative adverse events were also infrequently reported but were possibly somewhat higher for gastric bypass. Long-term AEs were inconsistently reported, although it appeared that revision rates were higher for VBG.

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, vertical-banded gastroplasty, or horizontal gastroplasty.⁵⁹ The percent of patients with greater than 50% excess weight loss (EWL) at 3 years' follow-up was 67% for gastric bypass, 48% for vertical-banded gastroplasty, and 17% for horizontal gastroplasty (p<0.001). There were no demonstrable differences in adverse events among groups.

A second, smaller randomized controlled trial (RCT) by Sugerman and colleagues randomized 40 patients to receive either a vertical-banded gastroplasty or a gastric bypass procedure.⁶⁰ 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.

Case Series

Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the U.S. An example of these results are a large case series with long-term follow-up by MacLean et al, who reported on 201 patients undergoing VBG who were followed up for a minimum of 2 years.⁶¹ 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.

Section Summary: Vertical-Banded Gastroplasty

A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG with gastric bypass. The assessment found that weight loss was significantly greater with open gastric bypass compared with VBG. In addition, VBG has relatively high rates of complications, revisions, and reoperations.

Two-Stage Bariatric Surgery Procedures

Bariatric surgeries that are 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 with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a sleeve gastrectomy, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a biliopancreatic diversion (e.g., BPD), is performed.

Randomized Controlled Trial

Coffin et al (2017) published results on the use of intragastric balloons prior to a LGBP on patients with super obesity.⁶² Patients with BMI greater than 45 kg/m² were randomized to an intragastric balloon (IGB, n=55) or standard medical care (n=60) during the 6 months prior to a planned LGBP procedure. Five patients had the IGB removed earlier than 6 months due to complications (n=3) or patient request (n=2). Patients receiving IGBs during the first 6 months of the study experienced significantly more BMI reduction compared with patients receiving standard care: IGB (2.8 kg/m²; range 1.7-6.2 kg/m²) vs. standard care (0.4 kg/m²; range 0.3-2.2 kg/m²). Weight loss during months 6 through 12, after the LGBP procedure, was greater in the patients who received standard of care prior to the procedure. Duration of hospitalization after LGBP and quality of life did not differ between the groups.

Case Series

A majority of 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. A minority of patients undergoing the first stage actually proceed to the second-stage surgery. Cottam et al (2006) reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first phase of a planned 2-stage procedure.⁶³ The incidence of major perioperative complications for laparoscopic SG was 13%. After one year, the mean EWL was 46%. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. The incidence of major complications following the second procedure was 8%.

In a similar study, Alexandrou et al (2012) reported on 41 patients who underwent SG as the first stage of a planned 2-stage procedure.⁶⁴ After 1-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 patients (44% of total) were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al (2009) described the complication rates in 87 patients undergoing a stage I SG followed by a BPD in 27 patients.⁶⁵ For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal

abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

Section Summary: Two-Stage Bariatric Surgery Procedures

The evidence from an RCT and several case series does not support that 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 possible that overall complications are increased by this approach.

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 specifics of the technique are not standardized.

Systematic Reviews

In 2014, Ji et al reported a systematic review of studies reporting outcomes after laparoscopic gastric plication (see Table 7).⁶⁶ The study included 14 publications, including 1 nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports. Talebpour et al (2012) conducted the largest study and had the longest follow-up at a single institution where the technique was developed.⁶⁷ The mean preoperative BMI ranged from 31.2 to 44.5 kg/m². The 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 (see Table 8). 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 of 53.7% vs. 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no mortality was reported and the rate of major postoperative complications requiring reoperation ranged from 0% to 15.4% (average, 3.7%), most commonly due to gastric obstruction or gastric preformation. Surgical techniques were not standardized.

In a systematic review, Abdelbaki et al (2012) summarized outcomes from seven studies of laparoscopic gastric plication, 2 of which included more than 100 patients enrolled, for a total of 307 patients (see Table 7).⁶⁸ Results are summarized in Table 8. All studies reported some incidence of nausea and vomiting, most of which was mild. Twenty patients (6.5 %) were readmitted, of whom 14 (4.6 %) patients required reoperation, most commonly for gastric obstruction (8/14 [57%]).

Table 7. Systematic Review Characteristics for Laparoscopic Gastric Plication

Study	Dates	Studies	Participants	Design	Duration
Ji et al (2014) ⁶⁶	Jun 2013	14	1450	• 1 matched cohort • 10 case series	6 mo. to 10 y

Abdelbaki et al (2012) ⁶⁸	NR	7	307	• 3 case reports • 5 case series • 2 case reports	3 y
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NR: not reported

Table 8. Systematic Review Results for Laparoscopic Gastric Plication

Study	% Excessive Weight Loss	Complication Rate (Range), %	Conclusions
Ji et al (2014) ⁶⁶	31.8-74.4%	3.7 (0-15.4)	Favorable short-term efficacy and safety profile; long-term follow-up and prospective trials needed.
Abdelbaki et al (2012) ⁶⁸	6 mo: 51-54 12 mo: 53-67	8 (7-15.3)	Prospective randomized trials vs. gastric plication with established bariatric procedures needed.

Randomized Controlled Trials

In 2017, Sullivan et al published results from the ESSENTIAL trial, a randomized sham-controlled trial evaluating the efficacy and safety of endoscopic gastric plication (see Table 9).⁶⁹ Patients (N=332) were randomized 2:1 to receive active or sham procedure. All patients were provided low-intensity life-style therapy. The primary end point was total body weight loss (TBWL) at 12-month follow-up. The mean difference in TBWL for patients receiving the procedure compared with patients receiving the sham procedure was 3.6% (95% CI, 2.1% to 5.1%). Significant differences between the active and sham groups were also reported in change in weight from baseline, percent excessive weight loss, BMI, and improvement in diabetes (see Table 10). No significant differences were detected in improvements in hyperlipidemia or hypertension between the treatment groups.

Talebpour et al (2017) randomized patients to laparoscopic gastric plication (n=35) or laparoscopic SG (n=35) (see Table 9).⁷⁰ Patients were followed for 2 years. Both procedures were equally effective based on weight reduction outcomes (see Table 10). Adverse events (e.g., nausea, hair loss, vitamin D deficiency, iron deficiency) were similar between groups. One death due to pulmonary thromboembolism occurred in the gastric plication group.

Table 9. RCT Characteristics for Laparoscopic Gastric Plication

Author	Countries	Sites	Dates	Participants	Active	Comparator
Sullivan et al (2017) ⁶⁹	U.S.	11	2013-2014	- Patients 22-60 y - BMI ≥ 30 kg/m² and ≥ 1 obesity-related comorbidity or BMI ≥ 35 kg/m² and with or without obesity-related comorbidity	Endoscopic gastric plication (n=221)	Sham procedure (n=111)
Talebpour et al (2017) ⁷⁰	Iran	1	2012-2015	Patients with BMI ≥ 35 kg/m ² and ≥ 1 obesity-related comorbidity or BMI ≥ 40 kg/m ² and with or without obesity-related comorbidity.	Laparoscopic gastric plication (n=35)	Laparoscopic sleeve gastrectomy (n=35)

BMI: body mass index

Table 10. RCT Results for Laparoscopic Gastric Plication

Study, Trial Name	BMI Reduction		Weight Loss ^a	
	Mean Change (SD) ^b	Difference (95% CI)	Mean (SD) ^b	Difference (95% CI)
Sullivan et al (2017) ⁶⁹ , ESSENTIAL Endoscopic gastric plication sham	1.7 0.5	1.2 (0.6 to 1.9)	4.9 (7.0) 1.4 (5.6)	3.6 (2.1 to 5.1)
	Mean (SD) ^c	p	Mean (SD) ^c	p
Talebpour et al (2017) ⁷⁰ Laparoscopic gastric plication	30.1 (2.8)	0.7	72.9 (12.6)	0.9
Laparoscopic sleeve gastrectomy	30.5 (4.3)		72.3 (11.9)	

BMI: body mass index

^a For Sullivan et al, percent total body weight loss at 12 months; for Talebpour et al, percent excess weight loss

^b At 12-month follow-up

^c At 24-month follow-up

Observational Study

In 2013, Pattanshetti et al published results of a study that described the evolution of a laparoscopic adjustable gastric banded plication procedure, a hybrid procedure involving both adjustable gastric banding and greater curvature plication that was developed by the authors.⁷¹ Eighty patients were included, with mean BMI 38.05 (± 4.73) kg/m². At 6, 12, 18, and 24 months, mean percent EWL was 42.6% ($\pm 13.7\%$), 56.4% ($\pm 19.9\%$), 57.6% ($\pm 19.9\%$), and 65.8% ($\pm 17.3\%$), respectively. Five postoperative complications developed that required reoperation.

Section Summary: Laparoscopic Gastric Plication

There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication to other bariatric surgery procedures. A 2014 systematic review identified only 1 small comparative study, which was not randomized. Since the systematic review, 2 RCTs were published. One RCT compared endoscopic gastric plication with a sham procedure, reporting 1-year follow-up results in favor of the intervention. A second RCT compared laparoscopic gastric plication with sleeve gastrectomy, showing that the 2 procedures had similar outcomes after 2 years of follow-up. Longer term follow-up and additional comparative studies are needed.

Single Anastomosis Duodenoileal Bypass with Sleeve Gastrectomy (SADI-S)

No controlled trials of SADI-S were identified. Some case series have been published that report on weight loss and other clinical outcomes up to 5 years post surgery. One of the larger series was published in 2015 by Sanchez-Pernaute et al and reported on 97 patients with obesity and type 2 DM.⁷² The authors reported that control of DM, defined as HgA_{1c} <6.0%, was achieved in between 70% and 84% of patients at the 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 DM.

Observational Comparative Study

Torres et al (2017) published a retrospective chart review of patients from their center receiving bariatric procedures, evaluating outcomes at 3-year follow-up.⁷³ Outcomes were evaluated separately for patients with and without diabetes. For patients without diabetes, comparisons were made among patients who underwent RYGB (n=149) or SADI-S (n=106). For patients with diabetes, comparisons were made among patients who underwent RYGB (n=97), biliopancreatic diversion/duodenal switch (BPD/DS) (n=77), or SADI-S (n=97). Among the patients without diabetes, significant differences favoring SADI-S over RYGB were found in: percent excess weight loss; systolic blood pressure; total, HDL and LDL cholesterol; and insulin. Significant differences were not found in diastolic blood pressure or fasting glucose. Among the patients with type 2 diabetes, remission rates according to American Diabetic Association criteria were: 55%, 70%, and 76% for patients receiving RYGB, BPD/DS, and SADI-S, respectively. Patients with diabetes who underwent BPD/DS or SADI-S experienced significantly lower total cholesterol and triglyceride levels compared with those undergoing RYGB after 3 years of follow-up.

