7.01.47	Bariatric Surgery		
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Policy Statement

Bariatric Surgery in Adults with Morbid Obesity

The following bariatric surgery procedures may be considered **medically necessary** for the treatment of morbid obesity (see Policy Guidelines section for patient selection criteria) in adults who have failed weight loss by conservative measures:

- Open gastric bypass using a Roux-en-Y anastomosis
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis
- Laparoscopic adjustable gastric banding
- Sleeve gastrectomy
- Open or laparoscopic biliopancreatic bypass (i.e., Scopinaro procedure) with duodenal switch

Note: Bariatric surgery should be performed in appropriately selected patients, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up postsurgery.

The following bariatric surgery procedures are considered **investigational** for the treatment of morbid obesity in adults who have failed weight loss by conservative measures:

- Vertical-banded gastroplasty
- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., greater than150 cm)
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Endoscopic procedures 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) include, but are not limited to:
  - Insertion of the StomaphyX™ device
  - Insertion of a gastric balloon
  - Endoscopic gastroplasty
  - Use of an endoscopically placed duodenojejeunal sleeve
- Laparoscopic gastric plication

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

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

Revision Bariatric Surgery

Revision surgery to address perioperative or late complications of a bariatric procedure may be considered **medically necessary**. These include, but are not limited to:

- Staple-line failure
- Obstruction
- Stricture
- Nonabsorption resulting in hypoglycemia or malnutrition
- Weight loss of 20% or more below ideal body weight
- Slippage that cannot be corrected with manipulation or adjustment (see Policy Guidelines section).

Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band (documented by upper gastrointestinal examination or endoscopy) may be considered **medically necessary** when **both** of the following are met**:**

- If the initial procedure was successful in inducing weight loss prior to pouch dilation
- The patient has been compliant with a prescribed nutrition and exercise program.

Bariatric Surgery in Adolescents

Bariatric surgery in adolescents may be considered **medically necessary** according to the same weight-based criteria used for adults, but greater consideration should be given to psychosocial and informed consent issues (see Policy Guidelines section). In addition, any devices used for bariatric surgery must be in accordance with the U.S. Food and Drug Administration (FDA)-approved indications for use.

Concomitant Hiatal Hernia Repair with Bariatric Surgery

Repair of a hiatal hernia at the time of bariatric surgery may be considered **medically necessary** for patients who have a preoperatively-diagnosed hiatal hernia with indications for surgical repair (See Policy Guidelines section).

Repair of a hiatal hernia that is diagnosed at the time of bariatric surgery, or repair of a pre-operatively diagnosed hiatal hernia in patients who do not have indications for surgical repair, is considered **investigational.**

Policy Guidelines

Patient Selection Criteria

Morbid obesity is defined as:

- A body mass index (BMI) greater than 40 kg/m^2 ,or a BMI greater than or equal to 35 kg/m^2 with at least 1 clinically significant obesity-related disease or complication, including, but not limited to:
    - Type 2 Diabetes Mellitus
    - Hypertension
    - Coronary Artery Disease
    - Obstructive Sleep Apnea

While there is limited evidence on which to assess the long-term impacts of bariatric surgery for patients younger than age 18 years, very severely obese (BMI greater than 40 kg/m^2) adolescents with serious obesity-related comorbidities that are poorly controlled or who have a BMI of 50 kg/m^2 or greater with less severe comorbidities may be considered for bariatric surgery. The U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND® System indicates it is for use only in severely obese adult patients. (The clinical study that was submitted to FDA for approval of the LAP-BAND was restricted to adults aged 18-55 years.)

Patients should have documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure (e.g., Weight Watchers, Jenny Craig, OptiFast, MediFast). The timing, intensity and duration of the preoperative timeframe should be individualized and left to the discretion of the patient and provider. However, given the elective and life changing nature of these procedures, and the necessity of proper education and instruction in the lifestyle changes inherent in both the immediate and long term postoperative management, it is recommended that three months elapse between the initial bariatric consultation and the date of surgery.

Patients with a BMI greater than or equal to 50 kg/m^2 need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m^2. Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

BMI is calculated by dividing a patient's weight (in kilograms) by height (in meters) squared.

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

Patients who undergo adjustable gastric banding and fail to achieve adequate weight loss must show evidence of postoperative compliance with diet and regular bariatric visits prior to consideration of a second bariatric procedure.

Bariatric Surgery in Children and Adolescents

The evidence for bariatric surgery in patients younger than age 18 years consists primarily of studies of adolescents, with a lack of evidence for younger children. Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 with comorbidities to a BMI of 50. The majority of guidelines use weight-based criteria that parallel those for adult patients.

In addition to the weight-based criteria, there is greater emphasis on issues of developmental maturity, psychosocial status, and informed consent for adolescent patients. All guidelines mention these issues, but recommendations are not uniform for addressing them. The following are examples from U.S. guidelines published since 2005 that address issues of maturity and psychosocial status:

The Endocrine Society[1]

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

Institute for Clinical Systems Improvement[2]

- Recommendations for adolescents apply to "mature adolescents", which is defined as having reached skeletal maturity.
- Bariatric surgery in the adolescent patient is controversial and should be undertaken on a case-by-case basis in a high-volume bariatric surgery center.

The choice of procedure in adolescents may also differ from adults, but there is a lack consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents[3]:

- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices used for laparoscopic adjustable gastric banding do not have FDA-approval in the United States for individuals younger than age 18 years.
- Some guidelines for bariatric surgery in adolescents do not recommend biliopancreatic diversions in adolescents because of the greater frequency of nutritional deficiencies on long-term follow-up, but other guidelines do not specify that biliopancreatic diversion not be done in adolescents.

Hiatal Hernia Repair Guidelines

The Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia.[4] The authors note that the general methodologic quality of available studies is low. Recommendations for indications for repair are as follows:

- Repair of a type I hernia [sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm] in the absence of reflux disease is not necessary (moderate quality evidence, strong recommendation).
- All symptomatic paraesophageal hiatal hernias should be repaired (high quality evidence, strong recommendation), particularly those with acute obstructive symptoms or which have undergone volvulus.
- Routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient's age and comorbidities (moderate quality evidence, weak recommendation).

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

Description

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

Related Policies

- Gastric Electrical Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibit plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Forms of bariatric surgery performed without specific implantable devices are surgical procedures that are not regulated by FDA.

Several gastric bands for use in bariatric surgery have received FDA-approval through the PMA process and are summarized in Table 1 (FDA Product Code: LTI):

Table 1: FDA-Approved Gastric Band Devices

Device	Manufacturer	Original PMA Date	Labeled Indications
REALIZE Adjustable Gastric Band (Curved Adjustable Gastric Band)	Ethicon Endosurgery, Inc., Somerville, NJ, and Cincinnati, OH)	November 2007	Intended for use in 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 1 or more comorbid conditions, or those who are 45.4 kg or more over their estimated ideal weight. The band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise, and behavior modification programs.
LAP-BAND Adjustable Gastric Band	Apollo Endosurgery, Inc., Austin TX (original applicant: Allergan, Inc.)	June 2001	Indicated for use in weight reduction for severely obese patients with a BMI of at least 40 or a BMI of at least 30 with 1 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.

FDA: Food and Drug Administration; PMA: premarket approval.

Rationale

Background

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

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

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

Resolution (cure) or improvement of type 2 diabetes mellitus (T2DM) 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 T2DM. The various surgical procedures have different effects, and gastrointestinal rearrangement seems to confer additional anti-diabetic benefits independent of weight loss and caloric restriction. The precise mechanisms are not clear, and multiple mechanisms may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (1GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

The following summarizes the different types of bariatric surgery procedures.

1. Vertical-Banded Gastroplasty (CPT code 43842)

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

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

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

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

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

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

A second adjustable gastric banding device was approved by 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 next:

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

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

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications compared with other gastric restrictive procedures, including iron deficiency anemia, vitamin B_{12} deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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

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

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

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

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

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

A sleeve gastrectomy is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high-risk patients. Weight loss following sleeve gastrectomy may improve a patient's overall medical status and thus, reduce the risk of a subsequent more extensive malabsorptive procedure, such as biliopancreatic diversion.

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

With these procedures, access to the relevant anatomic structures is gained through the mouth without skin incisions. Primary and revision bariatric procedures are being developed to reduce 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 duodenojejeunal sleeve and gastric balloon.

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

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

a. A distal gastrectomy induces a temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.

b. A 200-cm long "alimentary tract" consists of 200 cm of ileum connecting the stomach to a common distal segment.

c. A 300- to 400-cm "biliary tract" connects the duodenum, jejunum, and remaining ileum to the common distal segment.

d. A 50- to 100-cm "common tract" is where food from the alimentary tract mixes with biliopancreatic juices from the biliary tract. Food digestion and absorption, particularly of fats and starches, are therefore limited to this small segment of bowel, i.e., creating a selective malabsorption. The length of the common segment will influence the degree of malabsorption.

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

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

9. Biliopancreatic Bypass With Duodenal Switch (CPT code 43845—gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and

ileoileostomy [50- to 100-cm common channel] to limit absorption [biliopancreatic diversion with duodenal switch])

CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is essentially a variant of the biliopancreatic bypass previously described. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the 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.

