Bariatric Surgery

Policy Number: 7.01.47  Last Review: 12/2017
Origination: 10/1988  Next Review: 12/2018

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for bariatric surgery when it is determined to be medically necessary because the criteria shown below are met.

Note: Many local contracts have a specific exclusion for morbid obesity surgery or the treatment of complications arising from the surgery, regardless of the medical necessity.

Bariatric Surgery in Adults with Morbid Obesity (18+)

The following bariatric surgery procedures may be considered medically necessary for the treatment of morbid obesity (see Considerations for patient selection criteria) in adults who have failed weight loss by conservative measures. 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 post-surgery.

- Open gastric bypass using a Roux-en-Y anastomosis (CPT 43846)
- Laparoscopic gastric bypass using a Roux-en-Y anastomosis (CPT 43644)
- Laparoscopic adjustable gastric banding (CPTs 43770, 43771, 43772, 43773, 43774, HCPCS S2083)
- Sleeve gastrectomy (CPT 43775)
- Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro procedure) with duodenal switch (CPT 43855)

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 (CPT 43842)
- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch (CPT 43645, 43847)
- Long-limb gastric bypass procedure (i.e., >150 cm) (CPT 43847)
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Laparoscopic gastric plication
- Single anastomosis duodenal ileal bypass with sleeve gastrectomy

The following endoscopic procedures may be considered as investigational 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):

- Insertion of the StomaphyX™ device
- Endoscopic gastroplasty
- Use of an endoscopically placed duodenojejunal sleeve
- Intragastric balloons
- Aspiration therapy device.

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

Bariatric surgery is 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 is considered medically necessary. These include, but are not limited to, staple-line failure, obstruction, stricture, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, and band slippage that cannot be corrected with manipulation or adjustment.

Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch (documented by upper gastrointestinal examination or endoscopy) is considered medically necessary if the initial procedure was successful in inducing weight loss prior to pouch dilation and the patient has been compliant with a prescribed nutrition and exercise program and the patient still meets criteria (BMI) for bariatric surgery.

**Bariatric Surgery for Adolescents** (patients who have attained Tanner 4 or 5 pubertal development or has a bone age of ≥13 years in girls or ≥15 years in boys)

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 Considerations). In addition, any devices used for bariatric surgery must be in accordance with the FDA-approved indications for use.

**Bariatric Surgery In Preadolescent Children**

Bariatric surgery is considered investigational for the treatment of morbid obesity in preadolescent children.
**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 Considerations)

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 **incidental and not separately payable**.

**Other**

Bariatric surgery not meeting medical necessity criteria is considered **not medically necessary**.

**Considerations**

**Body Mass Index (BMI) Calculator**

http://medicalpolicy.bluekc.com?Calculator=BMI

The National Institutes of Health (NIH) defines the BMI categories as follows:

- Underweight < 18.5
- Normal+ 18.5 - 24.9
- Overweight 25.0 - 29.9
- Obesity 30.0 - 34.9 (Class I)
- Obesity 35.0 - 39.9 (Class II)
- Extreme Obesity ≥ 40 (Class III)

Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m^2^ or a BMI greater than 35 kg/m^2^ with associated complications with at least one clinically significant obesity-related disease such as diabetes mellitus, obstructive sleep apnea, coronary artery disease, or hypertension for which these complications or diseases are not controlled by best practice medical management.

While there is limited evidence on which to assess the long-term impacts of bariatric surgery for patients under the age of 18 years, very severely obese (BMI >40 kg/m/m^2^) adolescents with serious obesity-related comorbidities that are poorly controlled or who have a BMI of 50 kg/m2 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 the 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. As a result, some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. However, there is a lack of evidence on the optimal timing,
intensity and duration of nonsurgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Patients with BMI greater than or equal to 50 kg/m² need a bariatric procedure to achieve greater weight loss. Thus, use of adjustable gastric banding, which results in less weight loss, should be most useful as one of the procedures used for patients with BMI less than 50 kg/m². Malabsorptive procedures, although they produce more dramatic weight loss, they 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:
- 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: The Institute for Clinical Systems Improvement’s 2013 obesity guidelines have indicated that bariatric surgery should only be considered in the pediatric population under the following conditions (Fitch, 2013).
• “The child has a BMI > 40 kg/m² or has BMI above 35 kg/m² with a significant, severe comorbidities such as type 2 diabetes mellitus, obstructive sleep apnea, or pseudotumor cerebri.”
• “The child has attained Tanner 4 or 5 pubertal development or has a bone age ≥13 years in girls or ≥15 years in boys.”
• “Failure of ≥6 months of organized attempts at weight management....”
• “The adolescent should have decisional capacity and also demonstrate commitment to comprehensive medical and psychological evaluation before and after surgery.”
• “A supportive family environment....”

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:

• As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
• Devices that used for laparoscopic adjustable gastric banding do not have FDA-approval in the U,S, 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.

Obesity associated/comorbid complications for the purposes of applying this policy are defined as the following:

1. Type I diabetes
2. Type 2 diabetes uncontrolled (HgA1c > 7.0) despite best practices (combination pharmacotherapy or multiple injections of insulin daily and blood glucose self monitoring 3-4 times a day)
3. Hypertension uncontrolled by pharmacotherapy (SBP >140 and /or DBP >90 despite maximized doses of combination pharmacotherapy)
5. Cardiovascular disease including stroke, myocardial infarction, stable or unstable angina pectoris, coronary artery bypass or other procedures, Pickwickian syndrome, cardiomyopathy.
6. Pulmonary hypertension with documentation supporting the diagnosis.
7. Osteoarthritis of the lower extremities for which joint replacement surgery of the hip, knee or ankle has been recommended but weight loss is necessary prior to surgical intervention.

The following criteria are to be assessed for members requesting bariatric surgery:
Physician records for the 12 months immediately preceding the request for bariatric surgery must be submitted. A physician’s summary letter is not sufficient documentation. The documentation should include the physician’s initial assessment, and subsequent assessment of progress at each visit documenting:

- The member’s participation in a physician-supervised nutrition and exercise program that includes dietician consultation, low calorie diet, increased physical activity, and behavioral modification for a total of at least 6 consecutive months within the 12 months prior to consideration for surgery, and
- Weight loss attempts (diet, exercise, medication, etc.) including the length of time for each method at the weight loss attained, and
- Medical records of the attending physician, which document the patient’s weight and progress at each visit, will be required for review, and
- Co-morbid conditions including treatment for those conditions.

The member must have attempted weight loss in the past without successful long-term weight reduction.

For members participating in a physician-administered nutrition and exercise program (e.g. OptiFast, MediFast), program records that document participation and progress, may substitute for the physician’s medical records.

Surgical Preparatory Regimen: Patient Selection
1) The member must have the benefit for the treatment of obesity or morbid obesity.
2) Completion of the requirements outlined in the section titled “Bariatric Surgery Initial Consultation: Conservative treatment.”
3) If the member has been pregnant, she must be at least 12 months post-partum from the date of receipt of the application for the surgery.
4) The Blue KC Bariatric Surgery Questionnaire (included at the end of this policy) must be completed, with all required attachments, and submitted for review.
5) After qualifying for surgery based on the guidelines above, and for three months immediately prior to the surgery, the member must participate in a physician directed organized multidisciplinary surgical preparatory regimen meeting all of the following criteria in order to improve surgical outcomes, reduce the potential for surgical complications and establish the member’s ability to comply with post-operative medical care and dietary restrictions:
   a. Consultation with a dietician or nutritionist, and
   b. Reduced-calorie diet program supervised by dietician or nutritionist, and
   c. Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional, and
   d. Behavior modification program supervised by qualified professional with lifestyle changes documented by all of the following:
e. Loss of 5% of his/her body weight in the 3 months prior to surgery
f. Diet record
g. Documentation in the medical record of the member’s participation in the multidisciplinary surgical preparatory regimen at each visit. (Note: a physician’s summary letter, without evidence of contemporaneous oversight is not sufficient documentation. Documentation should include medical records of the physician’s initial assessment of the member, and the physician’s assessment of the member’s progress at the completion of the multidisciplinary surgical preparatory regimen).

6) Documentation of social support prior to and after the surgery.
7) Documentation indicating the patient is willing to commit to long-term follow up and be compliant with recommendations.

**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 of Procedure or Service**

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

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

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

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

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

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

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

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2014 systematic review identified only 1 small comparative study (unrandomized) comparing laparoscopic gastric plication with other bariatric surgery procedures. Additional comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

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

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes 1 RCT and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at 1 year. One small case series reported on 15 patients at 2 years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism and nutrition and long-term durability of treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.
**Adults With T2D**

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

However, any bariatric surgery for diabetes in patients with a body mass index less than 35 kg/m² is not currently considered standard of care and is not supported in most current specialty society guidelines. Clinical input did not support the use of bariatric surgery as a stand-alone treatment for diabetes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Nondiabetic and Nonobese Adults**

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

**Adolescent Children With Morbid Obesity**

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

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

Background

BARIATRIC SURGERY

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

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

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

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

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

**Open Gastric Bypass**
The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure (CPT code 43846) 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 (ie, a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Surgical complications include leakage and operative margin ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications than with other gastric restrictive procedures, including iron deficiency anemia, vitamin B12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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 (ie, jejunal limb) of a gastric bypass has been lengthened to 150 cm. This length also serves to distinguish a standard gastric bypass with a very long, or very, very long gastric bypass, as discussed further here.

**Laparoscopic Gastric Bypass**
CPT code 43644 was introduced in 2005 and described the same procedure as open gastric bypass (CPT code 43846), but performed laparoscopically.
**Adjustable Gastric Banding**
Adjustable gastric banding (CPT code 43770) involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple.

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

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

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

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

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

**Sleeve Gastrectomy**
A sleeve gastrectomy (CPT code 43775) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His
to the distal antrum, resulting in a stomach remnant shaped like a tube or sleeve. The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum and avoiding the dumping syndrome (overly rapid transport of food through stomach into intestines) seen with distal gastrectomy. This procedure is relatively simple to perform and can be done as an open or laparoscopic procedure. Some surgeons have proposed the sleeve gastrectomy as the first in a 2-stage procedure for very high risk patients. Weight loss following sleeve gastrectomy may improve a patient’s overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (eg, BPD).

**Biliopancreatic Bypass Diversion**
The BPD procedure (also known as the Scopinaro procedure; CPT code 43847) developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPD 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, ie, 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 BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treatment with total parenteral nutrition. In addition, several case reports have noted liver failure resulting in death or liver transplant.

**BPD With Duodenal Switch**
CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is a variant of the BPD 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
BPD, 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 BPD, ie, producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

**Vertical-Banded Gastroplasty**
Vertical-banded gastroplasty (VBG; CPT code 43842) was formerly one of the most common gastric restrictive procedures performed in the United States, but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon. Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter 2 requiring reoperation. Dilation of the stoma is a common reason for weight regain. VBG may be performed using an open or laparoscopic approach.

**Long-Limb Gastric Bypass (ie, >150 cm)**
Variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures (CPT code 43847), 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 (eg, resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

**Laparoscopic Malabsorptive Procedure**
CPT code 43645 was introduced in 2005 to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.
Weight Loss Outcomes
There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. These 2 methods are generally preferred over the absolute amount of weight loss, because they reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 1 summarizes the variations in reporting weight loss outcomes.

Table 1. Weight Loss Outcomes

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

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

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

Short-Term Complications (Operative and Perioperative Complications <30 Days)
In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (eg, pneumonia, myocardial infarction).
Reoperation Rate
Reoperation may be required to either “take down” or revise the original procedure. Reoperation may be particularly common in VBG due to pouch dilation.

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

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

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

Table 2 shows forms of bariatric surgery with implantable devices approved by FDA through the premarket approval process.