Section Summary: Single Anastomosis Duodenoileal Bypass With SG

No published controlled trials have evaluated SADI-S. There are a few case series, the largest of which had fewer than 100 patients. A comparative chart review found that patients without diabetes experienced significantly better weight loss and lipid profiles when receiving SADI-S compared with RYGB and patients with diabetes experienced significantly higher rates of remission when receiving SADI-S compared with RYGB.

Stomach Intestine Pylorus Sparing Surgery (SIPS)

Neichoy et al (2018) performed a retrospective analysis on data from 225 patients who underwent a primary SIPS procedure by 2 surgeons at a single center. Two hundred twenty-five patients were identified for analysis. The mean preoperative body mass index (BMI) was 52.4 ± 9.1 kg/m². Forty-eight patients were beyond 2 years after surgery, with data available for 30 patients (62.5% follow-up). Three patients were lost to follow-up. At 2 years, the patients had an average change in BMI of 26.6 U (kg/m²) with an average of 88.7% of excess weight loss. Three deaths were related to the surgery. The most common short-term complication was a leak (2.2%), whereas the most common long-term complication was diarrhea (2.2%).

Mitzman et al (2016) also collected data from patients who underwent the SIPS procedure for analysis. Regression analyses were performed for all follow-up weight loss data. One hundred twenty-three patients were available. One hundred two patients were beyond 1 year postoperative, with data available for 64 (62% followed up). The mean body mass index (BMI) was 49.4 kg/m². Two patients had diarrhea (1.6 %), four had abdominal hematoma (3.2 %), and one had a stricture (0.8 %) in the gastric sleeve. Two patients (1.6 %) were readmitted within 30 days. One patient (0.8 %) was reoperated due to an early postoperative ulcer. At 1 year, patients had an average change in BMI of 19 units (kg/m²), which was compared to an average of 38 % of total weight loss or 72 % of excess weight loss. The authors concluded that the SIPS procedure had effective weight loss results.

Section Summary: Stomach Intestinal Pylorus Sparing Surgery (SIPS)

No published controlled trials have evaluated the SIPS procedure. Two retrospective analyses showed effective weight loss results. Morbidity appears to be comparable to other stapling reconstructive procedures; however, future analyses are required to determine if the SIPS procedure reduces the risk of future small bowel obstructions or micronutrient deficiencies.

Duodenojejunal Sleeve

The EndoBarrier (GI Dynamics, Lexington, MA) 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 2016.⁷⁴ 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%) than medical therapy. For diabetes control outcomes, trends toward greater improvement in the EndoBarrier group were not statistically significant. Mean difference in HgbA_{1c} 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 and type 2 DM.⁷⁵ 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. Thirty-eight patients were randomized to the EndoBarrier® group and 31 (82%) of 38 completed 12 months of treatment. Thirty-nine patients were randomized to medical treatment and 35 (90%) of 39 completed 12 months of treatment. At 6 months, the decrease in BMI was significantly greater in the EndoBarrier® group compared to medical therapy (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). The HgbA_{1c} 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 was not significantly different (7.3% vs. 8.0%, p=0.95).

Section Summary: Duodenojejunal Sleeve

A systematic review of evidence on a duodenojejunal sleeve included 5 RCTs and found significantly greater short-term weight loss (12-24 weeks) with duodenojejunal sleeves compared with medical therapy. There was no significant difference in symptom reduction associated with diabetes. All RCTs had small sample sizes and were judged by the systematic reviewers to be at high risk of bias.

Intragastric Balloon Devices

Intragastric balloons are placed in the stomach via endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2017, 3 gastric balloon devices have FDA approval; All are designed to stay in the stomach for no more than 6 months. The ReShape Duo is a salineinflated dual-balloon system, Obalon is a swallowable 3-balloon system, and the OBERA Intragastric Balloon System (previously marketed outside of the United States as BioEnterics) is a saline-inflated silicone balloon.

Systematic Reviews

Several systematic reviews of RCTs evaluating IGB devices for the treatment of obesity have been published; none was limited to FDA-approved devices.⁷⁶⁻⁷⁸

A systematic review by Tate et al (2017) focused on recent RCTs, published between 2006 and 2016.⁷⁹ Additional inclusion criteria were: sham, lifestyle modification, or pharmacologic

agent as comparator; at least 1 outcome of body weight change; and study duration of 3 or more months. Eight RCTs were included in the review, with four of the RCTs contributing to the meta-analysis. The meta-analysis included 777 patients and showed a significant improvement in % TBWL with IGB compared with control, 5.5% (95% CI, 4.3% to 6.8%). However, there was significant heterogeneity among the trials ($I^2=62\%$), so interpretation of results is limited. The % TBWL with IGB is lower than expected with RYGB (reported 27%) or with the most efficacious pharmacologic agent (reported 9%).

In 2017, Saber et al identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention.⁷⁶ IGB was compared with sham in 15 trials, behavioral modification in 4 trials, and pharmacotherapy in 1 trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between 3 and 6 months. In a meta-analysis of 7 RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group compared with the control group (mean effect size [ES], 1.59 kg/m²; 95% CI, -0.84 to 4.03 kg/m²; $p<0.001$). Findings on other outcomes were similar. A metaanalysis of 4 studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%; $p=0.02$). In addition, a meta-analysis of 6 studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg; $p=0.003$).

Although the review was not limited to FDA-approved devices, older devices were air-filled and newer devices, including the 2 approved by FDA in 2015, are fluid-filled. Sufficient data were available to conduct a sensitivity analysis of 3 month efficacy data. A meta-analysis of 4 studies did not find a significant difference in weight loss with air-filled IGB devices or a control intervention at 3 months (ES=0.26; 95% CI, -0.12 to 0.64; $p=0.19$). In contrast, a meta-analysis of 8 studies of fluid-filled devices found significantly better outcomes with the IGB than with control (ES=0.25; 95% CI, 0.05 to 0.45; $p=0.02$).

Randomized Controlled Trials

Pivotal trials on both FDA-approved devices have been published. In 2015, Ponce et al published a multicenter sham-controlled double-blinded trial evaluating the ReShape Duo intragastric balloon.⁸⁰ A total of 326 patients were randomized to 6 months of treatment with an IGB plus lifestyle therapy ($n=187$) or a sham device plus lifestyle therapy ($n=126$). Patients in the control group were given the option of active IGB treatment at 6 months. Key eligibility criteria were age 21 to 60 years, baseline BMI between 30 and 40 kg/m², 1 or more obesity-related comorbidities, and failure to lose sufficient weight in the past 36 months in a medically supervised weight loss program. A total of 176 IGB and 126 control patients (90% of the randomized population) completed the initial 6 month treatment and were included in the primary end point analysis. After 6 months, 77 patients in the control group opted to receive an IGB; these patients were also included in the IGB safety analysis.

Coprimary effectiveness outcomes, assessed at 6 months, were mean percent EWL and having at least 35% of patients in the IGB group achieving at least a 25% EWL. Both primary effectiveness outcomes were met. In the intention-to-treat (ITT) analysis, the mean percent EWL at 6 months was 25.1 in the IGB group and 11.3 in the control group ($p=0.004$). The proportion of patients who achieved at least a 25% EWL was 48.8%, with a lower confidence bound of 41.6%. Most adverse events were anticipated accommodative symptoms (e.g., nausea, vomiting, abdominal pain), which generally resolved after 3 to 7 days; they were

severe in 1% to 2% of patients and were successfully treated. Most device-related serious adverse events (75% [21/28]) were emergency department visits for treatment of accommodative symptoms. There were no deaths, intestinal obstructions, gastric perforations, or device migrations.

In 2017, Courcoulas et al published a multicenter, pivotal RCT evaluating the Obera IGB in the United States (as noted, the device has been used in other countries).⁸¹ A total of 317 patients were randomized and initiated 6 months of treatment with an IGB plus lifestyle therapy (n=137) or lifestyle therapy only (n=136). Patients were followed for an additional 6 months. Key eligibility criteria were age 18 to 65 years, baseline BMI between 30 and 40 kg/m², a history of obesity for at least 2 years, and having failed previous weight loss attempts. Nineteen patients in the IGB group and 121 in the control group completed the 6-month treatment period.

Coprimary effectiveness outcomes, assessed at 9 months, were mean percent EWL and difference in mean weight loss. Mean percent EWL at 9 months was 26.4% in the IGB group and 10.1% in the control group (difference, 16.2%; 95% CI, 12.3% to 20.2%; p<0.001). Mean weight loss at 9 months was -8.8 kg (-19.4 lb) in the IGB group and -3.2 kg (-7.1 lb) in the control group (p<0.001). There were also significant between-group differences in mean weight loss and mean percent EWL at 6 and 12 months.

As in the trial on the Reshape Duo device, most adverse events in the Obera pivotal trial were anticipated accommodative symptoms. A total of 139 (87%) patients reported nausea, 121 (76%) reported vomiting, and 92 (58%) reported abdominal pain. Fewer than 5% of these adverse events were serious; most were mild or moderate. Thirty patients in the device group had the IGB removed before month 6 because of an adverse event (n=15) or patient request (n=15). There were no deaths and 9 serious adverse events unrelated to device accommodation; among others, they included 1 case of gastric outlet obstruction and 1 case of gastric perforation with sepsis.

The Courcoulas et al pivotal trial was not blinded or sham-controlled; however, a double-blind sham controlled RCT evaluating the BioEnterics gastric balloon (previous called the Obera device) was published by Genco et al in 2006.⁸² This crossover trial included 32 obese patients ages 25 to 50 years with a mean BMI of 47.3 kg/m². Patients received, in random order, 3 months of an IGB and 3 months of sham. (Both groups underwent upper gastrointestinal endoscopy, but no device was placed in the sham group.) Patients who initially received the IGB had a mean BMI reduction of 5.8 kg/m² after 3 months; after crossover to sham, they had a mean additional BMI reduction of 1.1 kg/m². Patients initially in the sham group had an initial mean BMI reduction of 0.4 kg/m²; after crossover to an active device, they had a mean BMI reduction of 5.1 kg/m². The between-group difference in BMI reductions was statistically significant (p<0.001). Findings on other outcomes (mean percent EWL, mean weight loss) were similar.

