Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Bariatric Surgery

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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)
- Endoscopic procedures (e.g., insertion of the StomaphyX™ device) 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).

Bariatric Surgery in Patients with a BMI less than 35 kg/m^2

Bariatric surgery is considered **investigational** for patients with a BMI less than 35 kg/m^2.

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

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.

Other

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

Bariatric surgery is considered **investigational** as a cure for type 2 diabetes mellitus.

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.)

To determine whether or not patients have responded to conservative measures for weight reduction, patients must have been active participants in non-surgical weight reduction programs that include frequent, e.g., monthly, documentation of weight, dietary regimen, and exercise. In general, patients must have participated in these programs for at least 6 months. These conservative attempts must be reviewed by the practitioner seeking approval for the surgical procedure.

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/m^2. 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

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

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

The Endocrine Society (1):
- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

Institute for Clinical Systems Improvement (2):
- Recommendations for adolescents apply to "mature adolescents", which is defined as having reached skeletal maturity.
- Bariatric surgery in the adolescent patient is controversial and should be undertaken on a case-by-case basis in a high-volume bariatric surgery center.

The choice of procedure in adolescents may also differ from adults, but there is a lack consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (3):
- As in adults, laparoscopic gastric bypass is the most common procedure in adolescents.
- Devices 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 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)
2. Hypertension uncontrolled by pharmacotherapy (SBP >140 and /or DBP >90 despite maximized doses of combination pharmacotherapy)
3. Clinically Significant OSA obstructive sleep apnea with an Apnea-Hypopnea Index (AHI) ≥15 uncontrolled by conservative treatment.
4. Cardiovascular disease including stroke, myocardial infarction, stable or unstable angina pectoris, coronary artery bypass or other procedures, Pickwickian syndrome, cardiomyopathy.
5. Pulmonary hypertension with documentation supporting the diagnosis.
6. 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:

Bariatric Surgery Initial Consultation: Conservative treatment.

- 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:
        i) Loss of 5% of his/her body weight in the 3 months prior to surgery
        ii) Diet record
    e) 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.

Description of Procedure or Service

Surgery for obesity, termed 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.

Bariatric surgery is performed for the treatment of morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m^2 or a BMI greater than 35 kg/m^2 with associated complications including, but not limited to, diabetes, hypertension, or obstructive sleep apnea. Morbid obesity results in a very high risk for weight-related complications, such as diabetes, hypertension, obstructive sleep apnea, and various types of cancers (for men: colon, rectum, and prostate; for women: breast, uterus, and ovaries), and a shortened life span. A morbidly obese man at age 20 can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy.

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

When conservative measures fail, some patients may consider surgical approaches. A 1991 National Institutes of Health (NIH) Consensus Conference defined surgical candidates as those patients with a BMI* of greater than 40 kg/m^2, or greater than 35 kg/m^2 in conjunction with severe comorbidities such as cardiopulmonary complications or severe diabetes. (*See Policy Guidelines on how to calculate BMI.)

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

The following summarizes the different types of bariatric surgery procedures.

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

2. Adjustable Gastric Banding (CPT code 43770—laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device [e.g., gastric band and subcutaneous port components])
Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple. Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe; currently, one such device is approved by the U.S. Food and Drug Administration (FDA) for marketing in the U.S., Lap-Band (BioEnterics, Carpinteria, CA). The labeled indications for this device are as follows:

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

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

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

3. Open Gastric Bypass (CPT code 43846—gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb [150 cm or less] Roux-en-Y gastroenterostomy)
The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “sweets eaters.” Operative complications include leakage and marginal ulceration at the anastomotic site. Because the normal flow of food is disrupted, there are more metabolic complications compared to other gastric restrictive procedures, including iron deficiency anemia, vitamin B-12 deficiency, and hypocalcemia, all of which can be corrected by oral supplementation. Another concern is the ability to evaluate the “blind” bypassed portion of the stomach. Gastric bypass may be performed with either an open or laparoscopic technique.

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

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

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

5. Mini-Gastric Bypass (no specific CPT code)
Recently, a variant of the gastric bypass, called the mini-gastric bypass, has been popularized. Using a laparoscopic approach, the stomach is segmented, similar to a traditional gastric bypass, but instead of creating a Roux-en-Y anastomosis, the jejunum is anastomosed directly to the stomach, similar to a Billroth II procedure. This unique aspect of this procedure is not based on its laparoscopic approach but rather the type of anastomosis used. It should also be noted that CPT code 43846 explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

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

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

8. Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure) (CPT code 43847— gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)
Biliopancreatic bypass (BPB) procedure, developed and used extensively in Italy, was designed to address some of the drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many of the complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPB consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components.