Table 2: FDA-Approved Bariatric Surgery Devices

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>PMA Date</th>
<th>Labeled Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>AspireAssist System®</td>
<td>Aspire Bariatrics</td>
<td>Jun 2016</td>
<td>For long-term use in conjunction with lifestyle therapy and continuous medical monitoring in obese adults &gt;22 y, with a BMI of 35.0 to 55.0 kg/m2 and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy</td>
</tr>
<tr>
<td>ORBERA® intragastric balloon system</td>
<td>Apollo Endosurgery</td>
<td>Aug 2015</td>
<td>For use in obese adults (BMI, 30-40 kg/m2) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.</td>
</tr>
<tr>
<td>ReShape® Integrated Dual Balloon System</td>
<td>ReShape Medical</td>
<td>Jul 2015</td>
<td>For use in obese adults (BMI, 30-40 kg/m2) and ≥1 comorbid conditions who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon delivered transorally and inflated with saline.</td>
</tr>
<tr>
<td>REALIZE® Adjustable Gastric Band</td>
<td>Ethicon Endosurgery</td>
<td>Nov 2007</td>
<td>For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m2, or a BMI of at least 35 kg/m2 with ≥1 comorbid conditions, or</td>
</tr>
<tr>
<td>LAP-BAND® Adjustable Gastric Banding System</td>
<td>Apollo Endosurgery (original applicant: Allergan)</td>
<td>April 2010</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>For use in weight reduction for severely obese adults with BMI of at least 40 kg/m² or a BMI of at least 30 kg/m² with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (eg, supervised diet, exercise, behavior modification programs).</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**Rationale**
This evidence review was originally created in July 1996 and has been updated regularly with searches of the MEDLINE database. The most recent update with literature review covers the period through December 22, 2016.

**OVERVIEW: BARIATRIC SURGERY IN ADULTS WITH MORBID OBESITY**
There is a vast literature on bariatric surgery for adults with morbid obesity. This literature is characterized by a preponderance of single-arm clinical series from individual institutions. These types of studies can be used to determine the amount of weight loss expected from surgery, the durability of the weight loss, and the rate of adverse events. However, these studies are not adequate for determining the comparative efficacy of bariatric surgery versus conservative treatment, or the comparative efficacy of different bariatric surgery techniques. Some comparative trials, including randomized and nonrandomized designs, compare bariatric surgery with conservative therapy and/or compare outcomes of different bariatric surgery procedures. The emphasis for this evidence review will be on comparative trials of bariatric surgery and nonsurgical therapy or of different types of bariatric surgery procedures.

Randomized controlled trials (RCTs) of bariatric surgery have been performed but are limited and insufficient to draw conclusions about comparisons of bariatric surgery and conservative treatments for weight loss.(2) 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 preferences for treatment, which result in a select population that might agree to randomization and, therefore, limited generalizability. As a result, the literature that is most important in determining the efficacy of bariatric surgery is from nonrandomized studies.

**Swedish Obese Subjects Trial**
The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34 kg/m² at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were
recruited and offered bariatric surgery. Thus, SOS patients self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of comorbidities in the surgery group. A total of 2010 people chose surgery and 2037 people chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each surgeon chose the surgical procedure offered. Most procedures were vertical-banded gastroplasty (VBG; >70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. Patients were followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

Many publications from this trial have reported on methods, weight loss, and clinical outcomes.(3-7) The following general conclusions can be drawn from the SOS study:

- Weight loss was greater with bariatric surgery than with conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight compared with a weight gain of 1.6% in the conservative treatment group.
- There was definite improvement in glucose control for diabetics and reduced incidence of new cases of diabetes.
- The effect on other cardiovascular risk factors (eg, hypertension, lipidemia) was also positive, but less marked than that seen for diabetes.
- Mortality was reduced by 29% after a mean follow-up of 10.9 years.
- Quality of life improved 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 (RYGB) or laparoscopic adjustable gastric banding (LAGB) with follow-up through 3 years postprocedure.(8) The study enrolled 2458 subjects, with median a BMI 45.9 kg/m2 (interquartile range [IQR], 41.7-51.5 kg/m2). For their first bariatric surgical procedure, 1738 participants underwent RYGB, 610 LAGB, and 110 other procedures. At 3-year follow-up, for 1533 Roux-en-Y patients with available data, percentage of baseline weight lost was 31.5% (IQR, 24.6%-38.4%). For the 439 adjustable gastric banding (AGB) patients with available data at 3 years, percentage of baseline weight loss was 15.9% (IQR, 7.9%-23.0%). At 3 years postsurgery, 67.5% and 28.5% of RYGB and AGB patients, respectively, had at least partial diabetes remission. Dyslipidemia was in remission in 61.9% and 27.1% of RYGB and AGB patients, respectively. Subsequent bariatric procedures (revision or reversal) were required in 0.3% (95% confidence interval [CI], 0.1% to 0.9%) of the RYGB patients and in 17.5% (95% CI, 13.8% to 21.9%) of LAGB patients.
Systematic Reviews
Numerous systematic reviews have assessed the efficacy of bariatric surgery compared with conservative therapy, some of which are older and do not include the full range of available studies.(9,10)

In 2014, Colquitt et al updated 2003 and 2009 Cochrane reviews of bariatric surgery for obesity.(11) They identified 22 randomized trials that compared bariatric surgery with nonsurgical obesity management or that compared different bariatric surgery procedures, with 1798 participants (sample size range, 15-250 participants). All 7 RCTs comparing surgery with nonsurgical interventions found benefits of surgery on measures of weight change at 1- to 2-year follow-ups. However, reviewers noted that adverse event rates and reoperation rates were poorly reported across trials, and long-term follow-up (beyond 1-2 years) was limited.

Gloy et al (2013) conducted a systematic review and meta-analysis of RCTs comparing current bariatric surgery techniques with nonsurgical treatment for patients with BMI of 30 kg/m2 or more.(12) Eleven studies (total N=796 patients) were included. Overall, patients after bariatric surgery lost more body weight than patients after nonsurgical treatment (mean difference [MD], -26 kg; 95% CI, -31 to -21 kg; p<0.001). Remission of type 2 diabetes (T2D) was more likely for bariatric surgery patients than for nonsurgical patients (relative risk [RR] of remission with T2D, 22.1; 95% CI, 3.2 to 154.3; p<0.000); similarly, remission of metabolic syndrome was more likely for bariatric surgery patients (RR=2.4; 95% CI, 1.6 to 3.6; p<0.001). After bariatric surgery, 21 (8%) of 261 patients required reoperations (5/124 after AGB, 4/69 after RYGB, 1/49 after sleeve gastrectomy [SG], 1/19 after biliopancreatic diversion [BPD]). Similar to the Colquitt meta-analysis, no studies reported longer term follow-up (>2 years) and heterogeneity between studies was high.

Chang et al (2014) published a systematic review and meta-analysis of RCTs and observational studies to evaluate the effectiveness and risks of bariatric surgery.(13) Reviewers included 164 studies (37 RCTs, 127 observational studies), with a total of 161,756 patients. Mean presurgery BMI was 45.62 kg/m2 and, among the studies that provided information about obesity-related comorbidities, 26.2% of patients had T2D, 47.39% had hypertension, 27.97% had dyslipidemia, 7.15% had cardiovascular disease, and 25.30% had obstructive sleep apnea (OSA). Perioperative complications were relatively low, with a perioperative mortality rate in RCTs of 0.08% (95% CI, 0.01% to 0.24%) and in observational studies of 0.22% (95% CI, 0.14% to 0.31%). Complication rates were 17% (95% CI, 11% to 23%) for RCTs, and 10% for observational studies (95% CI, 7% to 13%). At 1-year follow-up, mean change in BMI was -13.53 kg/m2 (95% CI, -15.51 to -11.55 kg/m2) in RCTs and -11.79 kg/m2 (95% CI, -13.89 to -9.69 kg/m2) in observational studies. Decreases in BMI were generally sustained over 2 to 4 years of follow-up among studies with reporting this outcome.

Many systematic reviews have reported improvements in specific obesity-related comorbidities following bariatric surgery. These reviews have relied primarily on
the results of observational studies and included the outcomes of hypertension, T2D, hyperlipidemia, cardiovascular events, quality of life, cancer, knee pain, and liver disease. (14-29)

Puzziferri et al (2014) conducted a systematic review of studies of bariatric surgery reporting follow-up beyond 2 years, which included 29 studies (total N=7971 patients). (30) At follow-up, which ranged from 2 to 5 years postprocedure, the mean sample size–weighted percentage of excess weight loss (EWL) was higher for gastric bypass (65.7%) than for gastric banding (45.0%). Reviewers noted that few studies reported sufficient long-term results to minimize bias.

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

Evidence for Specific Types of Bariatric Surgery Procedures
Gastric Bypass
The body of literature on improved weight loss has been instrumental in establishing gastric bypass as the reference procedure to which other procedures are compared. Practice patterns in the United States have indicated surgeons have adopted this approach, with gastric bypass now comprising most of the bariatric procedures performed.

Comparative trials summarized in the 2003 TEC Assessment (31) consistently reported favorable outcomes for open gastric bypass compared with VBG, including 2 RCTs. Some nonrandomized trials that compared open gastric bypass with procedures other than VBG were also summarized in the TEC Assessment. While there were 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 were seen more frequently in gastric bypass patients than those receiving a VBG. Anemia, iron deficiency, vitamin B12 deficiency, and red blood cell folate-deficiency were commonly seen. Marginal ulcerations were also seen in gastric bypasses, particularly in those whose gastric pouches were too large and included acid-secreting parietal cells.

A 2005 TEC Assessment focused on laparoscopic gastric bypass, which intends to reproduce the open procedure via minimally invasive techniques. (32) This technically complex surgery requires a dedicated team and a relatively high degree of skill and experience in laparoscopic technique. This Assessment reviewed 7 comparative trials of open gastric bypass and laparoscopic gastric bypass,
including 3 RCTs. In addition, 18 large clinical series of laparoscopic gastric bypass were included.

The 2005 TEC Assessment concluded that weight loss at 1 year was similar for laparoscopic and open gastric bypass approaches. (32) Longer follow-up periods were less well-reported but appeared to be similar for both approaches. While comparisons of complication rates were less certain, some patterns were evident and consistent across the data examined. The profile of adverse events differed between the 2 approaches, with each having advantages and disadvantages. Laparoscopic gastric bypass offered a less invasive procedure associated with decreased hospital stay and earlier return to usual activities. Mortality might be lower with the laparoscopic approach, although both procedures had mortality rates less than 1%. Postoperative wound infections and incisional hernias were also less frequent with laparoscopic gastric bypass. On the other hand, anastomotic problems, gastrointestinal tract bleeding, and bowel obstruction appeared to be higher with the laparoscopic approach, though not markedly higher. Given these data, the overall the benefit-risk profile for these 2 approaches appeared to be similar.

In 2016, Yan et al published a systematic review of RCTs comparing gastric bypass and medical treatment in obese patients (ie, BMI ≥30 kg/m^2) with T2D. (33) The primary study outcome was remission of T2D, which was reported in 5 of the 6 studies. A pooled analysis found a significantly higher remission rate after gastric bypass than after medical treatment (odds ratio [OR], 76.37; 95% CI, 20.70 to 271.73; p<0.001). In addition, a pooled analysis found a significantly lower final BMI in the gastric bypass group than in the medical treatment group (MD = -6.54 kg/m^2; 95% CI, -9.28 to -3.80 kg/m^2; p<0.001).

**Section Summary: Gastric Bypass**

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

**Laparoscopic Adjustable Gastric Banding**

A 2006 TEC Assessment updated the evidence on LAGB, and compared outcomes with gastric bypass. (34) This Assessment concluded that, for patients considering bariatric surgery, there was sufficient evidence to allow an informed choice between gastric bypass and LAGB. An informed patient might reasonably choose open gastric bypass or LAGB as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (eg, extent of weight loss and frequency and timing of potential complications) of the 2 procedures to optimize choice based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirmed that weight loss at 1 year was lower for LAGB than for open gastric bypass. The percentage of EWL at 1 year was approximately 40%, compared with 60% or higher for open gastric bypass. At time points beyond 1 year, some comparative
studies have reported that the difference in weight loss between LAGB and open gastric bypass narrows, but other studies did not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up did not support the hypothesis that the difference in weight loss shrinks after 1 to 2 years of follow-up. It appears more likely from the current data that attrition bias might have accounted for the diminution of the difference in weight loss over time, particularly when patients with bands removed or deflated were excluded from analysis.

These studies also confirmed that short-term (perioperative) complications are very low with LAGB and lower than with open gastric bypass or LAGB. Death was extremely rare, and serious perioperative complications probably occurred at rates less than 1%.

The reported rates of long-term adverse events vary considerably. In the comparative trials, reoperations were reported in approximately 25% of patients, while, in the single-arm studies, the composite rate for reoperations were approximately 50% lower (11.9%). The rates of other long-term complications were also highly variable; eg, the range of rates for band slippage was 1% to 36%, and the range for port access problems was 2% to 20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials was not systematic or consistent. While impossible to determine the precise rates of long-term complications from these data, it is likely that complications have been underreported in many studies due to incomplete follow-up and lack of systematic surveillance. The rates of long-term complications reported in some studies also raise concern about the impact of these events on the overall benefit-risk profile for LAGB.