Case Series

A case series of patients treated with an IGB with up to 60-month follow-up was published by Kotzampassi et al in 2012.⁸³ A total of 500 patients were treated with the BioEnterics IGB. Twenty-six patients did not complete the initial 6 months of treatment and another 77 patients did not comply with dietary restrictions and did not have satisfactory weight loss at 6 months. Among 352 patients with data available, BMI was 44.5 kg/m² at baseline, 35.7 kg/m² at device removal, 38.8 kg/m² 12 months after device removal, and 40.1 kg/m² 24 months after device

removal. Mean percent EWL was 43.9% at device removal, 27.7% 12 months after device removal, and 17% 24 months after device removal. Among the 195 patients with available 5-year data, mean baseline BMI was 43.3 kg/m², mean BMI at device removal was 33.8 kg/m², and mean BMI at 5 years was 40.1 kg/m². Mean percent EWL at 5 years was 13.0%. Overall, patients who initially complied with 6 months of IGB device use and lost weight, slowly gained weight over time but weighed less at final follow-up than at baseline.

Section Summary: Intra-gastric Balloon Devices

Evidence includes RCTs, a case series with long-term follow-up on 1 of these devices, and systematic reviews on various IGB devices. RCTs have found significantly better weight loss outcomes with IGB devices compared with sham treatment or lifestyle therapy alone. There are some adverse events, and in a minority of cases, these adverse events can be severe. The FDA wrote 2 letters in 2017 to health care providers, one warning of spontaneous balloon inflation and pancreatitis and the other reporting 5 unanticipated deaths occurring in 2016-2017 following the IGB procedure. Health care providers are encouraged to monitor patients receiving IGBs.

Aspiration Therapy Device

Aspiration therapy involves an FDA-approved device (AspireAssist) that allows patients to drain a portion of the stomach contents after meals via an implanted tube connected to an external skin port. One RCT has been published. The trial, by Thompson et al (2016), randomized 207 participants to 52 weeks of AspireAssist therapy plus lifestyle counseling (n=127) or lifestyle counseling alone (n=70).⁸⁰ Participants were between 21 and 65 years of age, with a BMI ranging from 35 to 55 kg/m². Coprimary outcomes were mean EWL at 52 weeks and the proportion of patients with 25% or more EWL at 52 weeks. Investigators did a modified ITT analysis including all patients in the AspireAssist group who attempted tube placement (n=111) and all patients in the lifestyle counseling group who attended at least 1 therapy session (n=60). Mean EWL at 52 weeks was 31.5% in the AspireAssist group and 9.8% in the lifestyle counseling group. The difference between groups was 21.7% (95% CI, 15.3% to 28.1%), which was greater than the 10% difference needed to meet the a priori definition of success. The proportion of patients with 25% or more EWL at 52 weeks was 58.6% in the AspireAssist group and 22% in the lifestyle counseling group (p<0.001). Bulimia or binge eating disorder were exclusion criteria and, during the study, there was no evidence that patients developed bulimia or that devices were overused (i.e., used >3 times a day). Most of the adverse events (~90%) in the AspireAssist group were associated with placement of a percutaneous endoscopic gastric tube. All 5 serious adverse events occurred in the AspireAssist group (mild peritonitis, severe abdominal pain and 1 case of product malfunction). Durability of a treatment effect beyond 1 year was not reported.

In addition to the RCT, a 2016 case series by Noren and Forssell evaluated AspireAssist use by 25 obese patients.⁸⁵ Patients had 1 year of aspiration therapy and also participated in a cognitive-behavioral therapy weight loss program for the initial 3 months. Patients were instructed to aspirate 3 times a day after meals. Twenty (80%) patients completed the 1-year intervention period. Mean baseline weight was 107.4 kg. In a per protocol analysis, the mean EWL was 54.5% at 12 months. Data on 15 (60%) patients were available at 24 months; mean EWL was 61.5%.

Section Summary: Aspiration Therapy Device

The evidence consists of 1 RCT with 1-year follow-up and a small case series with up to 2 years of follow-up. The RCT found significantly greater weight loss (measured several ways) with aspiration therapy compared with lifestyle therapy at 1 year. The case series followed only 15 patients more than 1 year; at 2 years, study completers had not regained weight and instead had lost additional excess weight. The total amount of data on aspiration therapy remains limited and additional studies need to be conducted before conclusions can be drawn about the long-term effects of treatment on weight loss, metabolism, and nutrition.

REVISION BARIATRIC SURGERY

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities 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.⁸⁶ The Bariatric Outcomes Longitudinal Database is a large multi-institutional bariatric surgery-specific database to which data was submitted from June 2007 through March 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric surgery. Reoperations were further divided into corrective operations (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) There were a total of 449,473 bariatric operations in the database of which 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3 %) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective operations and 8750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N=204,705, 49.1%), AGB (N=153,142, 36.5%), SG (N=42,178, 10%), and BPD±DS (N=4,260, 1%), with the rest classified as miscellaneous. AGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to Roux-en-Y gastric bypass). Compared with primary operations, mean length of stay was longer for corrections (2.04±6.44 vs. 1.8±4.9, p<0.001) and for conversions (2.86±4.58 vs. 1.8±4.9, p<0.001). The mean percent EBWL at 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 compared with primary operations (0.31% vs. 0.17%, p<0.001), but not for corrections compared with primary operations (0.24% vs. 0.17%, p=NS). One-year serious adverse event (SAE) rates were higher for conversions compared with primary operations (3.61% vs. 1.87%, p<0.001), but not for corrections compared with primary operations (1.9% vs. 1.87%, p=NS). The authors conclude that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

As part of the American Society for Metabolic and Bariatric Surgery Revision Task Force, Brethauer et al (2014) conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews.⁸⁷ The review is primarily descriptive, but the authors make the following conclusions:

“The current evidence regarding reoperative bariatric surgery includes a diverse group of patient populations and procedures. The majority of the studies are single institution case series reporting short- and medium-term outcomes after reoperative procedures. The reported outcomes after

reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.”

Endoscopic Revision Procedures

While bariatric surgery revision/correction can be conducted using standard operative approaches, novel endoscopic procedures are being publicized as an option for these patients. Some of these procedures use devices that are also being evaluated for endoscopic treatment of GERD. The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate).⁸⁸ 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.⁸⁹ 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.⁹⁰ 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, Eid et al reported results from a single-center RCT of the StomaphX device compared with a sham procedure for revision procedures in patients with prior weight loss after RYGBP at least 2 years earlier.⁹¹ 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 after 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-Roux-en-Y gastric bypass excess weight by $\geq 15\%$, excess BMI loss, and BMI < 35 , at 12 months post procedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1 of 29 (3.4%) of the sham control group ($p < 0.01$).

A survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons indicates different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures.⁹² 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.”⁹³

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.

BARIATRIC SURGERY AS A TREATMENT FOR TYPE 2 DIABETES (T2DM)

Current indications for bariatric surgery view poorly or uncontrolled diabetes mellitus as a comorbidity whose presence supports the medical necessity of surgery for patients with BMI of 35 to 40 kg/m². There also is growing interest in gastrointestinal surgery to treat patients with type 2 diabetes in patients with lower BMI. This section will focus on RCTs and systematic reviews of RCTs of bariatric surgery versus medical therapy.

T2D and BMI 30 to 34.9 kg/m²

In 2016, Wu et al published a meta-analysis of studies comparing bariatric surgery and nonsurgical interventions for patients with T2D.⁹⁴ Eight RCTs with 619 patients were included. RCTs addressed RYGBP (6 studies), LAGB (3 studies), LSG (1 study), and BPD (1 study). Mean BMI across studies was 29 kg/m² or higher; in 6 of 8 studies, mean BMI was 35 kg/m² or higher. One study had 5-year follow-up and the others had 1 to 3 years of follow-up. The study with 5-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m².⁹⁵ All 8 studies reported remission of T2D as an efficacy end point. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR=5.76; 95% CI, 3.15 to 10.55; p<0.001). Another diabetes-related outcome (mean reduction in HgbA_{1c} levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD = -1.29; 95% CI, -1.70 to -0.87). In addition, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD = -5.80; 95% CI, -6.95 to -4.64; p<0.001).

Since publication of the Wu meta-analysis, 5-year follow-up has been reported for the Schauer et al RCT, which is shown in Table 11. When the Wu et al meta-analysis was published, only 3 year findings of the Schauer study were available. The study included patients with T2D who had BMI 27-43 kg/m². The RCTs evaluating bariatric surgery in patients with T2D, including the 5-year follow-up of the Schauer study, are summarized in Table 11.

Observational studies evaluating patients undergoing bariatric surgery in patients with T2D with follow-up to 3 or more years are shown in Table 12.

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m².⁹⁶ Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified. Follow-up was between 1 and 3 years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR=14.1; 95% CI, 6.7 to 29.9; p<0.001). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD = -5.5 kg/m²; 95% CI, -6.7 to -4.3 kg/m², p<0.001), a lower HgbA_{1c} level (MD = -1.4%; 95% CI, -1.9% to -0.9%; p<0.001), lower rates of hypertension (OR=0.25; 95% CI, 0.12 to 0.50; p<0.001), and lower rates of dyslipidemia (OR=0.21; 95% CI, 0.10 to 0.44; p<0.001).

Also in 2015, Rao et al published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m² or less who underwent RYGBP.⁹⁷ 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 HgbA_{1c} levels (WMD = -2.76; 95% CI, -3.41 to -2.11; p<0.000). Reviewers reported that longer term follow-up would be needed.