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

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

9. Biliopancreatic Bypass with Duodenal Switch (CPT code 43845—gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy [50- to 100-cm common channel] to limit absorption [biliopancreatic diversion with duodenal switch])
CPT code 43845, which specifically identifies the duodenal switch procedure, was introduced in 2005. The duodenal switch procedure is essentially a variant of the biliopancreatic bypass described above. In this procedure, instead of performing a distal gastrectomy, a sleeve gastrectomy is performed along the vertical axis of the stomach. This approach preserves the pylorus and initial segment of the duodenum, which is then anastomosed to a segment of the ileum, similar to the biliopancreatic bypass, to create the alimentary limb. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum. The sleeve gastrectomy also decreases the volume of the stomach and decreases the parietal cell mass. However, the basic principle of the procedure is similar to that of the biliopancreatic bypass, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

10. Long-Limb Gastric Bypass (i.e., >150 cm) (CPT code 43847—Gastric restrictive procedure with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption)
Recently, variations of gastric bypass procedures have been described, consisting primarily of long-limb Roux-en-Y procedures, which vary in the length of the alimentary and common limbs. For example, the stomach may be divided with a long segment of the jejunum (instead of ileum) anastomosed to the proximal gastric stump, creating the alimentary limb. The remaining pancreaticobiliary limb, consisting of stomach remnant, duodenum, and length of proximal jejunum, is then anastomosed to the ileum, creating a common limb of variable length in which the ingested food mixes with the pancreaticobiliary juices. While the long alimentary limb permits absorption of most nutrients, the short common limb primarily limits absorption of fats. The stomach may be bypassed in a variety of ways, i.e., either by resection or stapling along the horizontal or vertical axis. Unlike the traditional gastric bypass, which is essentially a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses. Note that CPT code for gastric bypass (43846) explicitly describes a short limb (<150 cm) Roux-en-Y gastroenterostomy, and thus would not apply to long-limb gastric bypass.

11. Laparoscopic Malabsorptive Procedure (CPT code 43645—Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)
CPT code 43645 was introduced in 2005 to specifically describe a laparoscopic malabsorptive procedure. However, the code does not specifically describe any specific malabsorptive procedure.

Rationale

This policy was created in July 1996 and updated periodically with literature review. The most recent update with literature review covers the period of June 2012 through August 2013.

Definition of Outcomes

Outcomes of bariatric surgeries are notoriously difficult to evaluate in part due to the constantly evolving nature of the surgery. Small modifications are commonly made to decrease the incidence of postoperative and long-term complications. In addition, few controlled studies have directly measured the weight loss and complications associated with the different surgical approaches, particularly comparing gastric restrictive procedures with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. The outcomes for specific surgeries may widely differ among institutions or surgeons, perhaps due to small

variations in surgical technique, intensity of follow-up, or patient selection criteria. However, during the 1970s and 1980s, both vertical-banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These two procedures were the focus of the 1991 National Institutes of Health (NIH) Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass (BPB). (4)

A 2003 TEC Assessment (5) summarized studies comparing open gastric bypass and vertical-banded gastroplasty. These comparisons demonstrated that open gastric bypass resulted in a greater amount of weight loss than vertical-banded gastroplasty, with no definite differences in complication rates. Therefore, gastric bypass is considered the gold standard for the purpose of this discussion, and this is supported by the increasing acceptance of gastric bypass by the surgical community, representing greater than 80% of all bariatric surgery procedures performed in 2002. (6) Therefore, the results of open gastric bypass will be compared to the newer procedures not addressed by the 1991 NIH conference; i.e., gastric banding and BPB with or without duodenal switch. The following outcomes are considered relevant for bariatric surgery:

- Weight loss

There is no uniform standard for reporting results of weight loss and no uniform standard for describing a successful procedure. Common methods of reporting the amount of body weight loss are percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. These 2 methods are generally preferred over the absolute amount of weight loss, since 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. The following table summarizes the variation in reporting weight loss outcomes.

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

- Durability of weight loss

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

- Short-term complications—Operative and perioperative complications that occur within 30 days are considered in this category.

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and problems with wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications such as pneumonia or myocardial infarction.

- Reoperation rate

Reoperation may be required to either "take down" or revise the original procedure. Reoperation may be particularly common in vertical-banded gastroplasty due to pouch dilation.

- Long-term complications—Metabolic side effects, nutritional deficiencies, are included in this category.

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

- Improved health outcomes in terms of weight-related comorbidities.