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

A 2012 systematic review by Chakravarty et al(35) comparing LAGB with other bariatric surgery procedures had a conclusion similar to the TEC Assessment. Reviewers included 5 RCTs. The RCTs found that patients using LAGB lost weight, but less weight than with other procedures (eg, gastric bypass or sleeve gastrectomy [SG]). However, the short-term complication rate was lower with LAGB and no difference was found in quality of life after LAGB versus other procedures.
Section Summary: Laparoscopic Adjustable Gastric Banding

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

Sleeve Gastrectomy

Systematic Reviews

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

A 2016 systematic review by Juodeikis and Brimas summarized evidence on long-term results after SG.(36) Reviewers included 1 RCT and 19 retrospective studies, with a total of 2713 patients who received SG. Mean preoperative BMI was 46.9 kg/m². Mean duration of follow-up ranged from 5 to 11 years and mean proportion of patients followed for 5 years was 68.5%. Seventeen studies (n=1501 patients) reported 5-year follow-up data; mean percent EWL was 58.4%. At 5 years, resolution of T2D was observed in 77.8% of patients who had SG; arterial hypertension, dyslipidemia, OSA, gastroesophageal reflux disease (GERD), and degenerative joint diseases also improved in most patients. Two studies reported weight loss after 7 and 8 years; percent EWL rates were 56.6% and 54.8%, respectively.

In 2009, Brethauer et al reviewed 36 studies (total N=2570 patients) for a systematic review of SG as a staged and primary procedure, the largest trials coming from European centers.(37) Two RCTs, 1 nonrandomized, matched cohort analysis, and 33 case series were examined. Thirteen studies (n=821 patients) reported on high-risk patients having a staged approach and 24 studies (n=1749 patients) on SG as primary procedure. Mean percentage of EWL, reported in 24 studies (n=1662 patients), was 55.4% overall (range, 33%-85%). Mean postoperative BMI, reported in 26 studies (n=1940 patients), decreased from a baseline of 51.2 to 37.1 kg/m². Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost; all had significant reductions from baseline. Follow-up ranged from 3 to 60 months. Ten studies included detailed postoperative comorbidity data (n=754 patients); more than 70% of patients had improved control or remission of T2D, and significant reductions were seen in hypertension and hyperlipidemia, OSA, and joint pain. Rates of major postoperative complications ranged from 0% to 23.8% for all studies and from 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 (n=2570 patients). All extracted studies reported mortality data, with 5 deaths within 30 days of surgery (overall mortality rate, 0.19%; 2 in the high-risk/staged group, 3 in the primary procedure group).
In a 2015 meta-analysis of 21 randomized and nonrandomized studies (total N=18,766 patients) comparing SG with LRYGB for morbid obesity, Zhang et al reported no significant difference in percent EWL from 0.5- to 1.5-year follow-ups.(38) However, after 1.5 years, Roux-en-Y bypass was associated with higher percent EWL (2-year MD=5.77; 95% CI, 4.29 to 7.25; p<0.05). Adverse events were more frequent following Roux-en-Y bypass (OR for major complication, 1.29; 95% CI, 1.22 to 3.22; p<0.01).

In 2013, Trastulli et al conducted a systematic review of 15 RCTs (total N=1191 patients) that compared SG with other bariatric procedures.(39) Reviewers reported mean complication rates with SG of 12.1% (range, 10%-13.2%) compared with 20.9% with LAGB (range, 10%-26.4%). Percent EWL ranged from 49% to 81% with SG and from 62.1% to 94.4% with LAGB.

**Randomized Controlled Trials**

Himpens et al (2006) reported on a randomized trial comparing LAGB and laparoscopic isolated SG in 80 patients and reported 3 year follow-up.(40) Median baseline BMI was 37 kg/m2 (range, 30-47 kg/m2) in the LAGB group and 39 kg/m2 (range, 30-53 kg/m2) in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, GERD, complications, and reoperations were recorded at 1- and 3-year follow-ups. Median decrease in BMI in the gastric bypass group was 15.5 kg/m2 (range, 5-39 kg/m2) after 1 year and 18 kg/m2 (range, 0-39 kg/m2) at 3 years after LAGB. One year after SG, decrease in BMI was 25 kg/m2 (range, 0-45 kg/m2) and 27.5 kg/m2 (range, 0-48 kg/m2) after 3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the difference was not statistically significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relation reversed at 3 years; between-group differences were not statistically significant at either time point. Two SG patients required reoperation for complications. Seven late complications required reoperation after LAGB, including pouch dilations treated by band removal (n=2) or conversion to RYGB (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 system disconnections that required reconnection. Four patients had reoperations for lack of efficacy (2 LAGB patients underwent conversion to RYGB, 2 SG patients underwent conversion to duodenal switch). The authors noted that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group.

Karamanakos et al (2008) carried out a double-blind RCT to compare outcomes of laparoscopic RYGB and laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery.(41) Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI were marked and comparable in each group. EWL was greater after LSG than laparoscopic RYGB at 6 months (55.5% vs 50.2%; p=0.04) and 12 months (69.7% vs 60.5%; p=0.05), all respectively. Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but decreased more after LSG.
An RCT comparing short-term outcomes of LSG with gastric bypass was published in 2012. Trialists compared 30-day outcomes for 117 patients randomized to gastric bypass and 121 patients randomized to LSG. The rate of major complications (no deaths in either group) was 9.4% in the gastric bypass group compared to 5.8% in the LSG group (p=0.29). Minor complications were more common in the gastric bypass group than in the LSG group (17.1% vs 7.4%, p=0.02), as were combined major and minor complications (26.5% vs 13.2%, p=0.01).

**Section Summary: Sleeve Gastrectomy**

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

**BPD With Duodenal Switch**

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

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

Prachand et al (2006) published the largest comparative study of 350 super-obese patients with BMI greater than 22.7 kg (50 lb) who underwent RYGB (n=152) or Scopinaro BPD combined with the DeMeester duodenal switch (BPD-DS) (n=198). In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The BPD-DS patients differed from RYGB patients on weight and BMI; mean weight in pounds was 167 kg (368.2 lb; range, 267.4-596.5 lb) in BPD-DS patients and 157 kg (346.3 lb; range, 239.8-504.9 lb) in the RYGB group, and mean BMI was 26.7 kg/m2 (58.8 lb; range, 50-96 lb) in BPD-DS patients versus 25.6 kg/m2 56.4 lb; range, 49.5-84.2 lb) in the RYGB group. At 1 year, data were reported for 143 BPD-DS patients and 81 RYGB patients. EWL was greater for BPD (64.1%) versus RYGB (55.9%; p<0.01), and the reduction in BMI
was also greater for BPD (10.7 kg/m² [23.6 lb]) versus RYGB (8.8 kg/m² [19.4 lb]; $p<0.001$). Complications and data on resolution of comorbidities were not reported in this study. Strain et al (2007) published a smaller comparative study of 72 patients who underwent RYGB ($n=50$) or BPD ($n=22$). Choice of surgery was by the surgeon and/or patient, and the patient populations differed by age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 10.6 kg/m² (23.3 lb) for BPD compared with 7.5 kg/m² (16.5 lb) for RYGB ($p<0.001$).(45)

The largest case series of this procedure is by Marceau et al (2009), who reported their 15-year experience with duodenal switch in 1423 patients from 1992 to 2005.(46) Follow-up evaluations were available for 97% of patients. Survival rate was 92%. After a mean of 7 years (range, 2-15 years), 92% of patients with an initial BMI of 50 kg/m² or less obtained a BMI of less than 35 kg/m², and 83% of patients with BMI greater than 50 kg/m² achieved a BMI of less than 40 kg/m². Diabetes medication was discontinued in 92% and decreased in others. Use of continuous positive airway pressure was discontinued in 92% of patients, and the prevalence of cardiac risk index greater than 5 decreased by 86%. Operative mortality was 1%, the revision rate was 0.7%, and the reversal rate was 0.2%. Revision for failure to lose sufficient weight was needed in only 1.5% of patients. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage.

**Section Summary: BPD With Duodenal Switch**

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

**BPD Without Duodenal Switch**

The available evidence on BPD-DS was reviewed in the 2006 TEC Assessment, and BPB outcomes, with or without DS, were compared with those of gastric bypass.(34) One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 year were in the same range as for gastric bypass. While these data were not sufficient to distinguish small differences in weight loss between the 2 procedures, they did not support the hypothesis that BPB resulted in greater weight loss than open gastric bypass.

Complication rates have been poorly reported in these trials. The data have suggested that mortality is low (1%) and in the same range as for open gastric bypass. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data have suggested that long-term nutritional and vitamin deficiencies occur at a high rate following BPB. Slater et al (2004) focused specifically on vitamin and calcium deficiencies following BPB.(47) They reported high rates of vitamin and calcium abnormalities in their population over a 4-year period. By year 4, 48% of patients had low calcium and 63% had low levels of vitamin D. Other fat-soluble vitamins showed similar patterns of abnormalities. Low vitamin A was found in 69% of patients at 4 years, low vitamin K in 68%, and low zinc in 50%. Dolan et al (2004) reported similar
data in a study that compared several technical variations of BPB.(48) They reported low calcium levels in 12% to 34% of patients, low vitamin D in 22.2% to 70.6%, low vitamin A in 53% to 67%, and low vitamin K in 44% to 59%. In addition, this study reported high rates of iron deficiency (11%-47%) and anemia (11%-40%).

Skroubis et al (2006) randomized 130 patients with a BMI of 35 to 50 kg/m² to RYGB or BPB without duodenal switch using a variant of BPB that included Roux-en-Y gastrectomy in place of SG.(49) All patients were followed for at least 2 years. Weight loss outcomes were superior for the BPD group at every interval examined up to 2 years. EWL at 1 year was 73.7% for RYGB and 83.1% for BPD (p<0.001); at 3 years, EWL was 72.6% for RYGB and 83.1% for BPD (p<0.001). There were more early complications in the RYGB group, but this difference was not statistically significant (6 complications vs 1, respectively; p=0.12). Late complications also did not differ significantly between the RYGB group (16 complications) and BPD groups (22 complications; p=0.46).

Numerous clinical series of BPB have been published but high-quality trials directly comparing outcomes of this procedure with gastric bypass are lacking. The largest experience with BPB (total N=1217 patients) was reported by Scopinaro et al (1996), who developed the procedure.(50) With follow-up of up to 9 years, the authors reported a durable EWL of 75%, suggesting that weight loss is greater with this procedure than with gastric restrictive procedures. In addition, most patients reported disappearance or improvement of complications such as OSA, 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 could require inpatient treatment with total parenteral nutrition. To address protein malnutrition, 4% of patients underwent reoperation to elongate the common limb (thus increasing protein absorption) or to have the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity and, presumably, patient eating habits, with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients were encouraged to maintain an oral calcium intake of 2 g/d, with monthly vitamin D supplementation.

**Section Summary: Biliopancreatic Bypass Without Duodenal Switch**

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

VBG is a purely restrictive procedure that has been replaced by LAGB or SG. Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50%.(51,52)

A small body of literature has compared outcomes between VBG and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study (1990), randomized 310 morbidly obese patients to gastric bypass, VBG, or horizontal gastroplasty.(53) The percentage of patients with greater than 50% EWL at 3-year follow-up was 67% for gastric bypass, 48% for VBG, and 17% for horizontal gastroplasty (p<0.001). There were no demonstrable differences in adverse events across groups. A second, smaller RCT by Sugerman et al (1987) randomized 40 patients to receive a VBG or a gastric bypass procedure.(54) 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 37% of excess weight.

A number of other nonrandomized, comparative studies of open gastric bypass versus VBG were included in the 2003 TEC Assessment (N=8 studies, total N=3470 patients).(31) All 8 studies reported greater amounts of weight loss with open gastric bypass. These studies reported a 44% to 70% improvement in total weight loss, a 28% to 43% improvement in the percent EWL, and 19% to 36% more patients with more than 50% EWL for those undergoing gastric bypass compared with VBG. Comparison of adverse events was difficult, because the data did not permit rigorous assessment. Nevertheless, the data suggested that the mortality rate for both surgeries was low overall. Serious perioperative adverse events were also infrequently reported, but somewhat higher for gastric bypass. Long-term adverse events were inconsistently reported, although it appeared that revision rates were higher for VBG.