Previously, a 2012 TEC Assessment evaluated bariatric surgery in diabetic patients with a BMI less than 35 kg/m².⁹⁸ The evidence consisted mainly of case series. The Assessment identified only observational studies. Based on the data, the assessment concluded that gastric bypass met TEC criteria as a treatment for diabetes in patients with a BMI less than 35 kg/m² but that other procedures did not meet the TEC criteria for this indication:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with a BMI less than 35 kg/m². There was only 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 study was a randomized clinical trial of gastric bypass versus SG; in it, diabetes remission associated with gastric bypass was 93% versus 47% for SG at 1 year.
- Two studies reported outcomes of SG. Diabetes remission rates were 55% and 47% at 1 year.
- One study reported outcomes of ileal interposition. The diabetes remission rate at a mean follow-up time of 39.1 months was 78.3%.
- Two studies reported outcomes of gastric banding. The outcomes reported were not considered to be rigorous, because the only measure of diabetes outcome was withdrawal of diabetes medication. Reported remission rates were 27.5% and 50% at variable follow-up times.
- One study of BPD reported a remission rate of 67% for subjects with a BMI between 30 and 35 kg/m² and 27% for subjects with a BMI between 25 and 30 kg/m² at 12-month follow-up.
- One study reported outcomes of duodenojejunal exclusion. Subjects in this study had more severe diabetes than subjects enrolled in other studies; 100% were on insulin treatment and the duration of diabetes was between 5 and 15 years. The diabetes remission rate was 17% at 6 months.

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

Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/m². The greatest amount of evidence assesses gastric bypass, with some comparative studies on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HgbA_{1c} levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have 1 to 3 years of follow-up; 1 RCT, which included patients with BMI between 30 and 34.9 kg/m², had 5-year follow-up data.

Table 11. RCTs^a Comparing Bariatric Surgery in Patients With T2D to Control

Study (Country)	N	BMI Range, kg/m ²	Patient s w/BMI ≤35 kg/m ²	Length of FU, years	Definition Diabetes Remission	Diabetes Remission Rate			
						Surgery (LAGB)	Control (ILI/A1c-R)	P	
Dixon et al (2008) ⁸⁹ (US)	60	30-40	22%	2	% achieving FBS <126mg/dl HgbA _{1c} <6.2% (off meds)	22/30 (93%)	4/30 (13%)	<0.001	
Ikramuddin et al (2015) ⁹⁰ (US)	120	30-40	59%	2	% achieving all 3 ADA goals: -HgbA _{1c} <7.0% -LDL<2.59 mmol/L -SBP<130 mm Hg	Surgery (RYGB)	Control (HILI/A1c-R)	<0.001	
						26/60 (43%)	8/59 (14%)	<0.001	
Liang et al (2013) ⁹¹ (China)	108	>28 ^g		1	T2D remission ^b	Surgery (RYGB)	Control 1 (GCP/A1c-R)	Control 2 (GCP/A1c-S)	<0.05
						28/31 (90%)	0%	0%	
Courcoulas et al (2015) ⁹² (US)	61	30-40	43%	3	Partial: HgbA _{1c} <6.5% Full: HgbA _{1c} <5.7% (off meds)	Surgery (RYGB)	Surgery (LAGB)	Control (HILI/A1c-S)	0.004
						8/20 (40%) Full: 3/20 (15%)	6/21 (29%) Full: 1/21 (5%)	0%	
Schauer et al (2017) ⁹³ (US)	150	27-43	37%	5 ^h	% HgbA _{1c} <6.0% (± meds)	Surgery (RYGB)	Surgery (LSG)	Control (ILI/A1c-S)	0.01 ^c / 0.03 ^d
						14/49 (29%)	11/49 (23%)	2/28 (5%)	
						Completers			
						Surgery (RYGB)	Surgery (LSG)	Control (ILI/A1c-S)	0.08 ^e / 0.17 ^f
						26.4%	20.4	7.3%	
						Intention-to-Treat			
Mingrone et al (2015) ⁸⁵ (Italy)	60	35+	0%	5	% HgbA _{1c} ≤6.5% (% meds x 1 y)	Surgery (RYGB)	Surgery (BPD)	Control (GCP/A1c-S)	<0.001
						8/19 (42%)	13/19 (68%)	0%	
						Surgery (LAGB)	Control (ILI/A1c-R)		
Wentworth et al (2014) ⁹⁴ (Australia)	51	25-30	100%	2	<125mg/dl or 200mg/dl 2-h OGTT (off meds x 2 d)	12/23 (52%)	2/25 (8%)	0.001	
						Surgery (RYGB)	Control (HILI/A1c-S)		

Halperin et al (2014) ⁹⁵ (US)	43	30-42	30%	1	% HgbA _{1c} <6.5%	11/19 (58%)	3/19 (16%)	0.03
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ADA: American Diabetes Association; A1c-R: HgbA_{1c} reasonable goal of <7%; A1c-S: HgbA_{1c} stringent goal of <6.5%; BMI: body mass index; BPD: biliopancreatic diversion; FBS: fasting blood sugar; FU: follow-up; GCP: good clinical practice; HgbA_{1c}: hemoglobin A_{1c}; HILI: highly intensive lifestyle intervention; ILI: intensive lifestyle intervention; LAGB: laparoscopic adjustable gastric banding; LDL: low-density lipoprotein; LSG: laparoscopic sleeve gastrectomy; OGTT: oral glucose tolerance test; RCT: randomized controlled trials; RYGB: roux-en Y gastric bypass; SBP: systolic blood pressure; T2D: type 2 diabetes.

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

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

^c Unadjusted (RYGB vs. control).

^d Unadjusted (LSG vs. control).

^e RYGB vs. control.

^f LSG vs. control.

^g WHO Asia-Pacific Obesity Classification.

^h Through February 2017.

Table 12: Observational Studies on Bariatric Surgery in Patients with T2D with Follow-up ≥3 years

Study (Country)	N	BMI Range, kg/m ²	Pts with BMI ≤35 kg/m ²	Length of FU	Interv	Mean HgA _{1c}		Mean BMI, kg/m ²		Diabetes Remission Rate
						Base	FU	Base	FU	
Group I										
Scopinaro et al (2014) ⁹⁶ (Italy)	20*; 27**	30-34.9	100%	3 year	RYGB	9.5%	7.0% ^a	32.9	26.0 ^a	5/20 (25%)
					Control	9.3%	7.7% ^a	33.0	32.6	
Lanzarini et al (2013) ⁹⁷ (Chile)	31	30-35	100%	30 mo ^c	RYGB	7.9%	5.5% ^a	33.1	24.7 ^a	29/31 (94%)
Boza et al (2011) ⁹⁸ (Chile)	30	<35	100%	2 years	RYGB	8.1%	≈6.2% ^{a,b}	33.5	23.9 ^a	12 mo: 25/30 (83.3%) 2 y: 13/20 (65%)
DePaula et al (2012) ⁹⁹ (Brazil)	202	<35	100%	39 mo ^c	SG	8.7%	6.1% ^a	29.7	23.5 ^a	171/198 (86.4%)
Group II										
Lee et al (2008) ¹⁰⁰ (Taiwan)	544	32-77	NR	3 years	Bypass	6.2%	4.8%	41.3	28.0	NR
	116		NR		LAGB	5.9%	5.2%	41.9	32.7	

Group I is defined as poor control optimal medical management (may include insulin). Group II is defined as adequate control with medication (may include insulin).

Base: baseline; BMI: body mass index; Bypass: mini-gastric bypass; FU: follow-up; HgbA_{1c}: hemoglobin A_{1c}; Interv: intervention; LAGB: laparoscopic adjustable gastric banding; RYGB: Roux-en-Y gastric bypass; SG: sleeve gastrectomy.

^{*}Treated

^{**}Matched diabetic controls

^a p<0.05 (follow-up vs. baseline)

^b Estimated from figure

^c Mean

BARIATRIC SURGERY IN NONDIABETIC PATIENTS WITH A BMI LESS THAN 35 KG/M²

A 2012 TEC Assessment evaluated laparoscopic gastric banding in individuals without diabetes who had a BMI less than 35 kg/m².¹¹¹ 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.

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

There is limited evidence for bariatric surgery in patients who are not diabetic or morbidly obese. A few small RCTs and case series have reported loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population.

BARIATRIC SURGERY IN MORBIDLY OBESE ADOLESCENT CHILDREN

Multiple Bariatric Surgery Techniques

Systematic Reviews

In 2017, Qi et al published a systematic review and meta-analysis on the effects of bariatric surgery for the treatment of adolescents with obesity (see Table 13).¹¹² In a literature search conducted through July 2017, 49 studies were identified for inclusion. Study quality was assessed using the Newcastle-Ottawa Scale. Age of patients ranged from 14 to 20 years. BMI ranged from 34 to 63 kg/m². Overall results showed significant improvements in BMI, and glycemic and lipid control with bariatric surgery (see Table 14). RYGP showed the largest improvements compared with other procedures.

In a 2013 systematic review of 23 studies, Black et al concluded that the available literature demonstrates a high rate of significant short-term weight loss after bariatric surgery (see Table 13).¹¹³ Quality assessment of the included studies was not discussed. Ages of patients at time of surgery ranged from 5 to 23 years. A meta-analysis showed significant reductions in BMI (Table 14). Meta-analysis were not conducted on resolution of comorbidities due to heterogeneity in reporting. However, the majority of cases of hypertension, sleep apnea, type 2 diabetes, and dyslipidemia were reported to have resolved at 1 year follow-up. The authors note that complication and comorbidity rates were not well-defined.

Treadwell et al (2008) conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents (see Table 13).¹¹⁴ Their analysis included English language articles on currently performed procedures when data were separated by procedure and there was a minimum 1-year follow-up for weight and BMI. Studies must have reported outcome data for 3 or more patients aged 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on from 11 to 68 patients who were 21 years or younger. Eight studies of LAGB (mean BMI 45.8, median age range, 15.6–20 years); 6 studies on RYGB (mean BMI 51.8, median age range 16–17.6 years); 5 studies of other procedures (mean BMI 48.8, median age range 15.7–21 years) were included.

Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB (see Table 14). Comorbidity resolution was sparsely reported, but surgery appeared to resolve some medical conditions including diabetes and hypertension; 2 studies of LAGB showed large rates of diabetes resolution but low patient enrollment, and only 1 study of RYGB reporting relevant data. No in-hospital or postoperative death was reported in any LAGB study. The most frequently reported complications for LAGB were band slippage and micronutrient deficiency with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. More severe complications were reported for RYGB such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. No in-hospital death was reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 more died of causes that were not likely to have been directly related to the bariatric surgeries. No LAGB studies reported data on the impact of surgery on growth and development. One study of RYGB reported pre- and postoperative heights and concluded that there was no evidence of growth retardation at an average follow-up of 6 years, but it could not be determined from the data whether expected growth was achieved.