10. Long-Limb Gastric Bypass (i.e., greater than150 cm) (CPT code 43847—Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)

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

11. Laparoscopic Malabsorptive Procedure (CPT code 43645—Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)

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

12. Laparoscopic Gastric Plication (no specific CPT code)

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

Literature Review

Definition of Outcomes

Outcomes of bariatric surgeries are notoriously difficult to evaluate in part due to the constantly evolving nature of the surgery. Small modifications are commonly made to decrease the incidence of postoperative and long-term complications. In addition, few controlled studies have directly measured the weight loss and complications associated with the different surgical approaches, particularly comparing gastric restrictive procedures with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. The outcomes for specific surgeries may widely differ among institutions or surgeons, perhaps due to small variations in surgical technique, intensity of follow-up, or patient selection criteria. However, during the 1970s and 1980s, both vertical-banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These two procedures were the focus of the 1991 National Institutes of Health (NIH) Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass (BPB).[5]

A 2003 TEC Assessment[6] summarized studies comparing open gastric bypass and VBG. These comparisons demonstrated that open gastric bypass resulted in a greater amount of weight loss than VBG, with no definite differences in complication rates. Therefore, gastric bypass is considered the criterion standard for the purpose of this discussion, and this is supported by the increasing acceptance of gastric bypass by the surgical community, representing greater than 80% of all bariatric surgery procedures performed in 2002.[7] Therefore, the results of open gastric bypass will be compared with the newer procedures not addressed by the 1991 NIH conference; i.e., gastric banding and BPB with or without duodenal switch. The following outcomes are considered relevant for bariatric surgery.

Weight Loss

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

Table 2. Weight Loss Outcomes

Outcome Measure	Definition	Clinical Significance
Decrease in weight	Absolute difference in weight pre- and posttreatment	Unclear relationship to outcomes, especially in morbidly obese
Decrease in BMI	Absolute difference in BMI pre- and posttreatment	May be clinically significant if change in BMI clearly leads to change in risk category
% of excess weight loss	Amount of weight loss divided by excess body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance
% patients losing greater than 50% of EBW	No. patients losing greater than 50% EBW divided by total patients	Additional advantage of framing on per patient basis. Threshold for significance (greater than 50%) arbitrary
% 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 Occurring Within 30 Days)

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and problems with wound healing.

Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications such as pneumonia or myocardial infarction.

Reoperation Rate

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

Long-Term Complications (Metabolic Adverse Effects, Nutritional Deficiencies)

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

Improved Health Outcomes in Terms of Weight-Related Comorbidities

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

Bariatric Surgery in Adults With Morbid Obesity

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

Randomized controlled trials (RCTs) of bariatric surgery have been performed but are limited and insufficient to draw conclusions about the comparison of bariatric surgery with conservative treatments for weight loss.[8] RCTs are difficult in bariatric surgery because many experts consider it inappropriate or unethical to randomize patients to bariatric surgery. Also, most patients and clinicians have strong feelings about their preference for treatment, which results in a select population that might agree to randomization and therefore, limited generalizability. As a result, the literature that is most important in determining the efficacy of bariatric surgery is from nonrandomized studies.

Swedish Obese Subjects Trial

The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/m^2 at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients were self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of comorbidities in the surgery group. There were a total of 2010 people who chose surgery and 2037 people who chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each individual surgeon chose the surgical procedure offered. Most of the procedures were VBG (greater than 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.[9-13] The following general conclusions can be drawn from the SOS study:

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

Longitudinal Assessment of Bariatric Surgery Consortium

The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium study is a large prospective, longitudinal, noncomparative study of patients who underwent Roux-en-Y gastric bypass or laparoscopic adjustable gastric banding with follow-up through 3 years postprocedure.[14] 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 postsurgery, 67.5% and 28.5% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of Roux-en-Y gastric bypass and adjustable gastric banding patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the Roux-en-Y gastric bypass patients and 17.5% (95% CI, 13.8% to 21.9%) of laparoscopic adjustable gastric banding patients.

Systematic Reviews

Numerous systematic reviews have been published on the efficacy of bariatric surgery compared with conservative therapy, some of which are older and do not include the full range of available studies.[15,16]

In 2013, 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.[17] 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 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.[18] 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 less than 0.001). Remission of type 2 diabetes was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of remission with type 2 diabetes 22.1; 95% CI, 3.2 to 154.3; p less than 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 less than 0.001). After bariatric surgery, 21/261 (8%) patients required reoperations (15/124 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 published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery.[19] The authors included 164 studies (37 RCTs and 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 type 2 diabetes, 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 of follow-up, the 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.

Other systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery, including hypertension, type 2 diabetes, hyperlipidemia, cardiac structure and function (left ventricular [LV] hypertrophy, LV geometry and diastolic function, and left atrial size), and risk of myocardial infarction, stroke, and cardiovascular events[20-23] Puzziferi et al conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies with 7971 patients.[24] At follow-up, which ranged from 2 to 5 years postprocedure, the mean sample-size–weighted percentage of excess weight loss was higher for gastric bypass than for gastric banding (65.7% vs. 45.0%). The authors note that few studies report long-term results with enough follow-up to minimize bias.

Section Summary

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

Evidence for Specific Types of Bariatric Surgery Procedures

Vertical-Banded Gastroplasty

VBG 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%.[25,26]

A small body of literature compares outcomes between VBG and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study,[27] randomized 310 morbidly obese patients to gastric bypass, VBG, or horizontal gastroplasty. The percent of patients with greater than 50% excess weight loss (EWL) at 3 years' follow-up was 67% for gastric bypass, 48% for VBG, and 17% for horizontal gastroplasty (p less than 0.001). There were no demonstrable differences in AEs among groups. A second, smaller RCT by Sugerman et al randomized 40 patients to receive either a VBG or a gastric bypass procedure.[28] After 9 months, the gastric bypass patients had significantly greater weight loss that persisted at 3-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight.

A number of other nonrandomized, comparative studies of open gastric bypass versus VBG were included in the 2003 TEC Assessment (N equals 8 studies, 3470 patients).[6] All 8 of these studies reported greater amounts of weight loss with open gastric bypass. These studies reported a 44% to 70% improvement in total weight loss, a 28% to 43% improvement in the percent EWL, and 19% to 36% more patients with greater than 50% EWL for those undergoing gastric bypass compared with VBG. Comparison of AEs was more difficult, as the data in these studies did not allow rigorous comparison of AEs. Nevertheless, the data suggested that the mortality rate for both operations was low overall. Serious perioperative AEs were also infrequently reported but were possibly somewhat higher for gastric bypass. Long-term AEs were inconsistently reported, although it appeared that revision rates were higher for VBG.

Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the United States. An example of these results is a large case series with long-term follow-up by MacLean et al, who reported on 201 patients undergoing VBG who were followed up for a minimum of 2 years.[29] Staple line perforation occurred in 48% of patients, and 36% underwent reoperation either to repair the perforation or to repair a stenosis at the rate-limiting orifice. However, the more than 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight.

In 2014, Hseih et al reported a systematic review of studies reporting greater than 10-year follow-up for VBG, which included 3 studies with extractable data.[30] Mean EWL was 61.4% (±13.5%) from baseline to follow-up in the 3 included studies, but the authors note a lack of long-term evidence related to outcomes following VBG.

Gastric Bypass With Short Limb (less than150 cm)

While VBG was perhaps the dominant bariatric surgery in the 1980s, it has been surpassed in the U.S. by the gastric bypass procedure, based on a variety of studies that report improved weight loss with a gastric bypass procedure. This body of literature has been instrumental in establishing that gastric bypass should be the reference procedure to which other procedures are compared. Practice patterns in the United States have adopted this approach, with gastric bypass now composing most of all bariatric procedures performed.

Many clinical series reporting results of open gastric bypass have been published, and numerous systematic reviews of this evidence have been reported. Griffen summarized the experience of more than 10,000 gastric bypass operations from a number of bariatric surgeons.[31] Results showed that approximately 85% were able to reduce their weight to levels below 150% of their ideal weight. In about 5000 patients who were followed up for 10 years, 80% were able to maintain this result. Pories et al reported on 608 patients who underwent a gastric bypass procedure and were followed up for 1 to 14 years.[32] One of the unique features of this report is that only 3% of patients were lost to follow-up. The average weight loss was 75% of excess weight at 1 year, declining to 50% by the eighth year. The authors observed an immediate drop in both blood glucose and exogenous insulin requirements after surgery. Long-term observation of 298 patients with preoperative diabetes or impaired glucose intolerance revealed that 91% had normal values for blood glucose and hemoglobin $A1_c$ after surgery. The incidence of hypertension declined from 58% before surgery to 14% after gastric bypass.

Comparative trials summarized in the 2003 TEC Assessment[6] consistently report favorable outcomes for open gastric bypass when compared with VBG, including 2 RCTs. Some nonrandomized trials that compare open gastric bypass with procedures other than VBG were also summarized in the 2003 TEC Assessment.[6] While there are fewer trials for these other procedures, comparisons of open gastric bypass to gastric banding, horizontal gastroplasty, and silastic ring gastroplasty all reported that weight loss was superior with open gastric bypass.