Relatively high rates of complications, revisions, and reoperations led to the abandonment of VBG as a bariatric surgery procedure in the United States. An example of these results is a large case series with long-term follow-up by MacLean et al (1990), who reported on 201 patients undergoing VBG followed for a minimum of 2 years.(55) 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 (2014) conducted a systematic review of studies reporting greater than 10-year follow-up for VBG, which included 3 studies with extractable data.(56) Mean EWL was 61.4% from baseline to follow-up in the 3 studies, but reviewers noted a lack of long-term evidence related to outcomes following VBG.
**Section Summary: Vertical-Banded Gastroplasty**

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

**Two-Stage Bariatric Surgery Procedures**

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

The evidence on 2-stage procedures consists of case series of patients undergoing SG as the initial procedure. Many of these case series do not report on the second-stage surgery and, in those that do, only a minority of patients undergoing first-stage surgery proceed to second-stage surgery. For example, Cottam et al (2006) reported on 126 patients with a mean BMI of 65 kg/m² who underwent LSG as the first portion of a planned 2-stage procedure. The incidence of major perioperative complications for LSG was 13%. After 1 year, mean EWL was 46%. Thirty-six (29%) patients proceeded to the second-stage procedure, which was laparoscopic gastric bypass. The incidence of major complications following the second procedure was 8%. In a similar study, Alexandrou et al (2012) reported on 41 patients who underwent SG as the first-stage of a planned 2-stage procedure. After 1-year follow-up, 12 (29%) patients achieved a BMI of less than 35 kg/m² and were ineligible for the second-stage procedure. Of the remaining 28 patients, 10 (24%) underwent the second-stage procedure. The remaining 18 (44%) patients were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al (2009) described the complication rates in 87 patients who underwent a stage I SG followed by BPD in 27 patients. For the first stage, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, 29.6% had major complications, including bleeding, duodenoileal stenosis, and rhabdomyolysis.

This evidence does not indicate whether a 2-stage bariatric surgery procedure improves outcomes for patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced by this approach. Most patients who receive SG as the initial procedure lose sufficient weight during the first year that a second procedure is no longer indicated. In addition, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is likely that overall complications are increased by this approach.
Section Summary: Two-Stage Procedures
There is a lack of evidence indicating whether 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. Case series have shown a relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages.

Laparoscopic Gastric Plication
Laparoscopic gastric plication is a bariatric 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 requires 2 main steps—mobilization of the greater curvature of the stomach and suture plication of the stomach for achieving gastric restriction—but specific techniques are not standardized.

In 2014, Ji et al reported a systematic review of 14 studies reporting outcomes after laparoscopic gastric plication.(60) Reviewers included 1 nonrandomized matched cohort analysis, 10 uncontrolled case series, and 3 case reports (total N=1450 patients). The nonrandomized cohort study was small (N=19). The largest study, by Talebpour et al (2012), included 800 patients enrolled over 12 years at a single institution where the technique was developed.(61) Only 3 studies identified included more than 100 patients. The longest follow-up was to 120 months in the Talebpour study; other studies that provided follow-up reported to 24 months (2 studies), 18 months (2 studies), or 12 months (9 studies). Mean preoperative BMI ranged from 31.2 to 44.5 kg/m². Mean percent EWL after the procedure was reported in 9 studies (n=1407 patients), and ranged from 31.8% to 74.4% at follow-up times ranging from 6 to 24 months. One study reported weight loss in terms of percent decrease in BMI, with a reported decrease at 6 and 12 months of 66.4% and 60.2%, respectively. One study compared anterior plication and greater curvature plication, and reported increased weight loss with greater curvature plication (percent EWL, 53.7% vs 23.3%, respectively). Reporting of complications was heterogeneous across studies, but no deaths were reported and the rate of major postoperative complications requiring reoperation ranged from 0% to 15.4% (average, 3.7%), most commonly due to gastric obstruction or gastric preformation. Surgical techniques were not standardized. Reviewers concluded that laparoscopic gastric plication was a promising treatment for obesity, but available evidence was limited by small study size, lack of randomized trials comparing the technique with established bariatric surgery techniques, and little medium- to long-term follow-up data.

In a 2012 systematic review, Abdelbaki et al summarized outcomes from 7 studies of laparoscopic gastric plication, 2 of which enrolled more than 100 patients (total N=307 patients).(62) At 6-month follow-up, EWL ranged from 28.4% to 54% for the 5 studies reporting weight loss outcomes. All studies reported some incidence of nausea and vomiting, most of which was mild. Twenty (6.5%) patients were readmitted, of whom 14 (4.6%) patients required reoperation, most commonly for gastric obstruction (8/14 [57%]).
In 2013, Pattanshetti et al published results of a study that described the evolution of a LAGB plication procedure, a hybrid procedure involving both AGB and greater curvature plication developed by the authors.\(^{(63)}\) Eighty patients were included, with a baseline mean BMI of 38.05 kg/m\(^2\). At 6, 12, 18, and 24 months postsurgery, mean percent EWL was 42.6\%, 56.4\%, 57.6\%, and 65.8\%, respectively. Five postoperative complications required reoperation.

**Section Summary: Laparoscopic Gastric Plication**
There is a shortage of comparative studies, especially RCTs, comparing the safety and efficacy of laparoscopic gastric plication to other bariatric surgery procedures. A 2014 systematic review identified only 1 small comparative study, which was not randomized.

**Single Anastomosis Duodenoileal Bypass With SG**
No controlled trials of single anastomosis duodenoileal bypass with SG were identified. Some case series have reported on weight loss and other clinical outcomes up to 5 years postsurgery. One larger series was published in 2015 and reported on 97 patients with obesity and T2D.\(^{(64)}\) The authors reported that control of diabetes, defined as a hemoglobin A1c (HbA1c) levels less than 6.0\%, was achieved by between 70\% and 84\% of patients at different time points. Remission rates were higher for patients on oral therapy than those on insulin, and were higher in patients with a shorter duration of diabetes.

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

**Duodenojejunal Sleeve**
The EndoBarrier (GI Dynamics, Lexington, MA) is a fluoropolymer sleeve that is reversibly fixated to the duodenal bulb and extends 80 cm into the small bowel, usually terminating in the proximal jejunum. A systematic review of the effect of EndoBarrier on weight loss and diabetes control outcomes was published in 2016.\(^{(65)}\) It included 5 small RCTs (total N=235 patients; range, 18-77 patients), with follow-up ranging from 12 to 24 weeks. Comparators were diet and/or other lifestyle modifications, and 2 studies had sham controls. All studies were judged to be at high risk of bias using the Cochrane risk of bias tool.

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

The largest single trial was a multicenter RCT published in 2014; it included 77 patients with a BMI greater than 30 kg/m\(^2\) and T2D.\(^{(66)}\) Patients were treated for 6 months with EndoBarrier or medical therapy. At 6 months, the EndoBarrier was
removed and patients were followed for an additional 6 months. Thirty-eight patients were randomized to the EndoBarrier group and 31 (82%) of 38 completed 12 months of treatment. Thirty-nine patients were randomized to medical treatment and 35 (90%) of 39 completed 12 months of treatment. At 6 months, the decrease in BMI was significantly greater in the EndoBarrier group than in the medical therapy group (3.3 kg/m² vs 1.8 kg/m², p<0.05), and at 12 months the difference in BMI was of marginal statistical significance (2.2 kg/m² vs 1.3 kg/m², p=0.06), respectively. HbA1c level was significantly lower in the EndoBarrier group at 6 months (7.0% vs 7.9%, p<0.05), but at 12 months the difference between groups did not differ significantly (7.3% vs 8.0%, p=0.95).

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

**Intragastric Balloon Devices**
Intragastric balloon (IGB) devices are placed in the stomach using an endoscope or swallowing to act as space-occupying devices to induce satiety. As of 2015, 2 gastric balloon devices have FDA approval; both are designed to stay in the stomach for no more than 6 months. The ReShape Duo is a saline-inflated dual-balloon system and the OBERA Intragastric Balloon System (previously marketed outside of the United States as BioEnterics) is a saline-inflated silicone balloon.

**Systematic Reviews**
Several systematic reviews of RCTs evaluating IGB devices for the treatment of obesity have been published; none was limited to FDA-approved devices.(67-69) Most recently, in 2017, Saber et al identified 20 RCTs reporting weight loss outcomes after IGB implantation or a non-IGB control intervention.(67) IGB was compared with sham in 15 trials, behavioral modification in 4 trials, and pharmacotherapy in 1 trial. In 17 trials, patients received lifestyle therapy in addition to other interventions. Studies were published between 1987 and 2015 and sample sizes varied from 21 to 326 participants. Outcomes were reported between 3 and 6 months. In a meta-analysis of 7 RCTs reporting BMI loss as an outcome, there was a significantly greater BMI loss in the IGB group compared with the control group (mean effect size [ES], 1.59 kg/m²; 95% CI, -0.84 to 4.03 kg/m²; p<0.001). Findings on other outcomes were similar. A meta-analysis of 4 studies reporting percent EWL favored the IGB group (ES=14.25%; 95% CI, 2.09% to 26.4%; p=0.02). In addition, a meta-analysis of 6 studies reporting absolute weight loss favored the IGB group (ES=4.6 kg; 95% CI, 1.6 to 7.6 kg; p=0.003).

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

**Randomized Controlled Trials**

Pivotal trials on both FDA-approved devices have been published. In 2015, Ponce et al published a multicenter sham-controlled double-blinded trial evaluating the ReShape Duo intragastric balloon. (70) A total of 326 patients were randomized to 6 months of treatment with an IGB plus lifestyle therapy (n=187) or a sham device plus lifestyle therapy (n=126). Patients in the control group were given the option of active IGB treatment at 6 months. Key eligibility criteria were age 21 to 60 years, baseline BMI between 30 and 40 kg/m2, 1 or more obesity-related comorbidities, and failure to lose sufficient weight in the past 36 months in a medically supervised weight loss program. A total of 176 IGB and 126 control patients (90% of the randomized population) completed the initial 6 month treatment and were included in the primary end point analysis. After 6 months, 77 patients in the control group opted to receive an IGB; these patients were also included in the IGB safety analysis.

Coprimary effectiveness outcomes, assessed at 6 months, were mean percent EWL and having at least 35% of patients in the IGB group achieving at least a 25% EWL. Both primary effectiveness outcomes were met. In the intention-to-treat (ITT) analysis, the mean percent EWL at 6 months was 25.1 in the IGB group and 11.3 in the control group (p=0.004). The proportion of patients who achieved at least a 25% EWL was 48.8%, with a lower confidence bound of 41.6%. Most adverse events were anticipated accommodative symptoms (eg, nausea, vomiting, abdominal pain), which generally resolved after 3 to 7 days; they were severe in 1% to 2% of patients and were successfully treated. Most device-related serious adverse events (75% [21/28]) were emergency department visits for treatment of accommodate symptoms. There were no deaths, intestinal obstructions, gastric perforations, or device migrations.

In 2017, Courcoulas et al published a multicenter, pivotal RCT evaluating the Obera IGB in the United States (as noted, the device has been used in other countries). (71) A total of 317 patients were randomized and initiated 6 months of treatment with an IGB plus lifestyle therapy (n=137) or lifestyle therapy only (n=136). Patients were followed for an additional 6 months. Key eligibility criteria were age 18 to 65 years, baseline BMI between 30 and 40 kg/m2, a history of obesity for at least 2 years, and having failed previous weight loss attempts. Nineteen patients in the IGB group and 121 in the control group completed the 6-month treatment period.

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

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

The Courcoulas et al pivotal trial was not blinded or sham-controlled; however, a double-blind sham-controlled RCT evaluating the BioEnterics gastric balloon (previous called the Obera device) was published by Genco et al in 2006.(72) This crossover trial included 32 obese patients ages 25 to 50 years with a mean BMI of 47.3 kg/m². Patients received, in random order, 3 months of an IGB and 3 months of sham. (Both groups underwent upper gastrointestinal endoscopy, but no device was placed in the sham group.) Patients who initially received the IGB had a mean BMI reduction of 5.8 kg/m² after 3 months; after crossover to sham, they had a mean additional BMI reduction of 1.1 kg/m². Patients initially in the sham group had an initial mean BMI reduction of 0.4 kg/m²; after crossover to an active device, they had a mean BMI reduction of 5.1 kg/m². The between-group difference in BMI reductions was statistically significant (p<0.001). Findings on other outcomes (mean percent EWL, mean weight loss) were similar.