Table 13. Systematic Review Characteristics for Bariatric Surgery for Adolescents with Obesity

Study (Year)	Dates	Studies	Participants	Design	Duration
Qi et al (2017) ¹¹²	Jul 2017	49	• RYGP: 1216 • LABG: 1028 • LSG: 665 • Other: 98	• 1 RCT • 22 prospective • 26 retrospective	12-120 mo
Black et al (2013) ¹¹³	Jan 2013	23	• RYGP: 256 • LABG: 271 • LSG: 90 • Other: 20	• 1 controlled • 22 uncontrolled	6-120 mo
Treadwell et al (2008) ¹¹⁴	Dec 2007	18	• RYGB: 131 • LABG: 352 • Other: 158	• 1 prospective • 17 retrospective	NR

LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass

Table 14. Systematic Review Results for Bariatric Surgery for Adolescents with Obesity

Study (Year)	BMI Reduction Mean Difference (95% CI)	Fasting Blood Insulin, mIU/L Mean Difference (95% CI)	Total Cholesterol, mg/dL Mean Difference (95% CI)
Qi et al (2017) ¹¹²			
RYGP	18.5 (16.4 to 20.7)	24.8 (10.0 to 30.7)	29.4 (18.1 to 40.7)
LAGB	12.1 (11.0 to 13.3)	20.5 (16.4 to 24.6)	2.2 (-10.0 to 14.4)
LSG	16.0 (13.2 to 20.7)	18.4 (11.4 to 25.3)	13.6 (2.9 to 24.2)
Other	23.2 (15.6 to 30.7)	28.3 (5.7 to 50.9)	49.5 (29.9 to 69.2)
Black et al (2013) ¹¹³			
RYGP	17.2 (14.3 to 20.1)	NR	NR
LAGB	10.5 (9.1 to 11.8)	NR	NR
LSG	14.5 (11.7 to 17.3)	NR	NR
Other	NR	NR	NR
Treadwell et al (2008) ¹¹⁴			
RYGP	(17.8 to 22.3) ^a	NR	NR
LAGB	(10.6 to 13.7) ^a		

BMI: body mass index; CI: confidence interval; LAGB: laparoscopic adjustable gastric banding; LSG: laparoscopic sleeve gastrectomy; NR: not reported; RYGP: Roux-en-Y gastric bypass

^a No point estimate provided, only 95% CIs given

Observational Study

One of the larger observational studies included in the systematic reviews was by Inge et al reporting results from the Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study, a prospective, multicenter observational study of bariatric surgery in patients aged 19 or younger.¹¹⁵ The study enrolled 242 participants, with mean age 17.1 and median BMI 50.5 (IQR, 45.2-58.2) at the time of operation. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by sleep apnea (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). RYGBP, adjustable gastric banding, and vertical SG were performed in 66.5%, 5.8%, and 27.7%, respectively. Within 30 days of surgery, 20 major complications occurred in 19 patients (7.9%), most of which were perioperative complications. The cohort will be followed to assess longer-term outcomes.

Laparoscopic Adjustable Gastric Banding

Systematic Review

Willcox et al (2014) conducted a systematic review focusing on studies reporting biopsychosocial outcomes following LAGB in adolescents with obesity.¹¹⁷ The literature search, conducted through May 2013, identified 11 studies for inclusion. Significant weight loss was reported in all of the studies. Resolution of comorbidities was also reported, though the evidence was poor quality due to limited discussion of comorbidity assessment criteria. Reporting of psychosocial outcomes was considered limited, with the authors concluding that further research is needed to better understand the behavioral, emotional, and social factors experienced by adolescents undergoing LAGB.

Randomized Controlled Trial

One RCT of LAGB has been published. O'Brien et al (2010) reported on a prospective, randomized trial from Australia of 50 adolescents between the ages of 14 and 18 years with BMI greater than 35 who received either a lifestyle intervention or gastric banding and were

followed up for 2 years.² Twenty-four of 25 patients in the gastric-banding group and 18 of 25 in the lifestyle group completed the study. Twenty-one (84%) in the gastric banding group and 3 (12%) in the lifestyle group lost more than 50% of excess weight. Overall, the mean changes in the gastric-banding group were a weight loss of 34.6 kg (95% confidence interval [CI]: 30.2-39.0), representing an excess weight loss of 78.8% (95% CI: 66.6-91.0%). The mean losses in the lifestyle group were 3.0 kg (95% CI: 2.1-8.1), representing EWL of 13.2% (95% CI: 2.6%-21.0). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 operations (33%) were required in 7 patients for revisional procedures either for proximal pouch dilatation or tubing injury during follow-up.

Case Series

There are many case series of bariatric surgery in adolescents, and these generally report weight loss that is in the same range seen for adult patients. For example, Nadler et al (2008) reported on 73 patients aged 13 to 17 years who have undergone LAGB since 2001 at the authors' institution.¹¹⁸ Mean preoperative BMI was 48. The EWL at 6 months, 1 year, and 2 years postoperatively was 35% $\pm$ 16%, 57% $\pm$ 23%, and 61% $\pm$ 27%, respectively. Six patients developed band slippage, and 3 developed symptomatic hiatal hernias. Nutritional complications included asymptomatic iron deficiency in 13 patients, asymptomatic vitamin D deficiency in 4 patients, and mild subjective hair loss in 14. In the 21 patients who entered the authors' FDA-approved study and had reached 1-year follow-up, 51 comorbid conditions were identified, 35 of which completely resolved, 9 were improved, 5 were unchanged, and 2 were aggravated after 1 year.

Other Bariatric Procedures

In 2017, Manco et al published results from contemporaneous cohorts of adolescent patients with BMI of 35 kg/m² or more and nonalcoholic steatohepatitis (NASH) who chose between 3 treatment options.¹¹⁹ Twenty patients chose to undergo laparoscopic sleeve gastrectomy (LSG), 20 patients opted to ingest intragastric weight loss devices (IGWLD, either the BioEnterics Intragastric Balloon System or Obalon Gastric Balloon) plus lifestyle interventions, and 53 patients chose lifestyle interventions alone. All patients in the LSG and IGWLD groups completed the study; 22 of the 53 in the lifestyle intervention group completed the study. After 1 year follow-up: patients undergoing LSG lost 21% body weight; patients treated with IGWLD lost 3% body weight; and patients receiving lifestyle interventions only gained 2% body weight. NASH reverted in 100% of patients receiving LSG and in 24% receiving IGWLD. Patients receiving lifestyle interventions alone did not improve significantly.

Section Summary: Bariatric Surgery in Children and Adolescents

Several systematic reviews and meta-analyses have been conducted on observational studies evaluating the use of bariatric surgery for the treatment of adolescents with obesity. There is overlap of studies among the systematic reviews. The majority of evidence the use of gastric bypass, laparoscopic sleeve gastrectomy, or laparoscopic adjustable gastric banding. Two nonrandomized comparative studies were published after the systematic reviews. One compared RYGB with conservative treatment and with adults undergoing RYGB, and one compared LSG with gastric balloons and lifestyle interventions. The evidence on bariatric surgery in adolescents indicates that the percent of EWL and change in BMI are is approximately the same as that in adults. There are greater concerns for developmental maturity, psychosocial status, and informed consent in adolescents.

Guideline recommendations for bariatric surgery in adolescents lack uniformity, but generally correspond to the clinical selection criteria for adults and supplement these clinical selection criteria with greater attention to issues of maturity and psychosocial status.

BARIATRIC SURGERY IN MORBIDLY OBESE PREADOLESCENT CHILDREN

In 2013, Black et al (described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents.¹¹³ Most studies were limited to adolescents; only 2 included children less than 12 years old. One study, Silberhumer et al (2006), included 9- to 19-year-olds (mean age, 17 years); conclusions could not be drawn about the impact of bariatric surgery in this sample of preadolescent children.¹²⁰ Similarly, Alqahtani et al (2012) included children ages 5 to 21 years (mean age, 14 years) and did not provide conclusions separately for preadolescent children.¹²¹

Clinical practice guidelines (e.g., from the Endocrine Society [2008]¹²² and the Institute for Clinical Systems Improvement [2013]¹²³) have recommended against bariatric surgery in preadolescent children.

Section Summary: Bariatric Surgery in Morbidly Obese Preadolescent Children

There are few published data and no studies were identified that focused on bariatric surgery in preadolescent children. Clinical guidelines recommend against bariatric surgery in preadolescent children.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

Hiatal hernia is associated with obesity and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of hiatal hernia has been associated with complications after laparoscopic adjustable gastric banding,¹²⁴ although other studies report no differences in perioperative complications after laparoscopic adjustable gastric banding in patients with GERD and/or hiatal hernia and those without GERD and/or hiatal hernia.¹²⁵ Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management of hiatal hernia that recommends that, during operations for RYGBP, SG, and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate [Further research is likely to alter confidence in the estimate of impact and may change the estimate]).¹²⁶

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

Gulkarov et al reported results of a prospective cohort study comparing outcomes for patients who underwent laparoscopic adjustable gastric banding with or without concurrent hiatal hernia repair (N=1298 with adjustable gastric banding alone; N=520 with concurrent hiatal hernia repair).¹²⁷ The authors report that initially hiatal hernias were diagnosed based on preoperative esophagram and upper endoscopy, but this was discontinued after these studies were shown to have poor predictive value for small-to-medium size hernias; subsequent patients were diagnosed at the time of operation. It is not specified how many patients were diagnosed with each method, and how many of those had symptoms before gastric banding.

Fewer patients who underwent concurrent hiatal hernia repair required reoperation for a complication (3.5% vs. 7.9% in the adjustable gastric banding alone group; $p < 0.001$). Hiatal hernia repair added an average of 14 minutes to operative time. Weight loss outcomes did not differ significantly between the groups.

Santonicola et al (2014) evaluated the effects of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on GERD in obese patients.¹²⁸ The study included 78 patients who underwent sleeve gastrectomy with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia identified who underwent SG only. The prevalence of typical GERD symptoms did not improve from baseline to follow-up in patients who underwent concomitant hiatal hernia repair (38.4% presurgery vs. 30.8% post surgery, $p = 0.3$). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% pre-surgery vs. 19.6% post surgery, $p = 0.003$).