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

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.

The 2005 TEC Assessment[33] on laparoscopic gastric bypass concludes that weight loss at 1 year is similar between laparoscopic and open gastric bypass approaches. Weight loss at longer follow-up periods has been less well-reported but appears to be similar as well. While comparisons of complication rates are less certain, certain patterns are evident and relatively consistent across the data examined. The profile of AEs differs between the 2 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 2 approaches appears to be more similar than different.

The mini-gastric bypass has primarily been advocated by one surgeon. In 2001, Rutledge published his experience with 1274 patients who underwent the mini-gastric bypass procedure.[34] The mean operating time was 36 minutes, and the mean hospital stay was 1.5 days. Mean EWL was 51% at 6 months, 68% at 12 months, and 77% at 2 years. The overall complication rate reported was 5.2%. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices away from the stomach.

Laparoscopic Adjustable Gastric Banding

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

The data presented as part of the FDA-approval process for the Lap-Band is summarized in the package insert and represents one of the most rigorously performed clinical series of this procedure in the United States.[35] In a group of 299 patients, the mean EWL was 36.2% at 3 years. This figure contrasts with a 40% to 60% EWL reported in other series of VBG and 50% for gastric bypass. One of the challenges of VBG is dilation of the pouch, which may prompt surgical revision. The Lap-Band procedure is intended to address this complication, as any pouch dilation can be altered by percutaneous adjustment of the inflatable band. The incidence of adjustment of the band or how this maneuver affected weight loss is not provided in the package insert. For example, although a 24% incidence of band slippage or pouch dilation was reported, it was not reported whether this complication was resolved with adjustment of the gastric band. There was a 9% incidence of surgical revision procedures and an additional 24% of patients had their entire Lap-Band systems explanted, most commonly due to band slippage or pouch dilation but also due to erosion, infection, or gastrointestinal disorders.

A 2006 TEC Assessment[36] updated the evidence on LAGB, and compared outcomes with those of gastric bypass. This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the 2 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 EWL at 1 year is in the range of approximately 40%, compared with 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, reoperations are reported in approximately 25% of patients, while in the single-arm studies, the composite rate for reoperations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the range of rates for band slippage is 1% to 36%, and the range for port access problems is 2% to 20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are underreported in many studies due to incomplete follow-up and a lack of systematic surveillance. The rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit-risk ratio for LAGB.

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the benefits, as defined by the amount of weight loss, will also be less for LAGB. The patterns of long-term complications also differ between the 2 procedures. For LAGB, longer-term AEs related to the presence of a foreign body in the abdomen will occur and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

Sleeve Gastrectomy

SG 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.

In 2009, Brethauer et al reviewed 36 studies (N equals 2570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers.[37] Two RCTs, 1 nonrandomized, matched cohort analysis, and 33 case series were examined. Thirteen studies (n equals 821) reported on high-risk patients having a staged approach and 24 studies (N equals 1749) on SG as primary procedure. Mean percentage of EWL was reported in 24 studies (N equals 1662) and was 55.4% overall (range, 33%-85%). Mean postoperative BMI was reported in 26 studies (N equals 1940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. Follow-up periods were 3 to 60 months. Ten studies included detailed postoperative comorbidity data (N equals 754); more than 70% of patients had improvement or remission of type 2 diabetes, and significant reductions were seen in hypertension and hyperlipidemia, sleep apnea, and joint pain. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with more than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies reporting detailed complication data (N equals 2570). All extracted studies reported mortality data with 5 deaths within 30 days of surgery (overall mortality rate 0.19%, 2 in the high-risk/staged group and 3 in the primary procedure group). The authors comment that long-term follow-up is limited.

More recent systematic reviews have summarized the evidence for SG. Trastulli et al conducted a systematic review of randomized trials that compared sleeve gastrectromy with other bariatric procedures. A total of 15 RCTs with 1191 patients were included.[38] 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%). Percentage of EWL (%EWL) ranged from 49% to 81% with SG compared with 62.1% to 94.4% with LAGB.

Li et al conducted a systematic review and meta-analysis of RCTs comparing SG with laparoscopic Roux-en-Y gastric bypass for morbid obesity or type 2 diabetes that included 5 trials with a total of 396 patients.[39] Laparoscopic Roux-en-Y gastric bypass was associated with higher rates of type 2 diabetes remission and greater EWL, but higher rates of complications. In a separate systematic review of 21 randomized and non-randomized studies (18,766 patients) of SG compared with laparoscopic Roux-en-Y gastric bypass for morbid obesity, Zhang et al reported no significant difference in %EWL from 0.5- to 1.5 year-follow-up. However, after 1.5 years, Roux-en-Y bypass was associated with higher %EWL (mean difference at 2 years, 5.77; 95%

CI, 4.29 to 7.25; p less than 0.05).[40] AEs were more frequent following Roux-en-Y bypass (odds ratio [OR], for major complication: 1.29; 95% CI, 1.22 to 3.22; p less than 0.01).

Himpens et al[41] report on a randomized study comparing LAGB and laparoscopic isolated SG. Eighty subjects received surgery over a period of 1 year. Median BMI was 37 (range, 30-47) in the LAGB group versus 39 in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, gastroesophageal reflux disease (GERD), complications, and reoperations were recorded at 1- and 3-year follow-up. Median decrease in BMI in the gastric bypass (GB) group was 15.5 (range, 5-39) after 1 year and 18 (range, 0-39) at 3 years after LAGB. One year after SG, decrease in BMI was 25 (range, 0-45) and 27.5 (range, 0-48) 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 differences were not significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relationship reversed at 3 years; between group differences were not significant at either time point. Two SG patients required reoperation for complications. Late complications requiring reoperation after LAGB included pouch dilations treated by band removal (n equals 2) or conversion to Roux-en-Y gastric bypass (RYGB) (n equals 1), 1 gastric erosion treated by conversion to RYGB, and 3 disconnections of the system were reconnected. Four patients had reoperations for inefficacy; 2 GB patients underwent conversion to RYGB, and 2 SG patients had conversion to duodenal switch (DS). The authors note that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.[41] Karamanakos et al carried out a double-blind study[42] to compare outcomes of laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic SG (LSG) on body weight, appetite, and fasting and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery. Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI was marked and comparable in each group. EWL was greater after LSG at 6 months (55.5% vs. 50.2%, respectively; p equals 0.04) and 12 months (69.7% vs. 60.5%, respectively; p equals 0.05). Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but was greater after LSG.

An RCT comparing short-term outcomes of laparoscopic sleeve gastrectomy with GB was published in 2013.[43] The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to SG. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the SG group (p equals 0.29). Minor complications were more common in the gastric bypass group compared with SG (17.1% vs. 7.4%, p equals 0.02), as was combined major and minor complications (26.5% vs. 13.2%, p equals 0.01).

Several other publications report of SG compared to other bariatric procedures. In a comparative study from France, Chouillard et al performed a comparative analysis with 200 patients who had undergone either SG or RYGB between 2005 and 2008.[44] Patients in each group were matched for age, sex, and BMI. The postoperative complications, percentage of EWL, and the resolution of comorbidities in each group were compared at 6, 12, and 18 months postoperatively. The overall mortality rates were similar in both groups. However, the morbidity rate was significantly greater in the RYGB group (20.5%) compared to the SG group (6.5%; p less than 0.05). The overall remission of type 2 diabetes was significantly better in the RYGB group. However, the percentage of EWL at 6, 12, and 18 months, as well as the resolution of nondiabetic comorbidities, were comparable in both groups. The authors concluded that in this study, compared with SG, RYGB was associated with a greater short-term morbidity rate and RYGB could be associated with better diabetes control. They also note that additional studies are needed to evaluate the comparative efficacy of SG and RYGB for the treatment of morbid obesity and its comorbidities.

Leyba et al reported on a series of 117 patients from Venezuela who were treated with either SG or RYGB.[45] From January 2008 to December 2008, 117 obese patients who met criteria for bariatric surgery were assigned by patient choice after informed consent to either a laparoscopic RYGB procedure (n equals 75) or an LSG procedure. Both groups were comparable in age, sex, BMI, and co-morbidities. Mean operative time of LSG was 82 minutes, while LRYGB was 98 minutes (p less than 0.05). Differences in length of stay, major complications, improvement in comorbidities, and EWL were not significant (p greater than 0.05). One year after surgery, average EWL was 86% in LRYGB and 78.8% in LSG (p greater than 0.05). The authors concluded that in the short term, both techniques are comparable regarding safety and effectiveness.