Case Series
A case series of patients treated with an IGB with up to 60-month follow-up was published by Kotzampassi et al in 2012.(73) A total of 500 patients were treated with the BioEnterics IGB. Twenty-six patients did not complete the initial 6 months of treatment and another 77 patients did not comply with dietary restrictions and did not have satisfactory weight loss at 6 months. Among 352 patients with data available, BMI was 44.5 kg/m² at baseline, 35.7 kg/m² at device removal, 38.8 kg/m² 12 months after device removal, and 40.1 kg/m² 24 months after device removal. Mean percent EWL was 43.9% at device removal, 27.7% 12 months after device removal, and 17% 24 months after device removal. Among the 195 patients with available 5-year data, mean baseline BMI was 43.3 kg/m², mean BMI at device removal was 33.8 kg/m², and mean BMI at 5 years was 40.1 kg/m². Mean percent EWL at 5 years was 13.0%. Overall, patients who initially complied with 6 months of IGB device use and lost weight, slowly gained weight over time but weighed less at final follow-up than at baseline.

Section Summary: Intragastric Balloon Devices
There are RCTs on the 2 FDA-approved devices, a case series with long-term follow-up on 1 of these devices, and systematic reviews on various IGB devices. RCTs have found significantly better weight loss outcomes with IGB devices
compared with sham treatment or lifestyle therapy alone. There are some adverse 
events, mainly related to accommodation of the balloon in the stomach; in a 
minority of cases, these adverse events can be severe. One RCT followed patients 
for an additional 6 months after IGB removal and found sustained weight loss. A 
large case series with follow-up up to 5 years has suggested that patients regain 
weight over time. Additional long-term follow-up data are needed.

**Aspiration Therapy Device**

Aspiration therapy involves an FDA-approved device (AspireAssist) that allows 
patients to drain a portion of the stomach contents after meals via an implanted 
tube connected to an external skin port. One RCT has been published. The trial, by 
Thompson et al (2016), randomized 207 participants to 52 weeks of AspireAssist 
therapy plus lifestyle counseling (n=127) or lifestyle counseling alone (n=70).(74) 
Participants were between 21 and 65 years of age, with a BMI ranging from 35 to 
55 kg/m². Coprimary outcomes were mean EWL at 52 weeks and the proportion 
of patients with 25% or more EWL at 52 weeks. Investigators did a modified ITT 
analysis including all patients in the AspireAssist group who attempted tube 
placement (n=111) and all patients in the lifestyle counseling group who attended 
at least 1 therapy session (n=60). Mean EWL at 52 weeks was 31.5% in the 
AspireAssist group and 9.8% in the lifestyle counseling group. The difference 
between groups was 21.7% (95% CI, 15.3% to 28.1%), which was greater than 
the 10% difference needed to meet the a priori definition of success. The 
proportion of patients with 25% or more EWL at 52 weeks was 58.6% in the 
AspireAssist group and 22% in the lifestyle counseling group (p<0.001). Bulimia 
or binge eating disorder were exclusion criteria and, during the study, there was 
no evidence that patients developed bulimia or that devices were overused (ie, 
used >3 times a day). Most of the adverse events (ℇ90%) in the AspireAssist 
group were associated with placement of a percutaneous endoscopic gastric tube. 
All 5 serious adverse events occurred in the AspireAssist group (mild peritonitis, 
severe abdominal pain and 1 case of product malfunction). Durability of a 
treatment effect beyond 1 year was not reported.

In addition to the RCT, a 2016 case series by Noren and Forssell evaluated 
AspireAssist use by 25 obese patients.(75) Patients had 1 year of aspiration 
therapy and also participated in a cognitive-behavioral therapy weight loss 
program for the initial 3 months. Patients were instructed to aspirate 3 times a 
day after meals. Twenty (80%) patients completed the 1-year intervention period. 
Mean baseline weight was 107.4 kg. In a per protocol analysis, the mean EWL 
was 54.5% at 12 months. Data on 15 (60%) patients were available at 24 
months; mean EWL was 61.5%.

**Section Summary: Aspiration Therapy Device**

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

**REVISION BARIATRIC SURGERY**

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of comorbidities with somewhat higher complication rates than with primary surgery.

In 2015, Sudan et al reported safety and efficacy outcomes for reoperative bariatric surgeries using data from a national registry, the Bariatric Outcomes Longitudinal Database (BOLD). The BOLD is a large, multi-institutional bariatric surgery–specific database to which data were submitted from June 2007 through March 2012 by 1029 surgeons and 709 hospitals participating in the Bariatric Surgery Centers of Excellence (BSCOE) program. Surgeries were classified as primary or reoperative bariatric. Reoperations were further divided into corrective surgeries (when complications or incomplete treatment effect of a previous bariatric operation was addressed but the initial operation was not changed) or conversions (when an index bariatric operation was changed to a different type of bariatric operation or a reversal restored original anatomy.) Of 449,473 bariatric operations in the database, 420,753 (93.6%) operations had no further reoperations (primary operations) while 28,270 (6.3%) underwent reoperations. Of the reoperations, 19,970 (69.5%) were corrective and 8750 (30.5%) were conversions. The primary bariatric operations were RYGBP (n=204,705 [49.1%]), AGB (n=153,142 [36.5%]), SG (n=42,178 [10%]), and BPD-DS (n=4260 [1%]), with the rest classified as miscellaneous. AGB was the most common primary surgery among conversions (57.5% of conversions; most often [63.5%] to RYGBP). Compared with primary operations, mean hospital length of stay was longer for corrections (2.04 days vs 1.8 days, p<0.001) and for conversions (2.86 days vs 1.8 days, p<0.001). Mean percent EWL at 1 year was 43.5% after primary operation, 39.3% after conversions, and 35.9% after corrective operations (statistical comparison not reported). One-year mortality was higher for conversions (0.31%) than for primary surgeries (0.17%; p<0.001), but not for corrections (0.24%) compared with primary surgeries (0.17%; p=NS). One-year serious adverse event rates were higher for conversions (3.61%) than for primary operations (1.87%; p<0.001), but not for corrections (1.9%) compared with primary operations (1.87%; p=NS). The authors concluded that reoperation after primary bariatric surgery is relatively uncommon, but generally safe and efficacious when it occurs.

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

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

**Endoscopic Revision Procedures**

While bariatric surgery revision/correction can be conducted using standard surgical approaches, novel endoscopic procedures are being developed. Some procedures use devices also being evaluated for endoscopic treatment of GERD (see evidence review 2.01.38). The published data on use of these devices for treatment of regained weight is 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).(78) Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron et al (2008) reported on a feasibility study in animals.(79) Thompson et al (2006) reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who regained weight and had dilated gastrojejunal anastomoses after RYGB.(80) 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 StomaphyX device compared with a sham procedure for revisions in patients with prior weight loss after RYGBP at least 2 years earlier.(81) Enrollment was initially planned for 120 patients, but the trial was stopped prematurely after 1-year follow-up was completed by 45 patients in the StomaphyX group and 29 patients in the sham control group because preliminary analysis failed to achieve the primary efficacy end point in at least 50% of StomaphyX patients. The primary 12-month efficacy end point (reduction in pre-RYGBP excess weight by ≥15%, excess BMI loss, and BMI <35 kg/m2) was achieved by 10 (22.2%) of 45 in the StomaphyX group and 1 (3.4%) of 29 in the sham control group (p<0.01).

A survey of ASMBS members (bariatric surgeons) indicated different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures.(82) 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 2013 systematic review of studies reporting outcomes after endoluminal revision of primary bariatric surgery conducted by ASMBS 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.”(83)

**Section Summary: Revision Bariatric Surgery**

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

**BARIATRIC SURGERY AS A TREATMENT FOR T2D**

Current indications for bariatric surgery view poorly or uncontrolled diabetes as a comorbidity whose presence supports the need for surgery in patients with a BMI of 35 to 40 kg/m². There also is growing interest in gastrointestinal surgery to treat patients with T2D in patients with lower BMI. This section focuses on RCTs and systematic reviews of RCTs comparing bariatric surgery with medical therapy.

**T2D and BMI 30 to 34.9 kg/m²**

In 2016, Wu et al published a meta-analysis of studies on bariatric surgery versus nonsurgical interventions for patients with T2D.(84) Eight RCTs with 619 patients were included. RCTs addressed RYGBP (6 studies), LAGB (3 studies), LSG (1 study), and BPD (1 study). Mean BMI in the studies was 29 kg/m² or higher; in 6 of 8 studies, mean BMI was 35 kg/m² or higher. One study had 5-year follow-up and the others had 1 to 3 years of follow-up. The study with 5-year follow-up, by Mingrone et al (2015), was limited to patients with a BMI of at least 35 kg/m².(85) All 8 studies reported remission of T2D as an efficacy endpoint. A pooled analysis found a significantly higher rate of T2D remission in the bariatric surgery versus the nonsurgical treatment group (RR=5.76; 95% CI, 3.15 to 10.55; p<0.001). Another diabetes-related outcome (mean reduction in HbA1c levels) was significantly greater after bariatric surgery than nonsurgical treatment (MD = -1.29; 95% CI, -1.70 to -0.87). In addition, there was a significantly greater reduction in BMI with bariatric surgery than with nonsurgical treatment (MD = -5.80; 95% CI, -6.95 to -4.64; p<0.001).

Since publication of the Wu meta-analysis, in 2017, 5-year follow-up has been reported for the Schauer et al RCT. When the Wu et al meta-analysis was published, only 3 year findings of the Schauer study were available. The study included patients with T2d who had BMI 27-43 kg/m². The RCTs evaluating bariatric surgery in patients with T2D, including the 5-year follow-up of the Schauer study, are summarized in Table 3.

Observational studies evaluating patients undergoing bariatric surgery in patients with T2D with follow up to 3 or more years are shown in Table 4.

Muller-Stich et al (2015) published a systematic review of RCTs and observational studies on bariatric surgery in patients with T2D and a BMI less than 35 kg/m².(86) Eleven comparative trials of medical therapy versus bariatric surgery were included, with 5 RCTs and 6 nonrandomized comparative studies identified.
Follow-up was between 1 and 3 years. The primary outcome reported was remission of diabetes. On combined analysis, bariatric surgery was associated with a higher remission rate than medical therapy (OR=14.1; 95% CI, 6.7 to 29.9; \( p<0.001 \)). On secondary outcomes, surgery was associated with a greater decrease in BMI (MD = -5.5 kg/m²; 95% CI, -6.7 to -4.3 kg/m², \( p<0.001 \)), a lower HbA1c level (MD = -1.4%; 95% CI, -1.9% to -0.9%; \( p<0.001 \)), lower rates of hypertension (OR=0.25; 95% CI, 0.12 to 0.50; \( p<0.001 \)), and lower rates of dyslipidemia (OR=0.21; 95% CI, 0.10 to 0.44; \( p<0.001 \)).

Also in 2015, Rao et al published a meta-analysis of short-term outcomes for patients with T2D and a BMI of 35 kg/m² or less who underwent RYGBP.(87) Nine articles were included (total N=343 patients). After 12 months, patients with T2D had a significant decrease in BMI (weighted mean difference [WMD], -7.42; 95% CI, -8.87 to -5.97; \( p<0.001 \)) and improvements in HbA1c levels (WMD = -2.76; 95% CI, -3.41 to -2.11; \( p<0.000 \)). Reviewers reported that longer term follow-up would be needed.

Previously, a 2012 TEC Assessment evaluated bariatric surgery in diabetic patients with a BMI less than 35 kg/m².(88) The evidence consisted mainly of case series. The Assessment identified only observational studies. Based on the data, the Assessment concluded that gastric bypass met TEC criteria as a treatment for diabetes in patients with a BMI less than 35 kg/m² but that other procedures did not meet the TEC criteria for this indication:

- There were no randomized trials comparing bariatric surgery to medical treatment for diabetic subjects with a BMI less than 35 kg/m². There was only 1 randomized trial comparing 2 bariatric procedures. Therefore, studies were categorized by procedure type and presented as case series, regardless of the underlying study type.
- Nine studies reported diabetes remission rates and other outcomes in subjects undergoing gastric bypass. Diabetes remission rates varied between 48% and 100% at follow-up times of 1 year and beyond. One study was a randomized clinical trial of gastric bypass versus SG; in it, diabetes remission associated with gastric bypass was 93% versus 47% for SG at 1 year.
- Two studies reported outcomes of SG. Diabetes remission rates were 55% and 47% at 1 year.
- One study reported outcomes of ileal interposition. The diabetes remission rate at a mean follow-up time of 39.1 months was 78.3%.
- Two studies reported outcomes of gastric banding. The outcomes reported were not considered to be rigorous, because the only measure of diabetes outcome was withdrawal of diabetes medication. Reported remission rates were 27.5% and 50% at variable follow-up times.
- One study of BPD reported a remission rate of 67% for subjects with a BMI between 30 and 35 kg/m² and 27% for subjects with a BMI between 25 and 30 kg/m² at 12-month follow-up.
- One study reported outcomes of duodenojejunal exclusion. Subjects in this study had more severe diabetes than subjects enrolled in other studies; 100%
were on insulin treatment and the duration of diabetes was between 5 and 15 years. The diabetes remission rate was 17% at 6 months.