Reynoso et al reported outcomes after primary and revisional laparoscopic adjustable gastric banding in patients with hiatal hernia treated at a single hospital system.¹²⁹ Of 1637 patients with hiatal hernia undergoing primary gastric banding, 190 (11.6%) underwent concurrent hiatal hernia repair; of 181 patients undergoing revision gastric banding, 15 (8.3%) underwent concurrent hiatal hernia repair. For primary procedures, there were no significant differences in mortality, morbidity, length of stay, and 30-day readmission rates for patients who underwent adjustable gastric banding with and without hiatal hernia repair. However, it appears that this comparison is for patients without hiatal hernia compared with patients with hiatal hernia who also underwent hiatal hernia repair.

Ardestani et al analyzed data from the Bariatric Outcomes Longitudinal Database to compare outcomes for patients with and without hiatal hernia repair at the time of laparoscopic adjustable gastric banding.¹³⁰ Of 41,611 patients who underwent laparoscopic adjustable gastric banding from 2007 to 2010, 8120 (19.5%) had concomitant hiatal hernia repair. Those with hiatal hernia repair were more likely to have GERD preoperatively (49% vs. 40% in the non-hiatal hernia repair group; $p < 0.001$). Perioperative outcomes were similar between groups. Of those with GERD preoperatively, rates of improvement in GERD symptoms did not differ significantly 1 year post procedure (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 conclude that many repairs may involve small hernias with limited clinical effect.

In general, studies report that the addition of hiatal hernia repair at the time of bariatric surgery is safe and feasible. In a small case series of 21 patients, Frezza et al (2008) described the feasibility of crural repair at the time of laparoscopic adjustable gastric banding for patients with hiatal hernia.¹³¹ 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.¹³² For laparoscopic RYGBP, there were 206,559 and 9060 patients who underwent the procedure alone or with concomitant hiatal hernia repair, respectively. For laparoscopic AGB, there were 52,901 and 9893 patients who underwent the procedure alone or with hiatal hernia repair, respectively. The authors reported no evidence of increased risk of perioperative adverse events associated with the concomitant hiatal hernia repair. However, patients who underwent a concomitant hiatal hernia repair were *less* likely to have prolonged length of stay (PLOS), with an average treatment effect on the treated (ATT) of hiatal hernia repair of -0.124 (95% CI, -0.15 to -0.088) for PLOS for patients who underwent Roux-en-Y gastric bypass and

an ATT of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for PLOS for patients who underwent laparoscopic adjustable gastric banding.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery

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

SUMMARY OF EVIDENCE

Adults with Morbid Obesity

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

For individuals who are adults with morbid obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass; there is less weight loss with LAGB compared with gastric bypass, LAGB procedure is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies, evaluating SG alone and comparing SG with gastric bypass, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least 5 years. A metaanalysis found that short-term weight loss was similar after SG compared with gastric bypass. Long-term weight loss was greater after gastric bypass but SG is associated with fewer AEs. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

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

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes a small RCT and observational studies. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. The small RCT compared intragastric balloon plus gastric bypass with standard of care plus gastric bypass and did not detect a difference in weight loss at 6 months post-surgery. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes 2 RCTs, observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment related mortality and morbidity. A 2014 systematic review identified only a single small nonrandomized comparative study comparing laparoscopic gastric plication with other bariatric surgery procedures. Since the systematic review, 2 RCTs have been published, one comparing LGP with a sham procedure and one comparing LGP with SG. LGP was more effective than sham at 1-year follow-up and equally effective as SG at 2-year follow-up. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic

gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive single anastomosis duodenoileal bypass with SG (SADI-D), the evidence includes observational. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. No controlled trials were published evaluating single anastomosis duodenoileal bypass with SG. There are a few case series, the largest of which had fewer than 100 patients. A retrospective chart review of patients receiving gastric bypass, BPD, and SADI-S, reported that among patients with diabetes, SADI-S was more effective in weight loss and Cholesterol outcomes compared with gastric bypass. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of single anastomosis duodenoileal bypass with SG. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

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

metabolism and nutrition and long-term durability of treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

Revision Bariatric Surgery

For individuals with morbid obesity who experience complications from bariatric surgery who receive revision bariatric surgery, the evidence includes case series and registry data. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon, but generally safe and efficacious. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Adults With T2D

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

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

Nondiabetic and Nonobese Adults

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

Adolescent Children With Morbid Obesity

For individuals who are adolescent children with morbid obesity who receive gastric bypass or LAGB, the evidence includes RCTs, observational studies, and systematic reviews. Relevant

outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents is similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m². In addition, greater consideration should be placed on patient development stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Preadolescent Children With Morbid Obesity

For individuals who are preadolescent children with morbid obesity who receive bariatric surgery, the evidence includes no studies focused on this population. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old, but findings were not reported separately for preadolescent children. Moreover, clinical practice guidelines have recommended against bariatric surgery for preadolescent children. The evidence is insufficient to determine the effects of the technology on health outcomes.

Hiatal Hernia Repair with Bariatric Surgery

For individuals with morbid obesity and a preoperative diagnosis of hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes cohort 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. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of hiatal hernia was present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 15.

Table 15. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02741674	National patient-centered clinical research network (PCORnet) bariatric study	100,000	Jan 2018
NCT02881684 ^a	Weight reduction by aspiration therapy in Asian patients with morbid obesity	15	Dec 2018
NCT01766037 ^a	Pivotal aspiration therapy with adjusted lifestyle therapy study	171	Jun 2019
NCT02142257	Gastric bypass procedure and aspireAssist aspiration therapy system for the treatment of morbid obesity, observational study	100	May 2020

	over 5 years		
NCT03102697	Optimization and follow-up of the consecutive use of two intragastric balloons in the treatment of obesity	30	Dec 2018
NCT02792166	Single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S): a prospective cohort study	40	Jun 2024
NCT02779322	Laparoscopic roux-en-y gastric bypass vs. single anastomosis gastric bypass (MGB vs. LFGP)	20	Jun 2025
NCT02692469	Laparoscopic single anastomosis duodenal-jejunal bypass with sleeve gastrectomy vs. laparoscopic duodenal switch (DS vs. SADI)	140	Apr 2026
NCT03236142	DS vs. SIPS-bariatric surgery comparison	110	Jan 2022

NCT: national clinical trial

^a Denotes industry-sponsored or cosponsored trial

SUPPLEMENTAL INFORMATION

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to the request for input from physician specialty societies and academic medical centers, BCBSA received information from the American Gastroenterological Association (AGA) and 2 academic medical centers regarding use of the REALIZE band while the policy was under review in 2008. All 3 responses supported use of the REALIZE band as another surgical option for patients, as adopted into the policy in February 2008.

In response to the request for input from physician specialty societies and academic medical centers, BCBSA received information from 2 academic medical centers regarding the use of the new endoscopic placement of devices to remedy weight gain that occurs after bariatric surgery while the policy was under review in 2008. Input from both centers agreed that this approach is considered investigational, as adopted in the policy in February 2008.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Association of Clinical Endocrinologists et al

In 2017, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm.¹²⁰ The document states: “Bariatric surgery should be considered for adult patients with a BMI [body mass index] of 35 kg/m² or more and comorbidities, especially if therapeutic goals have not been reached using other modalities.”

In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity.¹²¹ The guidelines addressed 9 broad clinical questions with 123 recommendations. The authors noted that the 2013 guidelines specifically on bariatric surgery (see below) were considered adequate in the current form. With regard to bariatric surgery for these guidelines, the following recommendations were added to those in the 2013 guideline:

- Recommendation 35: “Patients with obesity (BMI ≥ 30 kg/m²) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and

weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion.” (Grade B; BEL1 [best evidence level], downgraded due to evidence gaps)

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

Joint guidelines on the bariatric surgery patient were published by AACE, the Obesity Society, and American Society for Metabolic and Bariatric Surgery (ASMBS) in 2013.¹²² Recommendations on the following questions are summarized below.

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.¹²³ The guidelines make the following recommendations related to bariatric surgery:

- For 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, advise that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation (NHLBI Grade A (strong); AHA/ACC class of recommendation: IIa; AHA/ACC level of evidence: A).
- For individuals with a BMI <35 kg/m², there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation)

Institute for Clinical Systems Improvement (ICSI)

In 2013, the ICSI published health care guidelines on the prevention and management of obesity in adults.¹¹⁰ The following were current indications for bariatric surgery:

- BMI >40 kg/m²
- BMI >35 kg/m² with significant comorbidity (diabetes, hypertension, dyslipidemia, sleep apnea, cardiovascular disease, gastroesophageal reflux, and pseudotumor cerebri)
- Need for significant weight loss prior to solid organ transplantation, abdominal wall hernia repair, or joint replacement
- Medical management to exclude untreated endocrinopathies, stabilize hypertension or type 2 DM, and demonstrate patient compliance
- Psychological stability, as determined by an experienced practitioner

American Society for Metabolic & Bariatric Surgery (ASMBS)

In 2016, ASMBS published a position statement on intragastric balloon therapy (the statement was also endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons [SAGES]).¹²⁴ The statement did not include specific recommendations for or against using these devices. A summary of key recommendations is as follows:

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

In 2012, ASMBS published a position on sleeve gastrectomy.¹²⁵ This updated statement provided the following conclusions:

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

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

In 2013, SAGES issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery.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).

Guidelines for Children and Adolescents

American Society for Metabolic and Bariatric Surgery

In 2012, ASMBS best practice guidelines found that current evidence was insufficient to discriminate between specific bariatric procedures, but allowed that there is an increasing body of data showing safety and efficacy of Roux-en-Y gastric bypass and adjustable gastric band for the pediatric population.¹²⁶ Bariatric surgery was recommended for pediatric patients with morbid obesity and the following comorbidities:

Strong indications:

- Type 2 diabetes mellitus
- Moderate or severe obstructive sleep apnea (apnea-hypopnea index >15)
- Nonalcoholic steatohepatitis
- Pseudotumor cerebri

Less strong indications:

- Cardiovascular disease
- Metabolic syndrome

The guidelines stated that depression and eating disorders should not be considered exclusion criteria for bariatric surgery. The guidelines also noted that depression should be monitored following the procedure that eating disorders should be treated, and the patient stabilized prior to the procedure.