In a comparative study from India, Lakdawala et al compared 50 patients who underwent LSG and LRYGB from 2007 to 2008.[46] Groups were matched for age, sex, and BMI. Patients were evaluated at 6 months and 1 year postoperatively. Resolution of most comorbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, joint pain, and percentage of EWL in both groups was comparable at the end of 6 months and 1 year. Early resolution of type 2 diabetes was better in the LRYGB group; the results were comparable at 1 year. There was increased incidence of GERD in LSG patients. Chiu et al reported a systematic review on the effect of SG on symptoms of GERD.[47] A total of 15 reports were retrieved; 2 reports analyzed GERD as a primary outcome, and 13 included GERD as a secondary study outcome. Of the 15 studies, 4 showed an increase in GERD after SG, 7 found reduced GERD prevalence after SG, 3 included only the postoperative prevalence of GERD, and 1 did not include data on prevalence of GERD. The authors concluded that the studies showed differing outcomes and that studies that objectively evaluate GERD after SG are needed.

A small number of clinical series also report on SG as the initial procedure of a 2-stage operation. This approach has been generally attempted in patients with “super” obesity (BMI greater than 50), in whom a more complex initial operation may be associated with higher risk. Weight loss following SG may reduce the risk of these patients undergoing a more complex malabsorptive procedure in the future. The available series to date report only on very small numbers of patients; for example, Regan et al (n equals 7) and Mognol et al (n equals 10).[48,49] The published data on outcomes following completion of both stages of a 2-stage operation are limited to case reports and case series with very small numbers of patients.

Biliopancreatic Bypass

Skroubis et al[50] randomized 130 patients with a BMI of 35 to 50 to either RYGB or biliopancreatic diversion (BPD) (without duodenal switch) using a variant of BPB that included Roux-en-Y gastrectomy in place of SG. All patients were followed up for at least 2 years. Weight loss outcomes were superior for the BPD group at every time period examined up to 2 years. The EWL at 1 year was 73.7% for RYGB and 83.1% for BPD (p less than 0.001); at 3 years, the EWL was 72.6% for RYGB and 83.1% for BPD (p less than 0.001). There were more early complications in the RYGB group, but this difference did not reach statistical significance (6 complications vs. 1, respectively; p equals 0.12). Late complications also did not differ significantly between the RYGB and BPD groups (16 complications vs. 22, respectively; p equals 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. The largest experience with BPB is reported by Scopinaro et al, who developed the procedure. In 1996, Scopinaro et al summarized their experience with 1217 patients.[51] With follow-up of up to 9 years, the authors reported a durable EWL of 75%, suggesting that weight loss is greater with this procedure compared with gastric restrictive procedures. In addition, most patients reported disappearance or improvement of such complications as obstructive sleep apnea, hypertension, hypercholesteremia, and diabetes. The authors considered protein malnutrition the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity, and presumably, eating habits of the patients, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients are encouraged to maintain an oral calcium intake of 2 g/day, with monthly vitamin D supplementation.

The available evidence was reviewed in the 2006 TEC Assessment,[36] and outcomes of BPB, with or without DS, were compared with those of GB. One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 year are in the same range as for GB. While these data are not sufficient to distinguish small differences in weight loss between the 2 procedures, these data do not support the hypothesis that BPB results in greater weight loss than open GB.

Complication rates are poorly reported in these trials. The data suggest that mortality is low (≈1%) and in the same range as for open GB. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data suggest that long-term nutritional and vitamin deficiencies occur at a high rate following BPB. Slater et al[52] focused specifically on vitamin and calcium deficiencies following BPB. These authors reported high rates of vitamin and calcium abnormalities in their population over a 4-year period. By year 4, approximately half (48%) of the patients were found to have low calcium, and 63% had low levels of vitamin D. Other fat-soluble vitamins showed similar patterns of abnormalities. Low vitamin A was found in 69% of patients at 4 years, low vitamin K in 68%, and low zinc in 50%. Dolan et al[53] reported similar data in a study that compared several technical variations of BPB. These authors reported low calcium levels in 12% to 34% of patients, low vitamin D in 22.2% to 70.6%, low vitamin A in 53% to 67%, and low vitamin K in 44% to 59%. In addition, this study reported high rates of iron deficiency (11%-47%) and anemia (11%-40%). The rates of nutritional deficiencies and the consequences of these deficiencies require further investigation.

Biliary Pancreatic Diversion With Duodenal Switch

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

The largest case series of this procedure is by Marceau et al, who reported their 15-year experience with DS in 1423 patients from 1992 to 2005. 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 of 50 or less 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.[54]

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 equals 896), 67% for RYGB (7 studies, N equals 1627), and 42% for AGB (11 studies, N equals 4456). At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies, aggregate N equals 174), 58% for RYGB (3 studies, N equals 176), and 55% for AGB (5 studies, N equals 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 1 procedure over another."[55]

Prachand et al[56] published the largest comparative series of 350 super-obese patients with BMI greater than 50 who underwent either RYGB (n equals 152) or Scopinaro BPD combined with the DeMeester duodenal switch (DS-BPD) (n equals198). 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. The EWL was greater for BPD versus RYGB (64.1% vs. 55.9%, respectively; p less than 0.01), and the reduction in BMI was also greater for BPD versus RYGB (23.6 vs. 19.4, respectively; p less than 0.001). Complications and data on resolution of comorbidities were not reported in this study. Strain et al published a smaller comparative study of 72 patients who underwent either RYGB (n equals 50) or BPD (n equals 22). 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 with 16.5 for RYGB (p less than 0.001).[57]

Gastric Bypass With Long Limb (greater than 150 cm)

As discussed in the Description section, the degree of malabsorption associated with long-limb gastric bypass will vary with the length of the alimentary and biliary limbs. These modifications have been developed in an effort to decrease the metabolic adverse effects associated with BPB. However, there has been limited published evidence on outcomes from this procedure and a large degree of variability in the technical aspects of the procedure among the published literature. Murr et al reported on 26 patients who underwent a "very very long-limb Roux-en-Y gastric bypass."[53] In comparison to a case series of 11 patients who underwent BPB, the authors reported similar weight loss but decreased metabolic or nutritional abnormalities, attributed in part to the increased length of the common segment, 100 cm compared with 50 cm used in BPB. Sugerman et al also attribute increasing the length of the common segment to decreasing metabolic morbidities.[58]

The 2005 TEC Assessment reviewed studies that compared outcomes of standard or "short-" limb gastric bypass with outcomes of "long-" limb gastric bypass. There were 6 comparative studies, 2 or more in which different lengths of the Roux limb were compared. However, although the categorization of patients into "standard" versus "long-limb" is based on the length of the Roux (alimentary) limb, there is not a definite cutoff for long- versus standard limbs. In these studies, there was variability in the lengths of the Roux limbs for both the standard gastric bypass and for the long-limb groups.

Most comparisons of weight loss do not reveal significant differences between short- and long-limb gastric bypass. The strongest evidence in this category is from 2 RCTs.[59,60] In both of these trials, there were no significant differences in weight loss between groups. Brolin et al[61] compared 3 limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at 1 year, while the other 2 groups had similar decrease in BMI. MacLean et al[62] examined morbidly obese and super-obese patients separately and reported a significant difference in favor of the long-limb gastric bypass group. However, this analysis compared the final BMI of the 2 groups and did not report the actual change in BMI or the initial BMI for each group.

AEs were poorly reported by these studies, with only 3 reporting data on AEs . Mason et al[63] reported the percent of patients with "major post-op complications," which was 2.3% for standard gastric bypass and 1.2% for long-limb gastric bypass. There was no further breakdown of the types of major complications recorded and no statistical testing for this outcome. In the remaining 2 studies, the rates of short-term AEs reported by Inabnet et al[60] were higher for standard gastric bypass, while the rates reported by Brolin et al[61] were higher for the long-limb gastric bypass. Data on long-term complications were scant and did not reveal any apparent differences between short- and long-limb procedures.

Two-Stage Procedures

Bariatric surgeries that are performed in 2 stages have been proposed as a treatment option, particularly for patients with “super-obesity” defined as a BMI greater than 50. The rationale for a 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 SG, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a BPD, is performed.

The evidence on 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 operation, and in those that do, only a minority of patients undergoing the first stage actually proceed to the second-stage surgery. For example, Cottam et al[64] reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned 2-stage procedure. The incidence of major perioperative complications for laparoscopic SG was 13%. After 1 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[65] reported on 41 patients who underwent SG as the first stage of a planned 2-stage procedure. 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[66] described the complication rates in 87 patients undergoing a stage I SG followed by a BPD in 27 patients. For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

This evidence does not indicate that a 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.

In 2014, Ji et al reported a systematic review of studies reporting outcomes after laparoscopic gastric plication.[67] The study included 14 publications, including 1 nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports, including a total of 1450 patients. The largest study, by Talebpour et al, included 800 patients who were enrolled over a 12-year period at a single institution where the technique was developed.[68] Only 3 studies were identified that included more than 100 patients. The longest follow-up was to 120 months in the

Talebpour et al study; other studies that reported a follow-up time had follow-up to 24 months (2 studies), 18 months (2 studies), or 12 months (9 studies). The mean preoperative BMI ranged from 31.2 to 44.5 kg/m^2. The mean %EWL after the procedure was reported in 9 studies (N equals 1407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from 6 to 24 months. One study reported weight loss in terms of percent decrease in BMI, with a reported decrease at 6 and 12 months of 66.4% and 60.2%, respectively. One study compared anterior plication and greater curvature plication and reported improved weight loss with greater curvature plication (% EWL of 53.7% vs. 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no mortality was reported and the rate of major postoperative complications requiring reoperation ranged from 0% to 15.4% (average 3.7%), most commonly due to gastric obstruction or gastric preformation. Surgical techniques were not standardized. The authors conclude that laparoscopic gastric plication may be a promising treatment for obesity, but the currently available evidence is limited by small study size, a lack of randomized trials comparing the technique with established bariatric surgery techniques, and limited medium- to long-term follow-up data.