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

Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for T2D in obese patients, including those with a BMI between 30 and 34.9 kg/m². The greatest amount of evidence is on gastric bypass, with some comparative studies also on LAGB, LSG, and BPD. Systematic reviews have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most of the RCTs in this population have 1 to 3 years of follow-up; 1 RCT that included patients with BMI between 30 and 34.9 kg/m² had 5 year follow-up data.

### Table 3. RCTsa Comparing Bariatric Surgery in Patients With T2D to Control

<table>
<thead>
<tr>
<th>Study (Country)</th>
<th>N</th>
<th>BMI Range, kg/m²</th>
<th>Patients With BMI ≤35 kg/m²</th>
<th>Length of FU, years</th>
<th>Definition Diabetes Remission</th>
<th>Diabetes Remission Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery (LAGB)</td>
<td>Dixon et al (2008)</td>
<td>60</td>
<td>30-40</td>
<td>Control (ILI/A1C-R)</td>
<td>22%</td>
<td>2</td>
</tr>
<tr>
<td>Surgery (RYGB)</td>
<td>Ikramuddin et al (2015)</td>
<td>120</td>
<td>30-40</td>
<td>Control (HILI/A1C-R)</td>
<td>59%</td>
<td>2</td>
</tr>
<tr>
<td>Surgery (RYGB)</td>
<td>Liang et al (2013)</td>
<td>91</td>
<td>&gt;28</td>
<td>Control1 (GCP/A1C-R)</td>
<td>T2D remission</td>
<td>28/31 (90%)</td>
</tr>
<tr>
<td>Surgery (RYGB)</td>
<td>Courcoulas et al (2015)</td>
<td>61</td>
<td>30-40</td>
<td>LABG</td>
<td>43%</td>
<td>3</td>
</tr>
<tr>
<td>Surgery (RYGB)</td>
<td>Schauer et al (2017)</td>
<td>150</td>
<td>27-43</td>
<td>LSG</td>
<td>37%</td>
<td>5</td>
</tr>
<tr>
<td>Surgery (LAGB)</td>
<td>Wentworth et al (2014)</td>
<td>51</td>
<td>25-30</td>
<td>BPD</td>
<td>35+</td>
<td>0%</td>
</tr>
<tr>
<td>Surgery (RYGB)</td>
<td>Halperin et al (2014)</td>
<td>43</td>
<td>30-42</td>
<td>Control (ILI/A1C-S)</td>
<td>30%</td>
<td>1</td>
</tr>
</tbody>
</table>

a All RCTs in this table are in the Wu et al (2016) meta-analysis; 7 of the 8 (except Mingrone et al) were in the Muller-Stich et al (2015) meta-analysis; the Rao et al (2015) meta-analysis and the TEC Assessment did not include RCTs. No additional RCTs comparing bariatric surgery to nonsurgical treatment in patients with type 2 diabetes were identified.
b Used secondary outcome. Primary outcome was change in left ventricular mass index.
c Unadjusted (RYGB vs control).
d Unadjusted (LSG vs control).
e RYGB vs control.
f LSG vs control. g WHO Asia-Pacific Obesity Classification. h Through February 2017.

### Table 4: Observational Studies on Bariatric Surgery in Patients With Type 2 Diabetes With Follow-Up ≥3 Years

<table>
<thead>
<tr>
<th>Study (Country)</th>
<th>N</th>
<th>BMI Range, kg/m²</th>
<th>Patients With BMI ≤35 kg/m²</th>
<th>Length of FU</th>
<th>Mean HbA1c</th>
<th>Mean BMI, kg/m²</th>
<th>Diabetes Remission Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scopinaro et al (2014) [96] (Italy)</td>
<td>20</td>
<td>30-34.9</td>
<td>100%</td>
<td>3 y</td>
<td>RYGB</td>
<td>9.5%</td>
<td>7.0%</td>
</tr>
<tr>
<td>Control Lanzarini et al (2013) [97] (Chile)</td>
<td>31</td>
<td>9.3%</td>
<td>30-35</td>
<td>100%</td>
<td>30 mo</td>
<td>RYGB</td>
<td>7.9%</td>
</tr>
<tr>
<td>Boza et al (2011) [98] (Chile)</td>
<td>30</td>
<td>&lt;35</td>
<td>100%</td>
<td>2 y</td>
<td>RYGB</td>
<td>8.1%</td>
<td>6.2%</td>
</tr>
<tr>
<td>DePaula et al (2012) [99] (Brazil)</td>
<td>202</td>
<td>&lt;35</td>
<td>100%</td>
<td>39 mo</td>
<td>SG</td>
<td>8.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td><strong>Group II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lee et al (2008) [100] (Taiwan)</td>
<td>544</td>
<td>32-77</td>
<td>Not reported</td>
<td>3 y</td>
<td>Bypass</td>
<td>6.2%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Group II LAGB</td>
<td>116</td>
<td>Not reported</td>
<td>LAGB</td>
<td>5.9%</td>
<td>5.2%</td>
<td>41.9</td>
<td>32.7</td>
</tr>
</tbody>
</table>

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

a p<0.05 (follow-up vs baseline).
b Estimated from figure.
c Mean.
BARIATRIC SURGERY IN NONDIABETIC PATIENTS WITH A BMI LESS THAN 35 KG/M2
A 2012 TEC Assessment evaluated laparoscopic gastric banding in individuals without diabetes who had a BMI less than 35 kg/m2.(101) This Assessment was prompted by FDA approval of LAP-BAND for this indication in 2011. The TEC Assessment concluded that LAGB did not meet TEC criteria in these patients and made the following summary statements:

- The evidence on LAGB for patients with lower BMIs is limited both in quantity and quality. There is only 1 small RCT, which has methodologic limitations, 1 nonrandomized comparative study based on registry data, and several case series. Using the GRADE evaluation, the quality of evidence on the comorbidity outcomes was judged to be low and the quality of the evidence on the weight loss outcomes was judged to be moderate.
- The evidence was sufficient to determine that weight loss following LAGB is greater than with nonsurgical therapy.
- Direct data on improvement in weight-related comorbidities was lacking. The limited evidence was not sufficient to conclude that the amount of weight loss is large enough that improvements in weight-related comorbidities can be assumed.
- There was very little data on quality of life in this population of patients.
- The frequency and impact of long-term complications following LAGB were uncertain, and this uncertainty has been one of the main reasons why it is difficult to determine whether the benefit of LAGB outweighs the risk for this population. While the short-term safety of LAGB has been well-established, the long-term adverse effects occur at a higher rate and are less well-defined.

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

BARIATRIC SURGERY IN MORBIDLY OBESE ADOLESCENT CHILDREN
Treadwell et al (2008) conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents.(102) 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 outcomes data for 3 or more patients ages 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on between 11 and 68 patients who were 21 years or younger. Eight studies of LAGB reported data on 352 patients (mean BMI, 45.8 kg/m2; median age range, 15.6-20 years); 6 studies on RYGB included 131 patients (mean BMI, 51.8 kg/m2; median age range, 16-17.6 years); 5 studies of other procedures included 158 patients (mean BMI, 48.8 kg/m2; 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 deaths were 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 deaths were reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 others died of causes 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.

In a 2013 systematic review of 23 studies, Black et al concluded that the available literature demonstrated a high rate of significant short-term weight loss after bariatric surgery, but that complication and comorbidity rates were not well-defined.(103) In a systematic review that included 11 studies of outcomes after LAGB in adolescents, Willcox et al (2014) found limited data on biopsychosocial outcomes.(104)

In RCT of LAGB, O’Brien et al (2010) reported on 50 adolescents between the ages of 14 and 18 years with a BMI greater than 35 kg/m2 who received a lifestyle intervention or gastric banding and were followed for 2 years.(2) Twenty-four of 25 patients in the gastric banding group and 18 of 25 in the lifestyle group completed the study. Twenty-one (84%) in the gastric banding group and 3 (12%) in the lifestyle group lost more than 50% of excess weight. Overall, mean weight loss in the gastric banding group was 34.6 kg (95% CI, 30.2 to 39.0 kg), representing an EWL of 78.8% (95% CI, 66.6% to 91.0%). Mean losses in the lifestyle group were 3.0 kg (95% CI, 2.1 to 8.1 kg), representing an EWL of 13.2% (95% CI, 2.6% to 21.0%). The gastric banding group experienced improved quality of life with no perioperative adverse events; however, 8 (33%) surgeries were required in 7 patients for revisional procedures, either for proximal pouch dilatation or tubing injury during follow-up. This trial offers evidence that, among obese adolescent participants, use of gastric banding compared with lifestyle intervention would result in a greater percentage 50% EWL.

There are many case series of bariatric surgery in adolescents, and they have generally reported weight loss in the same range seen for adults. For example, Nadler et al (2008) reported on 73 patients ages 13 to 17 years who had undergone LAGB since 2001 at the authors’ institution.(105) Mean preoperative BMI was 48 kg/m2. EWL at 6 months, 1 year, and 2 years postoperatively was
35%, 57%, and 61%, 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 ages 19 or younger.(106) The study enrolled 242 participants, with mean age 17.1 years and median BMI of 50.5 kg/m2 (IQR, 45.2-58.2 kg/m2) at the time of surgery. All patients had at least 1 obesity-related comorbidity, most commonly dyslipidemia (74%), followed by OSA (57%), back and joint pain (46%), hypertension (45%), and fatty liver disease (37%). Gastric bypass, LAGB and vertical SG were performed in 66.5%, 5.8%, and 27.7% of patients, respectively. Within 30 days of surgery, 20 major complications occurred in 19 (7.9%) patients, most of which were perioperative. The cohort is being followed to assess longer term outcomes.

**Section Summary: Bariatric Surgery in Morbidly Obese Adolescents**
The evidence on bariatric surgery in adolescents indicates that the percent of EWL is approximately the same as that in adults. There are greater concerns for developmental maturity, psychosocial status, and informed consent in adolescents. Guideline recommendations for bariatric surgery in adolescents lack uniformity, but generally correspond to the clinical selection criteria for adults and supplement these clinical selection criteria with greater attention to issues of maturity and psychosocial status.

**BARIATRIC SURGERY IN MORBIDLY OBESE PREADOLESCENT CHILDREN**
In 2013, Black et al (described above) published a systematic review of 23 studies on bariatric surgery in children and adolescents.(103) Most studies were limited to adolescents; only 2 included children less than 12 years old. One study, Silberhumer et al (2006), included 9- to 19-year-olds (mean age, 17 years); conclusions could not be drawn about the impact of bariatric surgery in this sample of preadolescent children.(107) Similarly, Alqahtani et al (2012) included children ages 5 to 21 years (mean age, 14 years) and did not provide conclusions separately for preadolescent children.(108)

Clinical practice guidelines (eg, from the Endocrine Society [2008](109) and the Institute for Clinical Systems Improvement [2013](110)) have recommended against bariatric surgery in preadolescent children.