European Society for Gastroenterology, Hepatology and Nutrition et al

A joint position paper was published by the European Society for Gastroenterology, Hepatology, and Nutrition and the North American Society for Gastroenterology, Hepatology, and Nutrition in 2015.¹²⁷ This document contained the following statements regarding indications for bariatric surgery in adolescents:

BMI >40 kg/m² with severe comorbidities

- Type 2 diabetes mellitus
- Moderate-to-severe sleep apnea
- Pseudotumor cerebri
- NASH with advanced fibrosis (ISHAK score >1)

BMI >50 kg/m² with mild comorbidities

- Hypertension
- Dyslipidemia
- Mild obstructive sleep apnea
- Chronic venous insufficiency
- Panniculitis
- Urinary incontinence
- Impairment in activities of daily living
- NASH

- GERD
- Severe psychological distress
- Arthropathies related to weight

Additional criteria:

- Have attained 95% of adult stature
- Have failed to attain a healthy weight with previously organized behavioral/medical treatments
- Demonstrate commitment to psychological evaluation perioperatively
- Avoid pregnancy for 1 year after surgery
- Have decisional capacity and will provide informed assent/consent, as age appropriate

Endocrine Society

The Endocrine Society published recommendations for the following for prevention and treatment of pediatric obesity in 2008. These guidelines contained the following recommendations for bariatric surgery¹⁰⁹:

“We suggest that bariatric surgery be considered only under the following conditions:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height. Tanner criteria can be accessed at http://www.childgrowthfoundation.org/CMS/FILES/Puberty_and_the_Tanner_Stages.pdf
- The child has a BMI 50 kg/m² or has BMI above 40kg/m² and significant, severe comorbidities.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a medical center employing a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family, and the institution is either participating in a study of the outcome of bariatric surgery or sharing data.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits
- Bariatric surgery is not recommended for preadolescent children, for pregnant or breast-feeding adolescents, and for those planning to become pregnant within 2 years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved eating disorder, untreated psychiatric disorder, or Prader-Willi syndrome

U.S. Preventive Services Task Force Recommendations

Not applicable.

Government Regulations

National:

Effective May 20, 2014:

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Michigan&Keyword=bariatric&KeywordLookUp=Title&KeywordSearchType=And&ncd_i

[d=100.1&ncd_version=3&basket=ncd%25253A100%25252E1%25253A3%25253ABariatric+Surgery+for+Treatment+of+Morbid+Obesity&bc=gAAAABAAAAAAAAAA%3d%3d&](http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Bariatric-Surgery.html)

Nationally Covered Indications

Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35 , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

Effective for dates of service on and *after* February 21, 2006, these procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006). **Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified.**

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determines that Type 2 diabetes mellitus is co-morbidity for purposes of this NCD.

A list of approved facilities and their approval dates are listed and maintained on the CMS Coverage Web site at <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Bariatric-Surgery.html>, and published in the Federal Register for services provided up to and including date of service September 23, 2013.

Nationally Non-Covered Indications

Treatments for obesity alone remain non-covered.

Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).

The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:

- **Open** adjustable gastric banding;
- **Open** sleeve gastrectomy;
- Laparoscopic sleeve gastrectomy (**prior to June 27, 2012**);
- Open and laparoscopic vertical banded gastroplasty;
- Intestinal bypass surgery; and,
- Gastric balloon for treatment of obesity.

Effective for services performed on and after June 27, 2012, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied:

- a. The beneficiary has a body-mass index (BMI) ≥ 35 kg/m²,
- b. The beneficiary has at least one co-morbidity related to obesity, and,
- c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-covered, for Medicare beneficiaries who have a body-mass index ≥ 35 , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs.

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for coverage on a case-by-case basis or pursuant to a local coverage determination. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

Local:

There is no current WPS LCD on this topic. There is a WPS Medical Affairs Policy & Procedure document available at <http://www.wpsic.com/providers/files/bariatric-surgery.pdf>, last reviewed August 2017;

Indications of Coverage:

Review member contract for exclusions and benefits. Gastric bypass, laparoscopic or open Roux-en-Y, biliopancreatic diversion (BPD), and Laparoscopic sleeve gastrectomy are considered medically necessary when all of the following criteria are met:

- Age 18 and over, with a body mass index (BMI) greater than 40, OR Age 18 and over, with BMI greater than 35 with one of the following comorbid conditions:
 - a. Coronary artery disease with evidence of previous CABG or PCI, or obesity-related cardiomyopathy
 - b. Diabetes Mellitus
 - c. Hypertension: difficult to control (defined as hypertensive despite a maximum dose of 3 antihypertensive agents) while compliant with medical therapy.
 - d. Severe sleep apnea (AHI greater than 40)
 - e. Pseudotumor cerebri
 - f. Degenerative joint disease with prior total joint arthroplasty or documentation of need for joint replacement
 - g. Metabolic syndrome
 - h. Gastro-Esophageal Reflux Disease (GERD)
- Documentation of complete history and physical (including evaluation and treatment of obesity related comorbidities, BMI history, history of previous weight loss attempts, and evaluation of surgical risks. Cardiac, pulmonary, endocrine, and GI evaluation is obtained as indicated.
- Nutritional evaluation: (by a Registered Dietician) that includes all of the following:
 - a. Minimum of three visits
 - b. Initial clinical nutrition evaluation (may include micronutrients)
 - c. Instruction for post-surgery diet
 - d. Documentation that there is a reasonable expectation based on the evaluation and adherence to the pre-surgical program, that the member will be able to comply with the post -surgical diet and plan.
- Documentation of a psychological evaluation that assesses appropriateness for surgery, issues related to addiction, and ability to comply with the pre and postoperative program. If

the member is receiving treatment for an active behavioral health disorder, clearance from the treating provider is required with documentation that the patient's psychiatric therapy has been optimally treated.

- Documentation that, within the past 12 months, there has been at least six months (three consecutive) of participation in a professionally supervised multidisciplinary weight loss program. Documentation must consist of actual progress notes for the dates of participation in the program. This documentation must include weight data as well as documentation that diet, exercise, and behavior modification were addressed. Participation that is summarized in the form of a letter is not acceptable. Appropriate documentation is:
 - Dated progress notes from one of the professionals (physician, dietician, or weight-loss professional) supervising diet, exercise, and behavior modification at least once every four to eight weeks during the six month period, with clear evidence that weight reduction management was the primary service provided to the patient on that date.
 - Surgery must be performed by a surgeon substantially experienced with appropriate procedures and working in a clinical setting with adequate support for all aspects of pre-operative, post-operative, and continued post-surgical follow up management and assessment.
- Repeat bariatric surgery requires physician review (when it is not an exclusion of the policy or health plan).
 - Requests for bariatric surgery on an individual under 18 years of age requires physician review.

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. Bariatric surgery for the management and treatment of GERD, gallbladder disease, or diabetes, osteoarthritis, gallstones, urinary stress incontinence, or gastroparesis without meeting BMI criteria, is considered experimental or investigational as there is insufficient peer-reviewed medical literature documenting the effectiveness of these procedures for the management of these conditions.
- E. Routine cholecystectomy (removal of the gallbladder) at the time of bariatric surgery, without preoperative identification of gallbladder disease is considered incidental to the bariatric surgery.
- F. The following bariatric procedures are considered experimental or investigational as there is insufficient peer-reviewed medical literature documenting the effectiveness of these procedures over standard bariatric procedures:
 - 1) Intragastric balloon
 - 2) Gastric plication
 - 3) Electrical neuromodulation, Gastric electrical stimulation with an implantable gastric stimulator (IGS))
 - 4) Vagus Nerve Blocking (VNB)
 - 5) Endoluminal vertical gastropasty
 - 6) Implantable gastric pacing
 - 7) Endoscopic gastrointestinal bypass device

Bariatric surgery is considered not medically necessary if any of the following conditions are documented:

1. Current drug abuse/alcohol abuse within the last three months
2. Terminal disease
3. Significant chronic obstructive pulmonary disease
4. Active untreated eating disorder or untreated psychiatric disorder
5. Cognitive impairment that would interfere with patient's ability to comply with the post-operative treatment plan.

Documentation Required:

- Office notes
- Psychological evaluation report
- X-rays (if applicable)

Michigan Department of Community Health:

Medicaid covers obesity treatment when done for controlling life-endangering complications such as hypertension and diabetes. This does not include treatment specifically for obesity, weight reduction and maintenance alone. The physician must request PA and document that other weight reduction efforts and/or additional treatment of conservative measures to control weight and manage the complications have failed.

The request for PA must include

- The medical history
- Past and current treatment and results
- Complications encountered
- All weight control methods that have been tried and have failed, and
- Expected benefits or prognosis for the method being requested.

If surgical intervention is desired, a psychiatric evaluation of the beneficiary's willingness/ability to alter his lifestyle following surgical intervention must be included.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Gastric Electrical Stimulation
Vagus Nerve Blocking for Morbid Obesity

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2018, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/22/02	5/22/02	5/22/02	Joint medical policy established
9/11/02	9/11/02	9/11/02	New procedure added
11/20/02	11/20/02	12/05/02	Criteria updated
2/9/04	2/9/04	3/1/04	Criteria updated maintenance review
5/5/04	5/5/04	6/1/04	Coding update S2085 which was effective 01/01/04 but was already payable with PC 43659 until 12/31/03
6/15/05	6/15/05	6/10/05	Maintenance review, coding update
10/24/05	10/24/05	10/24/05	New codes added for effective 1/1/06
7/1/06	5/5/06	6/28/06	Routine maintenance
7/1/07	N/A	6/24/07	Routine maintenance
1/1/08 – BCBSM 9/1/07 - BCN	10/16/07	11/12/07	Maintenance review new procedure added
11/1/08	8/19/08	10/30/08	Maintenance review new procedure added
7/1/09	4/21/09	4/20/09	Maintenance review
11/1/10	8/17/10	10/13/10	Re-presented at committee with addition of sleeve gastrectomy as established as a standard, stand-alone gastric surgical weight reduction procedure. Added CPT code for sleeve gastrectomy (43775).
5/1/12	2/21/12	2/21/12	Revised BCN benefit page. Title changed from “Gastric Surgery for Morbid Obesity” to “Bariatric Surgery (Gastric Surgery for Morbid Obesity).
5/1/13	2/19/13	2/19/13	Updated NCD and LCD to include coverage for sleeve gastrectomy for Medicare members. Updated policy to include discussion on bariatric surgery for adolescents. Updated references.