In an earlier systematic review, Abdelbaki et al summarized outcomes from seven studies of laparoscopic gastric plication, 2 of which included more than 100 patients enrolled, for a total of 307 patients.[69] At 6-month follow-up, EWL ranged from 28.4% to 54% for the 5 studies, which reported weight loss outcomes. All studies reported some incidence of nausea and vomiting, most of which was mild. Twenty patients (6.5 %) were readmitted, of whom 14 (4.6 %) patients required reoperation, most commonly for gastric obstruction (8/14; 57%).

In 2013, Pattanshetti et al published results of a study that described the evolution of a laparoscopic adjustable gastric banded plication procedure, a hybrid procedure involving both adjustable gastric banding and greater curvature plication which was developed by the authors.[70] Eighty patients were included, with mean BMI 38.05 (±4.73) kg/m^2. At 6, 12, 18, and 24 months, mean %EWL was 42.6% (±13.7), 56.4% (±19.9), 57.6% (±19.9), and 65.8% (±17.3), respectively. Five postoperative complications developed that required reoperation.

Endoluminal Bariatric Surgery Procedures

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

Duodenaljejunal Sleeve

Several endoscopically-placed sleeves designed to block absorption from the proximal small intestine have been investigated for the treatment of obesity and type 2 diabetes, although no devices currently have FDA approval. The most evidence appears to be related to the EndoBarrier® (GI Dynamics, Inc., Lexington, MA), which is a fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and extends 80 cm into the small bowel, usually terminating in the proximal jejunum. De Jonge et al reported results from a European pilot study of the use of the EndoBarrier in 17 patients with obesity and type 2 diabetes.[71] The device was implanted for 24 weeks, during which time patients lost a mean 12.7 kg (±1.3 kg; p less than 0.01) and had an average HbA1c improvement from 8.4% (±0.2%) to 7.0% (±0.2%; p less than 0.01).

Gastric Balloon

Intragastric balloons are placed in the stomach via endoscope or swallowing to act as space-occupying devices to induce satiety. No gastric balloons currently have FDA approval, but devices under investigation include the following. The ReShape Duo™ (ReShape Medical, San Clemente, CA) is a saline-inflated dual balloon system designed to remain in the stomach for 6 months. The Bioenterics® Intragastric Balloon System (Allergan, Irvine, CA) is a saline-inflated silicone balloon that is inserted endoscopically and designed to remain in the stomach for 6 months. The Obalon Balloon (Obalon Therapeutics, Carlsbad, CA) is a swallowable balloon that is inflated with gas and subsequently removed endoscopically. A 2011 review of endoluminal procedures for obesity reported that studies have demonstrated weight loss with gastric balloons in the short-term and mid-term ranges, but long-term weight loss, especially following balloon removal, has been equivocal.[72] Randomized trials of gastric balloons for obesity are underway.

Primary Obesity Surgery, Endoluminal (POSE)

The "POSE" procedure is an endoscopic gastroplasty procedure that uses tissue anchors to reduce the stomach's size and ability to stretch to accommodate a meal. The procedure uses the g-Cath EZ™ Suture Anchor Delivery Catheter (USGI Medical, Inc., San Clemente, CA) to create a durable fold in the stomach. In 2013, Espinos et al reported results from a prospective, single-center cohort study of the POSE procedure in patients with obesity ho refused surgical therapy.[73] Forty-five patients who had a technically-successful POSE procedure were included. Over 6 months of follow-up, patients had a mean %EWL of 49.4%, with a mean BMI decrease of 5.8. Randomized studies are ongoing in the United States, including an industry-sponsored randomized, blinded, sham-controlled trial, the USGI Medical ESSENTIAL Study for Weight Loss (NCT01958385).

Section Summary

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

Revision Bariatric Surgery

There are a number of reasons why patients who are treated with accepted forms of bariatric surgery may not lose weight or may regain weight that is initially lost. These reasons include issues of adherence (compliance), as well as technical (structural) issues. Some patients who regain weight after bariatric surgery, e.g., after RYGB, are found to have enlarged gastric stoma and/or enlarged gastric pouches. Correction of these abnormalities has been reported to again result in successful weight loss. However, some have questioned whether the association with enlarged stoma is as important as it is for enlarged pouches.[74]

Revision Surgical Procedures

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities with somewhat higher complication rates than for primary surgery. In 2014, Sudan et al reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database.[75] 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 8,750 (30.5%) were conversions. The primary bariatric operations were Roux-en-Y gastric bypass (N equals 204,705, 49.1 %), AGB (N equals 153,142, 36.5 %), SG (N equals 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 plus or minus 6.44 vs. 1.8±4.9, p less than 0.001) and for conversions (2.86±4.58 vs. 1.8±4.9, p less than 0.001). The mean %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 less than 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 less than 0.001), but not for corrections compared with primary operations (1.9% vs. 1.87%, p equals 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 conducted a systematic review of reoperations after primary bariatric surgery that included 175 studies, most of which were single-center retrospective reviews.[76] 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.

A sample of some of the outcomes reported in retrospective series of revision surgeries follows. Mognol et al reported on conversion of AGB to Roux-en-Y in 70 patients.[77] Indications for conversion were insufficient weight loss or weight regain after band deflation for gastric pouch dilatation in 34 patients (49%), inadequate weight loss in 17 patients (25%), symptomatic proximal gastric pouch dilatation in 15 patients (20%), intragastric band migration in 3 patients (5%), and psychological band intolerance in 1 patient. Median excess body weight loss was 70%. Sixty percent of patients achieved a BMI of less than 33 with mean follow-up 18 months. The early complication rate was 14.3% (10/70). Late major complications occurred in 6 patients (8.6%). Brolin and Cody, reporting on a series of 151 revision surgeries, observed that "Weight loss after revision of pure restrictive operations is significantly better than after revision of operations with malabsorptive components. Improvement of comorbidities in the great majority of patients justifies revision of all types of bariatric operations for unsatisfactory weight loss."[78] Bueter et al reported that of 172 patients who underwent adjustable gastric band placement between May 1997 and June 2006, 41 had one or more revision procedures.[79] There were no deaths following the reoperations. Band replacement (n equals 18), band repositioning (n equals 7), conversion to SG (n equals 2) and Roux-en-Y gastric bypass (RYGBP, n equals 2) or band removal without any further substitution (n equals 12) were performed as first reoperation. Seven patients had a second reoperation. Median follow-up since reoperation was 56 months (range, 7-113). Excess weight loss (EBWL %) of patients was 59.4% after RYGBP (n equals 5), 45.1% after rebanding (n equals 18), and 33.4% after SG (n equals 2). Comorbidities were further reduced or even resolved after reoperation.

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 (see Policy No. 2.01.38). 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).[80] 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.[81] 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.[82] 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 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.[83] 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 15% or more, excess BMI loss, and BMI less than 35, at 12 months postprocedure) was achieved by 10/45 (22.2%) of the StomaphyX group and 1/29 (3.4%) of the sham control group (p less than 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.[84] 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 the 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."[85]

Section Summary

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

Bariatric Surgery as a Treatment for Type 2 Diabetes Mellitus

Current indications for bariatric surgery view poorly or uncontrolled diabetes mellitus as a comorbidity whose presence supports the medical necessity of surgery for patients with BMI of 35 to 40. There also is growing interest in gastrointestinal surgery to treat patients with type 2 diabetes in patients with lower BMI. There are several small RCTs that have been published comparing bariatric surgery with medical treatment and many case series that describe rates of improvement and remission of diabetes following bariatric surgery. For patients with a BMI less than 35, there are case series that describe rates of improvement and remission in diabetes, along with a subgroup of patients in a larger RCT of bariatric surgery for patients with diabetes.

Morbidly Obese Patients

The Stampede trial[86] was an unblinded RCT of 150 patients with a BMI between 27 and 43 and uncontrolled diabetes. Most patients in this trial had a BMI greater than 35, but approximately one third of patients had a BMI of less than 35. Patients were randomized to 1 of 3 arms: medical treatment, RYGBP , or SG. Patients were followed for 1 year with the primary outcome being remission of diabetes, defined as a hemoglobin A_{1c} ($HgbA_{1c}$) of 6.0% or less. There was improvement in glycemic control for all groups. Starting from an Hgb baseline of 9.2%, the final value was 7.5% for the medical group, 6.6% in the SG group (p=0.003 vs. medical therapy), and 6.4% in the gastric bypass group (p less than 0.001 vs. medical therapy). The primary end point was reached by12% of patients in the medical therapy group, 37% in the SG group (p=0.008 vs. medical therapy), and 42% in the gastric bypass group (p=0.002 vs. medical therapy). The use of anti-diabetic medications increased in the medical therapy group and decreased in both the surgical groups. All patients in the GB group who achieved the primary end point did so without medications, while 28% of patients in the SG group who reached the primary end point required continued medication use.