**Section Summary: Bariatric Surgery in Morbidly Obese Preadolescent Children**
There are few published data and no studies were identified that focused on bariatric surgery in preadolescent children. Clinical guidelines recommend against bariatric surgery in preadolescent children.
HIATAL HERNIA REPAIR IN CONJUNCTION WITH BARIATRIC SURGERY

Hiatal hernia is associated with obesity and existing hiatal hernias may be worsened with bariatric surgery. In some studies, the presence of hiatal hernia has been associated with complications after LAGB,(111) although other studies have reported no differences in perioperative complications after LAGB in patients with GERD and/or hiatal hernia or those without GERD and/or hiatal hernia.(112) Hiatal hernias, either incidentally found at surgery or diagnosed preoperatively, are often repaired at the time of bariatric surgery. In 2013, the Society of American Gastrointestinal and Endoscopic Surgeons published guidelines on the management of hiatal hernia, recommending that, during operations for RYGBP, SG, and the placement of AGBs, all detected hiatal hernias should be repaired (grade of recommendation: weak; evidence quality moderate [further research is likely to alter confidence in the estimate of impact and may change the estimate]).(113)

There is limited evidence whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients with hiatal hernia who underwent repair during bariatric surgery to patients without hiatal hernia. Gulkarov et al (2008) reported results of a prospective cohort study comparing outcomes for patients who underwent LAGB with or without concurrent hiatal hernia repair (n=1298 with AGB alone; n=520 with concurrent hiatal hernia repair).(114) The authors reported 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 surgery. It was not specified how many patients were diagnosed with each method or how many of those had symptoms before gastric banding. Fewer patients who underwent concurrent hiatal hernia repair required reoperation for a complication (3.5% vs 7.9% in the AGB alone group; p<0.001). Hiatal hernia repair added an average of 14 minutes to surgical time. Weight loss outcomes did not differ significantly between groups.

Santonicola et al (2014) evaluated the effects of LSG with or without hiatal hernia repair on GERD in obese patients.(115) The study included 78 patients who underwent SG with concomitant hiatal hernia repair for a sliding hiatal hernia diagnosed intraoperatively, compared with 102 patients without hiatal hernia who underwent SG only. The prevalence of typical GERD symptoms did not improve from baseline to follow-up in patients who underwent concomitant hiatal hernia repair (38.4% presurgery vs 30.8% postsurgery, p=0.3). However, those in the SG only group had a significant decrease in the prevalence of typical GERD symptoms (39.2% presurgery vs 19.6% postsurgery, p=0.003).

Reynoso et al (2011) reported outcomes after primary and revisional LAGB in patients with hiatal hernia treated at a single hospital system.(116) Of 1637 patients with hiatal hernia undergoing primary gastric banding, 190 (11.6%) underwent concurrent hiatal hernia repair; of 181 patients undergoing revision gastric banding, 15 (8.3%) underwent concurrent hiatal hernia repair. For primary
procedures, there were no significant differences in mortality, morbidity, length of stay, and 30-day readmission rates for patients who underwent AGB with and without hiatal hernia repair. However, this compares patients with hiatal hernia undergoing repair to patients without hiatal hernia. The more relevant comparison would be comparing repair to no repair in patients who have hiatal hernia.

Ardestani et al (2014) analyzed data from the BOLD registry to compare outcomes for patients with and without hiatal hernia repair at the time of LAGB.(117) Of 41,611 patients who had LAGB from 2007 to 2010, 8120 (19.5%) had concomitant hiatal hernia repair. Those with hiatal hernia repair were more likely to have GERD preoperatively (49% vs 40% in the non–hiatal hernia repair group; p<0.001). Perioperative outcomes were similar between groups. Of those with GERD preoperatively, rates of improvement in GERD symptoms did not differ significantly at 1 year postprocedure (53% for hiatal hernia repair vs 52% for non–hiatal hernia repair; p=0.4). Although the hiatal hernia repair added minimal time (mean, 4 minutes) to surgery, the authors concluded that many repairs would have involved small hernias with limited clinical effect.

In general, studies have reported that the addition of hiatal hernia repair at the time of bariatric surgery is safe and feasible. In a small case series of 21 patients, Frezza et al (2008) described the feasibility of crural repair at the time of LAGB for patients with hiatal hernia.(118) Al-Haddad et al (2014) used data from the U.S. Nationwide Inpatient Sample to evaluate the surgical risk associated with hiatal hernia repair at the time of bariatric surgery.(119) For laparoscopic RYGB, there were 206,559 and 9060 patients who underwent the procedure alone or with concomitant hiatal hernia repair, respectively. For LAGB, 52,901 and 9893 patients, respectively, underwent the procedure alone or with hiatal hernia repair. The authors reported no evidence of increased risk of perioperative 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 RYGB and an ATT of hiatal hernia repair of -0.107 (95% CI, -0.159 to -0.0552) for PLOS for patients who underwent LAGB.

Section Summary: Hiatal Hernia Repair in Conjunction With Bariatric Surgery
Hiatal hernia repair is frequently undertaken at the time of bariatric surgery. The evidence related to whether hiatal hernia repair improves outcomes after bariatric surgery is limited, particularly for hiatal hernias that are incidentally diagnosed at the time of surgery. No studies were identified that compared outcomes after bariatric surgery with or without hiatal hernia repair in a population of patients with known hiatal hernia. For patients with a preoperative diagnosis of hiatal hernia, symptoms related to the hernia, and indications for surgical repair, it is reasonable to undertake this procedure at the time of bariatric surgery. For other patients, it is uncertain whether repair of a hiatal hernia at the time of bariatric surgery improves outcomes.
SUMMARY OF EVIDENCE
Adults With Morbid Obesity
For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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

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

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

For individuals who are adults with morbid obesity who receive BPD without duodenal switch, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status,
For individuals who are adults with morbid obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified 8 nonrandomized comparative studies evaluating VBG and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive 2-stage bariatric surgery procedures, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that 2-stage bariatric procedures improve outcomes compared with 1-stage procedures. Case series have shown relatively high complication rates in 2-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes observational studies and systematic reviews. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2014 systematic review identified only 1 small comparative study (unrandomized) comparing laparoscopic gastric plication with other bariatric surgery procedures. Additional comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

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

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

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

However, any bariatric surgery for diabetes in patients with a body mass index less than 35 kg/m² is not currently considered standard of care and is not supported in most current specialty society guidelines. Clinical input did not support the use of bariatric surgery as a stand-alone treatment for diabetes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Nondiabetic and Nonobese Adults**

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

**Adolescent Children With Morbid Obesity**

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

**Preadolescent Children With Morbid Obesity**

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

**SUPPLEMENTAL INFORMATION**

**CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS**

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

In response to the requests, input was received from 1 physician specialty societies and 2 academic medical centers on use of the REALIZE band while the policy was under review in 2008. All 3 responses supported use of the REALIZE band as a surgical option for patients, as adopted into the policy in 2008.

In response to the requests, input was received from 2 academic medical centers on the use of the new endoscopic placement of devices to remedy weight gain that occurs after bariatric surgery while the policy was under review in 2008. Input from both centers agreed that this approach is considered investigational, as adopted in the policy in 2008.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American Association of Clinical Endocrinologists et al**

In 2017, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) jointly published a comprehensive diabetes type 2 management algorithm.(120) The document states, Bariatric surgery should be considered for adult patients with a BMI of 35 kg/m² or more and comorbidities, especially if therapeutic goals have not been reached using other modalities.”
In 2016, AACE and ACE jointly published comprehensive clinical practice guidelines on medical care of patients with obesity. The guidelines addressed 9 broad clinical questions with 123 recommendations. The authors noted that the 2013 guidelines specifically on bariatric surgery (see below) were considered adequate in the current form. With regard to bariatric surgery for these guidelines, the following recommendations were added to those in the 2013 guideline:

- Recommendation 35: “Patients with obesity (BMI [body mass index] ≥30 kg/m²) and diabetes who have failed to achieve targeted clinical outcomes following treatment with lifestyle therapy and weight-loss medications may be considered for bariatric surgery, preferably Roux-en-Y gastric bypass, sleeve gastrectomy, or biliopancreatic diversion.” (Grade B; BEL 1 (best evidence level), downgraded due to evidence gaps)

- Recommendation 121. “Patients with a BMI of ≥35 kg/m² and 1 or more severe obesity-related complications, including type 2 diabetes, hypertension, obstructive sleep apnea, obesity-hypoventilation syndrome, Pickwickian syndrome, nonalcoholic fatty liver disease or nonalcoholic steatohepatitis, pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life may also be considered for a bariatric surgery procedure. Patients with BMI of 30 to 34.9 kg/m² with diabetes or metabolic syndrome may also be considered for a bariatric procedure, although current evidence is limited by the number of patients studied and lack of long-term data demonstrating net benefit.
  - BMI ≥35 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk (Grade A; BEL 1).
  - BMI ≥30 kg/m² and therapeutic target of weight control and improved biochemical markers of CVD risk (Grade B; BEL 2).
  - BMI ≥30 kg/m² and therapeutic target of glycemic control in type 2 diabetes and improved biochemical markers of CVD risk (Grade C; BEL 3).”

- Recommendation 122. “Independent of BMI criteria, there is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or CVD risk reduction alone (Grade D).”

- Recommendation 62: “Roux-en-Y gastric bypass should be considered as the bariatric surgery procedure of choice for patients with obesity and moderate to severe gastroesophageal reflux symptoms, hiatal hernia, esophagitis, or Barrett’s esophagus.” (intermediate recommendation, intermediate evidence). This recommendation also states, “Intragastric balloon for weight loss may increase gastroesophageal reflux symptoms and should not be used for weight loss in patients with established gastroesophageal reflux” (strong recommendation; strong evidence).

Joint guidelines on the bariatric surgery patient were published by AACE, the Obesity Society, and American Society for Metabolic and Bariatric Surgery (ASMBS) in 2013. Recommendations on the following questions are summarized below.
“Which patients should be offered bariatric surgery?”

- “Patients with a BMI ≥ 40 kg/m² without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for 1 of the procedures.”
- “Patients with a BMI ≥ 35 kg/m² and 1 or more severe obesity-related comorbidities.”
- “Patients with BMI of 30-34.9 kg/m² with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.”
- “There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria.”

“Which bariatric surgical procedure should be offered?”

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

**American College of Cardiology et al**

In 2013, the American College of Cardiology (ACC), American Heart Association (AHA), and the Obesity Society published joint guidelines on the management of obesity and overweight in adults.(123) The guidelines made the following recommendations related to bariatric surgery:

- “Advise adults with a BMI ≥ 40 kg/m² or BMI ≥ 35 kg/m² with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI Grade A (Strong); AHA/ACC COR [class of recommendation]: IIa; AHA/ACC LOE [level of evidence]: A”
- “For individuals with a BMI < 35 kg/m², there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade N (No Recommendation)”

**Institute for Clinical Systems Improvement**

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

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

**American Society for Metabolic and Bariatric Surgery**

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

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

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

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

The ASMBS therefore recognizes SG as an acceptable option as a primary bariatric procedure and as a first-stage procedure in high-risk patients as part of a planned staged approach.

From the current published data, SG has a risk/benefit profile that lies between LAGB and the laparoscopic RYGB [Roux-en-Y gastric bypass]. As with any bariatric procedure, long-term weight regain can occur and, in the case of SG, this could be managed effectively with reintervention. Informed consent for SG used as a primary procedure should be consistent with consent provided for other bariatric procedures and should include the risk of long-term weight gain.

Surgeons performing SG are encouraged to continue to prospectively collect and report outcome data in the peer-reviewed scientific literature.”
Society of American Gastrointestinal and Endoscopic Surgeons
In 2013, SAGES issued evidence-based guidelines for the management of hiatal hernia, which included a recommendation about repair of hiatal hernias incidentally detected at the time of bariatric surgery. These guidelines stated: “During operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired” (moderate quality evidence, weak recommendation).

Guidelines for Children and Adolescents

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

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

Less strong indications:
- Cardiovascular disease
- Metabolic syndrome

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

European Society for Gastroenterology, Hepatology and Nutrition et al
A joint position paper published by the European Society for Gastroenterology, Hepatology and Nutrition and the North American Society for Gastroenterology, Hepatology and Nutrition in 2015 made the following recommendations on indications for bariatric surgery in adolescents:

“BMI > 40 kg/m2 with severe comorbidities
- Type 2 diabetes mellitus
- Moderate-to-severe sleep apnea
- Pseudotumor cerebri
- NASH [nonalcoholic steatohepatitis] with advanced fibrosis (ISHAK score > 1)

BMI > 50 kg/m2 with mild comorbidities
- Hypertension
- Dyslipidemia
Mild obstructive sleep apnea
Chronic venous insufficiency
Panniculitis
Urinary incontinence
Impairment in activities of daily living
NASH
Gastroesophageal reflux disease
Severe psychological distress
Arthropathies related to weight"

Additional criteria included:

“Have attained 95% of adult stature

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

**Endocrine Society**
The Endocrine Society published recommendations on the prevention and treatment of pediatric obesity in 2008. These guidelines recommended the following (109):

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

1. The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
2. The child has a BMI > 50 kg/m2 or has BMI above 40 kg/m2 and significant, severe comorbidities.
3. Severe obesity and comorbidities persist, despite a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
4. Psychological evaluation confirms the stability and competence of the family unit.
5. 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.
6. The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

We recommend against bariatric surgery for preadolescent children, for pregnant or breast-feeding adolescents, and for those planning to become pregnant within 2 yr 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.”