1/1/14	10/15/13	10/25/13	Clarified language regarding repeat bariatric surgery: non-compliance vs. complications. Updated references and rationale. Added new Medicare decision memo information.
5/14/14	N/A	N/A	Deleted vertical banded gastroplasty, 43842, as an exclusionary criterion. It was originally added in error.
5/1/15	2/17/15	2/27/15	Routine maintenance. Added information regarding endoluminal bariatric procedures as experimental/investigational. Added references. No change in policy status.
7/1/16	4/19/16	4/19/16	Routine maintenance. Added single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) to the exclusions. Added word "trials" under SADI-S description, pg. 24.
3/1/17	12/13/16	12/13/16	Routine policy maintenance.
1/1/18			- Updated literature review focused on surgery in patients with type 2 diabetes and lower BMI February 9, 2017 - multiple references added (33, 36, 38, 65, 67, 68, 71, 74 and 75) - Intragastric balloon, aspiration therapy and bariatric surgery in preadolescents added to exclusions
7/1/18	4/17/18	4/17/18	Updated rationale section, added the following references: 11, 36, 38, 47, 50, 62, 69-70, 73, 79, 112, 116, 119, 139-141. Added the SIPS procedure to the policy as E/I. No change in policy status.

Next Review Date: 2nd Qtr, 2019

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 10/1/97	Revised: 5/8/01, 11/1/01
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BARIATRIC SURGERY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, see certificate for applicable deductibles and co-payments. The surgical procedures for severe obesity (including sleeve gastrectomy) are considered established treatment options if all the following criteria are met: • The patient has a BMI >40 or a BMI of >35 kg/m² with one or more comorbid conditions (such as degenerative joint or degenerative disc disease, hypertension, hyperlipidemia, coronary artery disease, presence of other atherosclerotic diseases, diabetes mellitus, sleep apnea and/or congestive heart failure). • Bariatric surgery may be indicated for patients over 18 years of age. Requests for bariatric surgery for patients less than 18 years of age should include documentation that the primary care physician has addressed the risk of surgery on future growth, the patient's maturity level and the patient's ability to understand the procedure and comply with postoperative instructions, as well as the adequacy of family support. Patients above 65 years of age may be considered if it is documented in the medical record that the patient's physiologic age and comorbid condition(s) result in a positive risk/benefit ratio. • The patient has been clinically evaluated by an MD or DO. The physician has documented failure of non-surgical management including a structured, professionally supervised (physician or non-physician) weight loss program for a minimum of 180-days within the last two years prior to the recommendation for bariatric surgery. This 180-day criteria is waived for individuals with a BMI ≥50 kg/m². The patient's weight is not to be "rounded up" to meet the 50 kb/m² requirement for waiving the full six month criteria. Note: <i>Programs that do not include direct professional supervision, including but not limited to online or telephonic weight loss programs, do not meet the criteria for a 180-day structured medical weight loss program.</i>
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	• The patient's medical record must demonstrate assessment and a therapeutic plan for each of the following elements: – Diet: It must demonstrate that appropriate caloric restriction was prescribed, explained and the members dietary intake was reviewed since the previous visit and caloric intake documented. The aim is to create a deficit of 500 to 1,000 calories (resulting in 1 to 2 lbs/week weight loss). – Physical activity: A physical exercise prescription appropriate for the member's age and physical condition should be developed and compliance should be monitored and documented at each visit. This prescription should be consistent with current BCN and NIH guidelines. A generally recommended regimen is 60-90 minutes of moderate intensity (swimming, walking, bicycling etc.) physical activity 5-7 days/week. – Behavioral Interventions: Specific strategies to provide tools for overcoming barriers and improving dietary compliance should be reviewed as appropriate. Examples of these strategies include but are not limited to self-monitoring of eating habits and physical activity (logbook), stress management, stimulus control, problem solving and social support. – Pharmacotherapy: FDA approved weight loss drugs in selected patients, may augment caloric restriction, physical activity and behavioral modification. The documentation should indicate that consideration of pharmacotherapy for weight loss was considered and discussed with the patient as a treatment option. Note: The above criteria are to be documented during a minimum of five visits over 180-days (<i>this will include the initial required evaluation by the MD or DO</i>). <u>This six-month criterion is waived for individuals with a BMI ≥ 50 kg/m².</u> There is a minimum of three physician (or professional non-physician) -office visits required in the first 90 days which includes the initial physician visit (more frequently as clinical circumstances dictate) and two visits in the subsequent three months, with the last visit being at the end of the 6 month period (or within 30 days after the end of the 6 month period). All of the above elements must be documented at each visit. This documentation must occur within two years of the bariatric surgery request
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	Note: BCN PCPs and medical specialists have access to a BCN form titled “Physician-Supervised Weight Loss Program Documentation” to concurrently document the assessment and treatment plan for obesity. This form can be obtained on e-Referral thru the following link: http://ereferrals.bcbsm.com/bariatric_surgery.shtml. <i>The use of this form is not mandatory.</i> • Weight loss programs that are not provided by the member’s PCP or medical specialists that do include direct professional supervision can be considered. For those programs, the following is required: – A complete description of the program including the program frequency of diet consultations; physical therapy consults/exercise specialists; and exercise classes (if the program includes this element); and behavioral health counseling (if the program includes this element). – Evidence of a minimum of 80% participation in the above program components (but no less than monthly for programs that only meet these elements on a monthly basis) by the member (e.g. for a program that requires weekly participation to review and modify dietary goals a member must attend a minimum of 21 out of 26 visits). • Documentation that the physician and the patient have a good understanding of the risks involved and reasonable expectations that the patient will be compliant with all post-surgical requirements. • A psychological evaluation must be performed as a pre-surgical assessment by a contracted mental health professional in order to establish the patient’s emotional stability, ability to comprehend the risk of surgery and to give informed consent and ability to cope with expectable post-surgical lifestyle changes and limitations. Such psychological consultations may include one unit total of psychological testing for purposes of personality assessment (such as the MMPI-2 or adolescent version, the MMPI-A). • Physicians need to be aware of long-term complications of gastric surgery and follow-up with these individuals. • In cases where a member previously had a sleeve gastrectomy as part of staged bariatric surgery, the member must at the time of the request for the subsequent bariatric surgery meet all the criteria
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	above (e.g. the BMI and obesity related comorbid conditions, psychological evaluation, etc.) except for the professionally supervised weight loss program. However, there must be documentation in the physician's record indicating compliance with the diet status post sleeve gastrectomy. • In cases where a revision of the original procedure is planned, documentation of all of the following is required: – Date and type of previous procedure – The factor(s) that precipitated failure – Any complications from the previous procedure that mandate (necessitate) the takedown – If the indication for the revision is a failure of the patient to lose a desired amount of weight then the patient must meet all of the initial preoperative criteria. Previous gastric restrictive procedures that have failed for anatomic or technical reasons (e.g., obstruction, staple dehiscence, etc.) are determined to be medically appropriate for revision without consideration of the initial preoperative criteria. Refer to the weight reduction procedures section of the certificate for appropriate deductibles and riders. Endoscopic procedures (e.g., insertion of the StomaphyX device) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches) are considered investigational Note: Gastric surgery is not a covered benefit under SRO Tier 2
Self-funded Groups: U-M Premier Care Grad Care	Surgery and procedures for weight reduction are covered when all of the following conditions are met: • BCN and BSC medical criteria are met • BCN pre-authorizes the procedure as medically necessary • The service is not considered to be experimental or investigational • The service is rendered in accordance with generally accepted medical practice; and • Surgery is performed in a BCN-approved bariatric facility Refer to the weight reduction section of the certificate for

	deductibles and copayments.
BCNA (Medicare Advantage)	Medicare Advantage member must meet the following criteria: • Bariatric surgery may be indicated for patients 18 to 65 years of age. Patients above 65 years of age may be considered if it is documented in the medical record that the patient's physiologic age and comorbid condition(s) result in a positive risk/benefit ratio • Covered when surgery performed at BCN contracted Medicare approved bariatric facility. • Services performed in connection with the treatment of obesity are covered by Medicare when the patient's BMI is more than 40 or more than 35 with at least one co-morbid condition and gastric surgery is an integral and necessary part of a course of treatment for these co-morbid conditions, including but not limited to hypothyroidism, Cushing's disease, hypothalamic lesions, cardiovascular diseases, respiratory diseases, diabetes and hypertension. • Effective for services performed on and after February 12, 2009, CMS determines that open and laparoscopic RYGBP, open and laparoscopic BPD/DS, and LAGB are covered for Medicare beneficiaries who have T2DM and a BMI ≥ 35. Additionally, CMS determines that T2DM is a comorbidity related to obesity as defined in Publication 10003, NCD Manual, section 100.1. • Effective February 15, 2013, WPS covers laparoscopic sleeve gastrectomy. • The patient has been clinically evaluated by an MD or DO. The physician has documented failure of nonsurgical management including a structured, professionally supervised (physician or non-physician) weight-loss program for a minimum of 180 days in the two years before the recommendation for bariatric surgery. This 180-day criteria is waived for individuals with a BMI ≥ 50. The patient's weight is not to be "rounded up" to meet the 50 kb/m² requirement for waiving the 180-day criteria. The following bariatric surgery procedures are non-covered for all Medicare beneficiaries: • <i>Open</i> adjustable gastric banding; • <i>Open</i> sleeve gastrectomy; and • <i>Open</i> and <i>laparoscopic vertical banded</i> gastroplasty Note: Programs that do not include direct professional

	supervision, including but not limited to online or telephonic weight loss programs, do not meet the criteria for a full <i>180-day</i> structured medical weight loss program. A BCNA member is eligible for a revision of a gastric surgery if the criteria stated above for an original gastric surgery is met. Endoscopic procedures (e.g., insertion of the StomaphyX device) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches are considered investigational. The following Bariatric Surgery procedures are non-covered for <u>all</u> Medicare beneficiaries: • Open adjustable gastric banding • <i>Open</i> sleeve gastrectomy; and • Open and laparoscopic vertical banded gastroplasty
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.