Three-year follow-up from the Stampede trial was published in 2014.[87] At 36 months, follow-up was available for 91% of subjects. The primary outcome (remission of diabetes), was met by 5% of patients in the medical therapy group, compared with 38% of those in the GB group (p less than 0.001) and 24% of those in the SG group (p=0.01). Compared with medical therapy patients, patients in the GB and SG groups required fewer diabetes medications: 2.6±1.1 in the medical therapy group compared with 0.48±0.80 in the GB group (p less than 0.001) and 1.02±1.01 in the SG group (p less than 0.001).

A second RCT published in 2012 compared bariatric surgery to medical therapy.[88] This trial randomized 60 patients to 1 of 3 arms: medical therapy, RYGBP , and BPD. Patients were followed for at least 1 year, with the primary end point being remission of diabetes, defined as a fasting glucose less than 100, $HgbA_{1c}$ less than 6.5%, and off all diabetic medications. There was a significant decrease in $HgbA_{1c}$ for all groups. The $HgbA_{1c}$ decreased by 8.9% in the medical group, 25% in the GB group, and 43% in the BPD group, with the differences between the medical and surgical groups reaching statistically significance. At 2-year follow-up, remission was achieved in 0% of the medical therapy group, 75% of patients undergoing gastric bypass, and 95% of patients undergoing BPD.

Two RCTs of bariatric surgery compared with medical therapy enrolled diabetic patients with a BMI between 30 and 40 kg/m². Ikramuddin et al performed an unblinded RCT of gastric bypass versus intensive medical therapy on 120 patients with type II diabetes for at least 6 months and an $HgbA_{1c}$ of at least 8.0%.[89] Patients were followed for 12 months with the primary end point being a composite of $HgbA_{1c}$ less than 7.0%, low-density lipoprotein (LDL) cholesterol less than 100 mg/dL and systolic blood pressure less than 130 mm Hg. A total of 28 patients in the surgery group achieved the primary outcome compared with 11 patients in the medical therapy group (OR, 4.8, 95% CI, 1.9 to 11.7). The percent of patients achieving $HgbA_{1c}$ of less than 7.0% was 75% in the surgery group compared with 32% of patients in the medical therapy group (OR, 6.0; 95% CI, 2.6 to 13.9). There were 22 serious complications in the surgery group, including 4 perioperative complications, compared with 15 serious complications in the medical group.

Dixon et al[90] performed an RCT designed to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI of greater than 30 kg/m² and less than 40 kg/m². (Results were not reported separately for patients with BMI less than 35 or greater than 35, and 47/60 patients had BMI greater than 35.) Sixty patients were enrolled, and 30 were randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the 2-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and 4 (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was less than 6.2% at baseline in 2 surgically and 4 conventionally treated patients versus 24 and 6 patients, respectively, at 2 years. At baseline, 2 surgically treated and 4 conventionally treated patients were using no pharmacotherapy versus 26 and 8, respectively, at 2 years. One surgical patient developed a wound infection, 2 developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band.

One RCT was identified that compared RYGBP to SG in patients with BMI of 35 kg/m^2 or more and type 2 diabetes.[91] Forty-one patients were randomized, 37 of whom completed the protocol, 19 in the RYGBP group and 18 in the SG group). At 12-month follow-up, the mean percent change in weight from baseline was 25.9 (SD 5.4) in the Roux-en-Y bypass group and 28.4 (SD 5.9) in the sleeve gastrectomy group (p=nonsignificant). The mean absolute improvement in HbA1c from baseline to 12 months was 1.57%±1.35% in the RYGBP group and 2.27%±2.22% in the SG group (p=nonsignificant).

The remaining evidence at the present time consists of small case series and case reports with short follow-up from non-U.S. centers employing procedures considered investigational in this policy. For example, Lee et al retrospectively identified 44 patients with type 2 diabetes and BMI less than 35 kg/m^2, 114 patients with BMI between 35 and 45, and 43 patients with BMI greater than 45 in a large series[92] of patients who underwent laparoscopic mini-gastric bypass. One year after surgery, fasting plasma glucose levels returned to normal in 89.5% of patients with BMI less than 35 and in 98% of those with BMI greater than 35. The treatment goal of hemoglobin A_{1c} less than 7%, LDL less than 150 mg/dL and triglyceride less than 150 mg/dL, was met in 76.5% of patients with BMI less than 35 and in 92.4% of those with BMI greater than 35.

Diabetic Patients Without Morbid Obesity

A TEC Assessment was completed in 2012 on bariatric surgery in diabetic patients with a BMI less than 35 kg/m^2.[93] The evidence consisted mainly of case series. This Assessment made the following conclusions:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with BMI less than 35 kg/m^2. There was only 1 randomized trial comparing 2 bariatric procedures. Therefore, studies were categorized by procedure type and presented as case series, regardless of the underlying study type.
- Nine studies reported diabetes remission rates and other outcomes in subjects undergoing gastric bypass. Diabetes remission rates varied between 48% and 100% at follow-up times of 1 year and beyond. One of the studies was a randomized clinical trial of gastric bypass versus sleeve gastrectomy; in this study, diabetes remission associated with gastric bypass was 93% versus 47% for sleeve gastrectomy at 1 year.
- Two studies reported outcomes of sleeve gastrectomy. The diabetes remission rates were 55% and 47% at 1 year.
- One study was selected that 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 in this study were not considered to be rigorous, as the only measure of diabetes outcome was withdrawal of diabetes medication. The reported remission rates were 27.5% and 50% at variable follow-up times.
- One study of biliopancreatic diversion reported a remission rate of 67% for subjects with BMI between 30 and 35 and 27% for subjects with BMI between 25 and 30 kg/m^2 at 12-month follow-up.

- One study reported outcomes of duodenal-jejunal exclusion. The subjects in this study had more severe diabetes than the subjects enrolled in other studies; 100% were on insulin treatment and the duration of diabetes was between 5 and 15 years. The diabetes remission rate was 17% at 6 months.

The TEC Assessment concluded that GB met the TEC criteria as a treatment for diabetes in patients with a BMI less than 35 but that other procedures did not meet the TEC criteria for this indication.

Since the publication of the 2012 TEC Assessment, Rao et al published a systematic review and meta-analysis of short-term outcomes for patients with type 2 diabetes (T2DM) and BMI of 35 kg/m^2 or less who undergo RYGBP.[94] Nine articles were included with a total of 343 patients. After 12 months, patients with T2DM had a significant decrease in their BMI (weighted mean difference [WMD], -7.42; 95% CI, -8.87 to -5.97; p less than 0.0001) and improvements in HbA1C (WMD, -2.76; 95% CI, -3.41 to -2.11; p less than 0.000). The authors report that longer-term follow-up is needed.

DePaula et al report on 39 patients with BMI less than 35 who underwent 1 of 2 laparoscopic procedures comprising different combinations of ileal interposition into the proximal jejunum via a sleeve or diverted SG . Mean BMI was 30.1 (range, 23.4-34.9). All had type 2 diabetes for at least 3 years (mean duration, 9.3 years; range, 3-22 years) and evidence of stable treatment with oral hypoglycemic agents or insulin for at least 12 months. Mean follow-up was 7 months (range, 4-16 months). Mean postoperative BMI was 24.9 (range, 18.9-31.7). Adequate glycemic control was achieved for 86.9% of patients, and 13.1% had important improvement. Four major complications occurred within 30 days of surgery, and mortality was 2.6%.[95] Scopinaro et al reported outcomes at mean follow-up of 13 years (range, 10-18 years) on 7 patients with BMI less than 35 who underwent BPD. In all patients, serum glucose levels were normalized at 1, 2, and 3 years. In 5 patients, a slight increase above 123 mg/dL was observed at or around 5 years. The values were maintained at all subsequent times with no one value higher than 160 mg being recorded. The other 2 patients had full resolution of diabetes at all follow-up times. Serum cholesterol and triglyceride values fell to normal 1 year after BPD and remained within the normal range. Blood pressure normalized in 6 cases and improved in 1. No patient had excessive weight loss at any postoperative time.[10] Kakoulidis et al investigated the role of SG for patients with BMI 30 to 35. Fifteen of the 79 patients in the study had type 2 diabetes. At a follow-up of 6 months or more, diabetes was resolved in 2 patients and improved in one.[96]

Section Summary

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

Bariatric Surgery in Nondiabetic Patients With BMI Less Than 35 kg/m^2

A TEC Assessment was completed in 2012 concerning laparoscopic gastric banding in nondiabetic individuals with a BMI less than 35.[97] This Assessment was prompted by FDA approval of Lap-Band™ for this indication in 2011. The TEC Assessment concluded that LAGB does not meet the TEC criteria in these patients and made the following summary statements:

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

Bariatric Surgery in Children and Adolescents

There is less evidence on bariatric surgery in children and adolescents than there is for adults. In the available studies, patient selection generally paralleled the criteria for adults. Studies included primarily adolescents, with some preadolescents but no children younger than the preadolescent stage. Some studies included additional selection criteria related to developmental and/or psychologic maturity.