**Institute for Clinical Systems Improvement**
In 2013, ICSI published guidelines on the prevention and management of obesity in children and adolescents.(110) The guidelines stated that there is limited long-term efficacy and safety data on bariatric surgery for the pediatric population, and that bariatric surgery should only be considered under the following conditions:

- “The child has a BMI > 40 kg/m2 or has BMI above 35 kg/m2 with a significant, severe comorbidities such as type 2 diabetes mellitus, obstructive sleep apnea, or pseudotumor cerebri.”
- “The child has attained Tanner 4 or 5 pubertal development or has a bone age ≥13 years in girls or ≥15 years in boys.”
- “Failure of ≥6 months of organized attempts at weight management....”
- “The adolescent should have decisional capacity and also demonstrate commitment to comprehensive medical and psychological evaluation before and after surgery.”
- “A supportive family environment....”

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**
Not applicable.

**MEDICARE NATIONAL COVERAGE**
The Centers for Medicare and Medicaid Services (CMS) published a national coverage decision on bariatric surgery.(128) CMS 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) ≥35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.”

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**
Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

<table>
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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<tr>
<td>NCT02741674</td>
<td>National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study</td>
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<td>NCT02881684a</td>
<td>Weight Reduction by Aspiration Therapy in Asian Patients with Morbid Obesity</td>
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<td>Dec 2018</td>
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<tr>
<td>NCT01766037a</td>
<td>Pivotal Aspiration Therapy with Adjusted Lifestyle Therapy Study</td>
<td>171</td>
<td>Jun 2019</td>
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<tr>
<td>NCT02142257</td>
<td>Gastric Bypass Procedure and AspireAssist</td>
<td>100</td>
<td>May 2020</td>
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</tbody>
</table>
Aspiration Therapy System for the Treatment of Morbid Obesity, Observational Study over 5 Years

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

References:


44. Prachand VN, Davee RT, Alverdy JC. Duodenal switch provides superior weight loss in the super-obese (BMI > or =50 kg/m2) compared with gastric bypass. Ann Surg. Oct 2006;244(4):611-619. PMID 16998370


88. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Bariatric Surgery In Patients With Diabetes And Body Mass Index Less Than 35 kg/m² *TEC Assessments.* 2012;Volume 27:Tab 2. PMID


101. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Laparoscopic adjustable gastric banding in patients with body mass index less than 35 kg/m² with weight-related comorbidity. *TEC Assessments.* 2012;Volume 27:Tab 3. PMID


<table>
<thead>
<tr>
<th>Billing Coding/Physician Documentation Information</th>
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<tbody>
<tr>
<td>S2083 Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline</td>
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<tr>
<td>43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
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<tr>
<td>43645 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
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<td>43659 Unlisted laparoscopy procedure, stomach</td>
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<tr>
<td>43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)</td>
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<tr>
<td>43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only</td>
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<tr>
<td>43772 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only</td>
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<tr>
<td>43773 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only</td>
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<tr>
<td>43774 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components</td>
</tr>
<tr>
<td>43775 Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)</td>
</tr>
<tr>
<td>43842 Gastric restrictive procedure, without gastric bypass for morbid obesity vertical banded gastroplasty</td>
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</tbody>
</table>
Gastric restrictive procedure, with gastric bypass for morbid obesity; other than vertical banded gastroplasty

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)

Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb Roux-en-Y gastroenterostomy

Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption

Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)

Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy

Gastric restrictive procedure, open; revision of subcutaneous port component only

Gastric restrictive procedure, open; removal of subcutaneous port component only

Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

ICD-10 Codes

E66.01 Morbid obesity
E66.2 Morbid obesity with alveolar hypoventilation
K91.0- Postprocedural complications and disorders of digestive system, code range
K91.3
K95.01, Complications of gastric band procedure, code range
K95.09
K95.81, Complications of other bariatric procedure, code range
K95.89

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/1/88 New policy. Gastric bypass with anastomosis (Roux-en-Y procedure only) and Gastric Stapling (aka vertically banded gastroplasty) may be considered medically necessary. Other procedures are investigational.

8/1/00 No policy statement changes.

8/1/01 Policy statement revised to clarify that open or laparoscopic Roux-en-Y or Gastric Stapling may be considered medically necessary.

8/1/02 No policy statement changes.

8/1/03 No policy statement changes.

2/1/04 No policy statement changes.

8/1/04 Policy statement revised to indicate laparoscopic approach to Roux-en-Y and Gastric Stapling are considered investigational. Open approach may still be considered medically necessary.
2/1/05  No policy statement changes.  Coding changes only
9/1/05  No policy statement changes.
1/1/06  Policy statement revised to indicate laparoscopic Roux-en-Y gastroenterostomy may be considered medically necessary.
8/1/06  No policy statement changes.
12/1/06  Policy statement revised to indicate that adjustable gastric banding can be considered for those needing bariatric surgery.  Policy statement revised to include discussion regarding sleeve gastrectomy (considered investigational).
2/1/07  No policy statement changes.  Policy considerations and rationale updated.
8/1/07  No policy statement changes.
12/1/07  Added NIH BMI categories.
8/1/08  Policy statement added that endoscopic procedures for those who regain weight are investigational.  Policy statement added to clarify bariatric surgery for adolescents is considered investigational.
12/1/08  Considerations section updated with definition of morbid obesity and comorbidities.  Sample benefit language was added.
8/1/09  Policy statement added which states that this surgery is investigational as a cure for type 2 diabetes mellitus; statement added that biliopancreatic diversion with duodenal switch may be considered medically necessary; Policy re-titled “Bariatric Surgery.”  Policy considerations section updated related to indications for surgery in adolescents.  Sample benefit language was removed from the Considerations section.  The Considerations section was also updated to further clarify obesity associated/comorbid complications.
1/1/10  Coding updated.
8/1/10  Policy statement added that revision surgery may be considered medically necessary in specific situations, statement on endoluminal/endoscopic bariatric procedures modified to indicate investigational as both primary and revision procedure.  The Considerations section was updated to outline specific criteria that must be met prior to bariatric surgery.  The BCBSKC Bariatric Surgery Questionnaire was included at the end of the policy.
8/1/11  Policy statement on sleeve gastrectomy changed to may be medically necessary.
8/1/12  No policy statement changes.  Considerations section clarified regarding conservative treatment and patient selection.
8/1/13  Vertical banded gastroplasty removed from list of medically necessary procedures; two-stage procedures added as investigational; policy statement added regarding bariatric surgery in adolescents as medically necessary with special considerations towards psychosocial and informed consent issues.
3/1/14  Language added to policy statement on revision surgery to include complications of laparoscopic adjustable gastric banding.
12/1/14  Laparoscopic gastric plication added to list of investigational procedures.  Statement added related to the repair of incidentally identified hiatal hernias.  Statement on bariatric surgery in patients with BMI<35
changed from investigational to not medically necessary.
12/1/15  No policy statement changes.
3/1/16   No policy statement changes.
12/1/16  No policy statement changes.
6/1/17   Added new investigational statement: Bariatric surgery is considered investigational for the treatment of morbid obesity in preadolescent children.
12/1/17  Added Type 1 diabetes to comorbidities.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.
Blue Cross and Blue Shield of Kansas City Bariatric Surgery Questionnaire

Patient’s Name: ____________________________________________________________
BSBCKC ID #: ___________________________________________________________
Requested Facility for Procedure: ____________________________________________

Procedure Requested:
☐ Laparoscopic Gastric Banding (Lap-band)
☐ Laparoscopic Roux-En Y Gastric Bypass
☐ Open Roux-En Y Gastric Bypass
☐ Vertical Sleeve Gastrectomy
☐ Other – Please specify: _________________________________________________

Name and address of physician referring the patient for bariatric surgery:
_____________________________________________________________________
_____________________________________________________________________

Female Patients:
LMP: _________________________________________________________________
Last Pregnancy: __________________________________________________________
Date of delivery: _________________________________________________________

Psychological Consult:
Name of psychiatrist/psychologist: __________________________________________
Date of evaluation for bariatric surgery: _____________________________________
Please submit a copy of the evaluation completed by the psychiatrist/psychologist.

Dietary Consult:
Name of provider: _________________________________________________________
Please submit a copy of the evaluation, diet/nutrition plan and office notes

Exercise Regimen:
Name of exercise therapist: _________________________________________________
Date of evaluation: _________________________________________________________
Name of pulmonologist: _____________________________________________________
Please include a copy of the evaluation and progress reports.
**Surgical History:**
(Please list all past operations or surgeries)

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**Medical History:**
(check all that apply and indicate the year diagnosed)

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<tr>
<td>Heartburn/Reflux</td>
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<tr>
<td>Hepatitis</td>
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<tr>
<td>Hiatal hernia</td>
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<tr>
<td>High blood pressure</td>
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<td>High cholesterol</td>
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<td>High triglycerides</td>
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<td>Hyperthyroid</td>
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<td>Hypothyroid</td>
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<td>IVC filter</td>
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<tr>
<td>Lupus</td>
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<tr>
<td>Myocardial infarction (heart attack)</td>
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<tr>
<td>Palpitations</td>
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<tr>
<td>Pneumonia</td>
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<tr>
<td>Psychiatric disorder</td>
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<tr>
<td>Pulmonary embolism (PE)</td>
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<tr>
<td>Sleep Apnea Syndrome</td>
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<td>On CPAP?</td>
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<tr>
<td>Stress incontinence</td>
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<tr>
<td>Use of Coumadin or Heparin</td>
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<tr>
<td>Venous leg ulcers</td>
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**Drugs, Medications, Vitamins, or Herbal Supplements:**

<table>
<thead>
<tr>
<th>Name</th>
<th>Dose</th>
<th>Frequency</th>
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</table>
Taking no medications

**Social History:**

**Marital Status (check one):**
- ☐ Single
- ☐ Married
- ☐ Divorced
- ☐ Widowed

**Tobacco:**
- ☐ Cigarettes; __ packs per day
- ☐ Cigars; ___ per day
- ☐ Pipes; ______ per day
- ☐ Chew; ______ per day
- ☐ Stopped ___ years ago
- ☐ Never Smoked

**Alcohol (including beer):**
- What kind?_________________________ # of drinks/week:_______ ☐ Don’t drink

If considered for surgery, at home support will be: ____________________________
Please indicate the patient’s most important reason for considering surgery:
_____________________________________________________________________________________

How much weight does the patient expect to lose?________________________________________
_____
**Weight Loss History:**
(Please check all that apply and add additional information if needed)

Obesity started:
- [ ] in childhood
- [ ] at puberty
- [ ] as an adult
- [ ] after pregnancy
- [ ] after a traumatic event
- [ ]

Additional information regarding onset of obesity:

________________________________________________________________________

________________________________________________________________________

Has the patient had surgery to aid in weight loss:
- [ ] No  [ ] Yes  Type of surgery: ____________________________
  Date of surgery: ____________________________

What exercise programs have been tried?

________________________________________________________________________

________________________________________________________________________

Is the patient currently doing any type of physical activity?
- [ ] No  [ ] Yes, if yes list below:

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<thead>
<tr>
<th>Activity (walking, swimming, etc.)</th>
<th>Frequency</th>
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</table>
Weight loss programs/diets/medications:

<table>
<thead>
<tr>
<th>Diet</th>
<th>Dates</th>
<th>Length of time</th>
<th>Amt. of weight loss</th>
<th>Form of Proof</th>
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<tbody>
<tr>
<td>Acutrim®</td>
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<tr>
<td>Atkins Diet®</td>
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<tr>
<td>Calorie Counting</td>
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<tr>
<td>Dexatrim®</td>
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<td>Diet Pills from physician</td>
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<td>Grapefruit Diet®</td>
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<td>Health Spa Program</td>
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<td>Hypnosis</td>
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<tr>
<td>Jenny Craig®</td>
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<td>Low fat diets</td>
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<tr>
<td>Meridia®</td>
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<td>Nutri-System®</td>
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<td>Overeaters Anonymous®</td>
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<td>Phen Fen®</td>
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<td>Physicians Weight Loss®</td>
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<td>Redux®</td>
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<td>Slim Fast®</td>
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<td>Supervised calorie counting by registered dietician</td>
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<tr>
<td>Weight Watchers®</td>
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<td>Xenical®</td>
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