Treadwell et al conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents.[98] 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 reported data on 352 patients (mean BMI, 45.8; median age range, 15.6-20 years); 6 studies on RYGB included 131 patients (mean BMI- 51.8; median age range, 16-17.6 years); 5 studies of other procedures included 158 patients (mean BMI- 48.8; median age range, 15.7-21 years). Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB. 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.

One RCT of LAGB has been published. O'Brien et al 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.[8] 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% CI, 30.2 to 39.0), representing an EWL of 78.8% (95% CI, 66.6% to 91.0%). The mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1 to 8.1), representing EWL of 13.2% (95% CI, 2.6 to 21.0). The gastric banding group experienced improved quality of life with no perioperative AEs ; however, 8 operations (33%) were required in 7 patients for revisional procedures either for proximal pouch dilatation or tubing injury during follow-up. This study offers evidence that among obese adolescent participants, use of gastric banding compared with lifestyle intervention results in a greater percentage achieving a loss of 50% of excess weight.

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[101] reported on 73 patients aged 13 to 17 years who have undergone LAGB since 2001 at the authors' institution. Mean preoperative BMI was 48. The EWL at 6 months, 1 year, and 2 years postoperatively was 35%±16%, 57%±23%, and 61%±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.

In 2014, Inge et al reported results from Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study, a prospective, multicenter observational study of bariatric surgery in patients aged 19 or younger.[102] 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.

A number of guidelines for bariatric surgery in adolescents have been published in the U.S. (see "Clinical Practice Guidelines" section).[1,2,103]

Section Summary

The evidence on bariatric surgery in adolescents supports that weight loss is approximately the same as with adult patients. There are greater concerns for developmental maturity, psychosocial status, and informed consent in adolescents. Guidelines for bariatric surgery in adolescents are not uniform in their recommendations but generally correspond to the clinical selection criteria for adult patients and supplement these clinical selection criteria with greater attention toward issues of maturity and psychosocial status.

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,[104] 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.[105] 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]).[4]

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).[106] 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 less than 0.001). Hiatal hernia repair added an average of 14 minutes to operative time. Weight loss outcomes did not differ significantly between the groups.

Santonicola et al evaluated the effects of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on GERD in obese patients.[107] The study included 78 patients who underwent sleeve gastrectomy with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia identified who underwent SG only. The prevalence of typical GERD symptoms did not improve from baseline to follow-up in patients who underwent concomitant hiatal hernia repair (38.4% presurgery vs. 30.8% postsurgery; p=0.3). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% presurgery vs. 19.6% postsurgery: p=0.003).

Reynoso et al reported outcomes after primary and revisional laparoscopic adjustable gastric banding in patients with hiatal hernia treated at a single hospital system.[108] 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.[109] 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 less than 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 described the feasibility of crural repair at the time of laparoscopic adjustable gastric banding for patients with hiatal hernia.[110] 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.[111] 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 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

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

There is a very large body of literature on bariatric surgery, but few high-quality randomized controlled trials. The available evidence, largely from nonrandomized comparative studies and case series, supports the conclusion that bariatric surgery results in greater weight loss and improvements in weight-related comorbidity compared with nonsurgical treatments. Gastric bypass (GB), performed by either the open or laparoscopic approach, improves health outcomes of morbidly obese patients by leading to substantial weight loss with relatively low rates of adverse events. GB accounts for more than 80% of bariatric operations performed in the United States and is considered the reference standard to which other procedures should be compared. There is also sufficient evidence that laparoscopic gastric banding, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch improve outcomes. For these procedures compared with GB, there is a tradeoff in terms of the amount of weight loss, short-term complications, and long-term complications. An informed choice between patients and surgeons should be made after a thorough consideration of the risks and benefits of each procedure. Other bariatric surgery procedures remain investigational, as listed in the policy statement.

Limited evidence is available on bariatric surgery in patients with a body mass index (BMI) of less than 35 kg/m^2. Case series report a high rate of remission of diabetes in undergoing GB surgery, and this indication was judged to meet the TEC criteria in 2012. However, bariatric surgery for diabetes in patients with a BMI less than 35 is not currently considered standard of care and is not supported in current specialty society guidelines. For patients without diabetes, there is limited evidence on outcomes of surgery and no evidence that health outcomes are improved. As a result, bariatric surgery for patients with a BMI less than 35 is considered not medically necessary.

Bariatric surgery for adolescents is considered medically necessary using the same indications as for adults. However, greater consideration should be placed on the development stage of the patient, the psychosocial aspects of obesity and surgery, and on ensuring that the patient is able to provide fully informed consent.

Limited evidence is available related to the repair of hiatal hernias at the time of bariatric surgery. Studies suggest that such repair is feasible and does not significantly increase perioperative complications. However, the evidence is not sufficient to allow conclusions about whether repair of hiatal hernias, either diagnosed at surgery or preoperatively, improves outcomes for patients who are undergoing bariatric surgery. Therefore, the repair of incidentally diagnosed hiatal hernia at the time of bariatric surgery repair is considered investigational.

To achieve optimal outcomes following bariatric surgery, similar to those reported in the literature from large bariatric surgery centers, certain conditions should be met. Careful patient selection and thorough preoperative screening are essential. Surgeons need to be adequately trained in the particular techniques and should perform a high volume of these procedures. The institution should provide a full range of ancillary services, such as nursing and psychological support, and should provide for life-long follow-up after surgery. These conditions are best attainable as part of a dedicated, comprehensive bariatric surgery program that focuses on multidisciplinary care of the bariatric surgery patient.

Supplemental Information

Practice Guidelines and Position Statements

Joint Guidelines were published by AACE/ASMBS/Obesity Society in 2013.[112] Recommendations on the following questions are summarized below.

Which patients should be offered bariatric surgery?

- Patients with a BMI greater than or equal to 40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for 1 of the procedures.
- Patients with a BMI greater than or equal to 35 kg/m^2 and 1 or more severe obesity-related comorbidities
- Patients with BMI of 30 to 34.9 kg/m^2 with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.
- There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.

Which bariatric surgical procedure should be offered?

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

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.[113] The guidelines make the following recommendations related to bariatric surgery:

- For adults with a BMI greater than 40kg/m2 or BMI greater than 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 less than 35 kg/m2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.

In 2012**,** the ASMBS updated its 2009 position on sleeve gastrectomy.[114] In 2009, the statement accepted sleeve gastrectomy as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients.[115] They cite the need for long-term data to confirm the effectiveness of the procedure as a stand-alone intervention. The 2011 update provides 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.
- The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first stage procedure in high risk patients as part of a planned staged approach.
- 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.

In January 2009, the ASMBS Emerging Technologies and Clinical Issues Committee issued a Position Statement on Emerging Endosurgical Interventions for Treatment of Obesity.[116] The committee stated that "use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention." It calls for trials to generate data for risk-benefit analysis, assessments of disability, durability, and resource utilization and notes that dramatic reduction in risk may allow for acceptance of interventions that do not provide durable benefits comparable to currently accepted bariatric procedures.

Recommendations from the National Institutes of Health stress the importance of a multidisciplinary approach to bariatric surgery patients, including such ancillary services as nutritional and psychological support.[5] It is also recommended that bariatric surgery programs provide lifelong follow-up for treated patients. However, no regulatory mechanisms ensure that these resources are present in all programs.

In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia, which includes a recommendation about repair of hiatal hernias that are incidentally detected at the time of bariatric surgery.[4] 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

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 surgery[1]:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI 50 kg/m^2 or has BMI above 40kg/m^2 and significant, severe comorbidities.
- Severe obesity and comorbidities persist, despite a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a 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.

Other guidelines provide statements related to children and adolescents. The Institute for Clinical Systems Improvement (ICSI) recommendations apply to "mature adolescents",[2] which is defined as those who have reached skeletal maturity. They acknowledge that bariatric surgery in the adolescent is controversial and should be approached on a case-by-case basis in conjunction with experts in obesity management. Guidelines from the Society of Gastrointestinal and Endoscopic Surgeons[103] state that bariatric surgery has been proven effective in adolescents and that patient selection criteria should be the same as used for adult bariatric surgery.

U.S. Preventive Services Task Force Recommendations

Bariatric surgery is not a preventive service.

Medicare National Coverage

Medicare has published a national coverage decision regarding bariatric surgery that concluded the following: ENREF_119[117]

> The Centers for Medicare and Medicaid Services (CMS) has determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), are reasonable and necessary for Medicare beneficiaries who have a body mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

In addition, CMS concluded that these procedures are eligible for coverage only when performed at either 1) A level 1 Bariatric Surgery Center, as designated by the American College of Surgeons, or 2) A Bariatric Surgery Center of Excellence, as designated by the American Society for Bariatric Surgery.

These coverage decisions were based on an internal review of the evidence by CMS, the recommendations from a Medicare Coverage Advisory Panel Meeting, and consideration of public comments. The advisory panel considered each bariatric surgery procedure separately and reviewed the evidence base to determine for each procedure whether evidence was sufficient to conclude that the intervention improves the net health outcome. The strongest recommendations were given for open or laparoscopic gastric bypass, with positive recommendations also given for LAGB and open or laparoscopic BPD with DS.

CMS did not consider the comparative efficacy of these procedures in their coverage determinations or attempt to specify whether any of the procedures were preferable for particular patient populations. This determination differs from those of the TEC Assessments on bariatric surgery, which first determined that open gastric bypass should be the reference procedure to which other interventions are compared and then attempted to determine the comparative efficacy of different bariatric procedures when compared to open gastric bypass. In the TEC Assessments, therefore, alternate procedures were required to demonstrate both that they improved the net health outcome and that the overall benefit/risk ratio for the procedure was at least as good as gastric bypass for a relevant patient population.

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Documentation for Clinical Review

Please provide the following documentation:

Bariatric Surgery in Adults with Morbid Obesity:

- History and physical including prior weight loss attempts and responses, and comorbidities:
  - Co-morbidities, including, but not limited to: (when BMI is greater than or equal to 35.0 kg/m^2 and less than 40.0 kg/m^2)
    - If diagnosed with coronary artery disease: Submit documentation from cardiologist that includes all previous and current treatments, as well as, member's current status

- If diagnosed with diabetes: Submit documentation from primary care provider or endocrinologist that includes all previous and current treatments, as well as, type of diabetes
- If diagnosed with hypertension: Submit documentation from primary careprovider that includes all previous and current treatments, as well as, member's current status
- If diagnosed with obstructive sleep apnea: Submit official sleep study report interpreted by a sleep disorders specialist MD or Doctor of Osteopathic (DO)medicine and documentation of all conservative therapies attempted with duration and outcomes

- Description of non-surgical weight-reduction program (e.g., Weight Watchers, Jenny Craig, OptiFast, MediFast,), initial weight, end weight, duration (start and end dates)
- Time lapse between the initial bariatric consultation and date of surgery (recommended 3 months)
- Documented failure to respond to conservative measures for weight reduction prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure.

Medical doctor (MD) order for surgery that includes current height, weight, and body mass index (BMI), surgery requested and recommendation

Reoperation/Revision and Repeat Bariatric Surgical Requests:

- History and physical or consultation notes including: prior surgery and complications(if applicable), indication for surgery, and treatment plan
- Post-surgical weight loss history (including pre- and post-surgical BMI), nutrition and exercise compliance
- Operative report(s) (if applicable)
- Diagnostic radiology, endoscopy or contrast study reports (if applicable)

Bariatric Surgery in Adolescents :

- History and physical or consultation including: the same weight-based criteria used for adults.
- Documentation of psychological counseling.
- Documentation of informed consent.
- Documentation that any device used for bariatric surgery is in accordance with the FDA-approved indication for use.

Concomitant Hiatal Hernia Repair

- Documentation of preoperatively-diagnosed hiatal hernia with indications for surgical repair.

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

MN/ IE

The following service/procedure may be considered medically necessary in certain instances and investigational in others. Services may be medically necessary when policy criteria are met. Services are considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	***See Policy Guidelines***	
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43659	Unlisted laparoscopy procedure, stomach
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
	43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
	43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
	43999	Unlisted procedure, stomach
HCPC	S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
ICD-9 Procedure	43.7	Partial gastrectomy with anastomosis to jejunum (biliopancreatic diversion)

Type	Code	Description
	43.82	Laparoscopic vertical (sleeve) gastrectomy
	43.89	Other partial gastrectomy (biliopancreatic diversion with duodenal switch and sleeve gastrectomy)
	44.31	High gastric bypass
	44.38	Laparoscopic gastroenterostomy
	44.39	Other gastroenterostomy with gastrectomy
	44.68	Laparoscopic gastroplasty
	44.69	Other repair of stomach
	44.95	Laparoscopic gastric restrictive procedure
	44.96	Laparoscopic revision of gastric restrictive procedure
	44.97	Laparoscopic removal of gastric restrictive device(s)
	44.98	(Laparoscopic) adjustment of size of adjustable gastric restrictive device
ICD-10 Procedure	***For dates of service on or after 10/01/2015***	
	0D160ZA	Surgical, gastrointestinal system, bypass, stomach, no device, jejunum, code by approach
	0D164ZA	Bypass Stomach to Jejunum, Percutaneous Endoscopic Approach
	0D168ZA	Bypass Stomach to Jejunum, Via Natural or Artificial Opening Endoscopic
	0DB60ZZ	Excision of Stomach, Open Approach
	0DB63ZZ	Excision of Stomach, Open Approach
	0DB64ZZ	Excision of Stomach, Percutaneous Endoscopic Approach
	0DB67ZZ	Excision of Stomach, Via Natural or Artificial Opening
	0DB68ZZ	Excision of Stomach, Via Natural or Artificial Opening Endoscopic
	0DP643Z	Surgical, gastrointestinal system, excision, stomach, code by approach
	0DP64CZ	Surgical, gastrointestinal system, removal, stomach, open, code by device (extraluminal device or intraluminal device)
	0DQ64ZZ	Surgical, gastrointestinal system, repair, stomach, percutaneous endoscopic approach
	0DV60CZ	Surgical, gastrointestinal system, restriction, stomach, open, code by device (extraluminal device, intraluminal device or no device)
	0DV60DZ	Restriction of Stomach with Intraluminal Device, Open Approach
	0DV60ZZ	Restriction of Stomach, Open Approach
	0DV63CZ	Surgical, gastrointestinal system, restriction, stomach, percutaneous, code by device (extraluminal device, intraluminal device or no device)
	0DV63DZ	Restriction of Stomach with Intraluminal Device, Percutaneous Approach
	0DV63ZZ	Restriction of Stomach, Percutaneous Approach
	0DV64CZ	Surgical, gastrointestinal system, restriction, stomach, percutaneous endoscopic, code by device (extraluminal device, intraluminal device or no device)
	0DV64DZ	Restriction of Stomach with Intraluminal Device, Percutaneous Endoscopic Approach
	0DV64ZZ	Restriction of Stomach, Percutaneous Endoscopic Approach
	0DW64CZ	Surgical, gastrointestinal system, revision, stomach, percutaneous endoscopic, extraluminal device
ICD-9 Diagnosis	All Diagnoses	

Type	Code	Description
ICD-10 Diagnosis	***For dates of service on or after 10/01/2015***	
	All Diagnoses	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
4/14/1970	New Policy Adoption	Medical Policy Committee
2/26/1997	Policy Review	Medical Policy Committee
11/10/1999	Administrative Review External Review of policy	Medical Policy Committee
4/17/2000	Administrative Review Deleted Metropolitan Tables	Administrative Review
1/22/2001	Administrative Review Morbid Obesity definition	Administrative Review
2/13/2002	BCBSA Medical Policy adoption Open and Laparoscopic adjustable silicone gastric banding	Medical Policy Committee
4/17/2002	Administrative Review Distal Gastric Bypass with Duodenal Switch clarification	Administrative Review
8/1/2002	Coding Update	Administrative Review
9/1/2003	Policy Revision Updated	Medical Policy Committee
12/1/2003	Policy Revision Updated	Medical Policy Committee
2/1/2004	Policy Revision Updated Duodenal Switch	Medical Policy Committee
6/1/2004	Policy Revision Coding update Laparoscopic Gastric Banding CTAF update	Medical Policy Committee
1/1/2005	Policy Revision Coding update	Administrative Review
9/1/2005	Policy Revision External review and recommendations for revision to policy statement: Duodenal Switch	Medical Policy Committee
12/1/2005	Policy Statement Revision	Medical Policy Committee
3/1/2006	Policy Revision Policy Statement Revision for Duodenal Switch and Lap Gastric-Bypass. Coding update	Medical Policy Committee
6/1/2006	Policy Name Change	Administrative Review
12/7/2006	BCBSA Medical Policy adoption	Medical Policy Committee
3/12/2007	Policy Review CTAF review	Medical Policy Committee
3/24/2008	Coding Update	Administrative Review
7/8/2008	Policy Revision Added lap banding adjustment, rationale, references. Coding update	Medical Policy Committee
9/25/2009	Policy Title Revision, criteria revised	Medical Policy Committee
2/5/2010	Policy revision with position change Coding update	Medical Policy Committee
8/6/2010	Policy revision with position change	Medical Policy Committee
9/13/2010	Documentation required for clinical review update	Administrative Review
11/4/2010	Policy revision for clarification of criteria	Medical Policy Committee

Effective Date	Action	Reason
11/12/2010	Policy revision for clarification of criteria	Medical Policy Committee
4/1/2011	Policy revision for clarification of criteria	Medical Policy Committee
6/28/2013	Coding Update	Administrative Review
4/30/2015	Policy revision with position change effective 6/30/2015	Medical Policy Committee
6/30/2015	Policy revision with position change	Medical Policy Committee
7/31/2015	Policy clarification update	Administrative Review

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.