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

Bariatric Surgery in Adults With Morbid Obesity

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

Randomized controlled trials (RCTs) of bariatric surgery have been performed but are limited and insufficient to draw conclusions about the comparison of bariatric surgery with conservative treatments for weight loss. (7) RCTs are difficult in bariatric surgery because many experts consider it inappropriate or unethical to randomize patients to bariatric surgery. Also, the majority of patients and clinicians have strong feelings about their preference for treatment, which results in a select population that might agree to randomization and therefore, limited generalizability. As a result, the literature that is most important in determining the efficacy of bariatric surgery is from nonrandomized studies.

Swedish Obese Subjects Trial. The Swedish Obese Subjects (SOS) trial is the most influential study of bariatric surgery versus conservative treatment. The SOS trial was started in 1987 with a registry containing a detailed questionnaire and clinical data on obese patients with a body mass index (BMI) greater than 34kg/m^2 at 480 primary health care centers in Sweden. From this registry, patients who met eligibility criteria were recruited and offered bariatric surgery. Thus, SOS patients were self-selected into treatment, and there were baseline differences between groups, primarily reflecting more excess weight and a higher incidence of co-morbidities in the surgery group. There were a total of 2,010 individuals who chose surgery and 2,037 individuals who chose conservative care. Each surgical patient was matched on 18 clinical variables with a patient from the registry who received nonsurgical treatment (usual care). Each individual surgeon chose the surgical procedure offered. Most of the procedures were vertical-banded gastroplasty (VBG) (over 70%), with gastric bypass (6%) and gastric banding (23%) procedures performed as well. Usual care in the SOS trial was the local practice of the primary care center and usually did not include pharmacologic treatment. The patients are followed at regular intervals with repeat questionnaires and physical examinations for at least 10 years.

There have been many publications from this trial reporting on methods, weight loss, and clinical outcomes. (8-12) The following general conclusions can be drawn from the SOS study:

- Weight loss is greater with bariatric surgery compared to conservative treatment. At 10 years of follow-up, weight loss in the surgery group was 16% of total body weight, compared to a weight gain of 1.6% in the conservative treatment group.

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

Systematic reviews. Numerous systematic reviews have been published on the efficacy of bariatric surgery compared to conservative therapy. These have included the few controlled trials, such as the SOS study discussed above, but have primarily consisted of single-arm trials of different bariatric surgery procedures. In 2004, Buchwald et al. (13) published a systematic review of 136 studies of bariatric surgery reporting on more than 22,000 patients. For all patients, there was a 61.2% of excess weight lost (95% confidence interval [CI]: 58.1-64.4%) with a 30-day mortality of less than 1%. Maggard et al. (14) reviewed 147 studies, 89 that reported on weight loss, 134 that reported on mortality, and 128 that reported on complications. Surgery resulted in a substantial weight loss, which was more pronounced for patients with a BMI of at least 40 kg/m^2 compared to patients with a BMI between 35 and 40. The overall rate of any adverse event was 20%. There was a high degree of heterogeneity among studies and evidence for different amounts of weight loss and different rates of complications among the various procedures

Section Summary. There is a lack of RCTs comparing bariatric surgery to nonsurgical treatment for the general population of patients with morbid obesity. Evidence from nonrandomized comparative studies and case series 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.

Types of Bariatric Surgery Procedures

Vertical-Banded Gastroplasty (VBG). VBG is one of the early types of bariatric surgery developed in the 1980s. This is a purely restrictive procedure that has been largely replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there is a high rate of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. The overall rates of revisions and reoperations at up to 10 years may be as high as 50%. (15, 16)

A small body of literature compares outcomes between vertical-banded gastroplasty and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study, (17) randomized 310 morbidly obese patients to gastric bypass, vertical-banded gastroplasty, or horizontal gastroplasty. The percent of patients with greater than 50% excess weight loss (EWL) at 3 years' follow-up was 67% for gastric bypass, 48% for vertical-banded gastroplasty, and 17% for horizontal gastroplasty ($p<0.001$). There were no demonstrable differences in adverse events among groups. A second, smaller randomized controlled trial (RCT) by Sugerman and colleagues randomized 40 patients to receive either a vertical-banded gastroplasty or a gastric bypass procedure. (18) After 9 months, the gastric bypass patients had significantly greater weight loss that persisted at 3-year follow-up. The gastric bypass patients lost approximately 64% of excess weight, whereas the gastroplasty patients lost only 37% of excess weight.

A number of other nonrandomized, comparative studies of open gastric bypass versus vertical-banded gastroplasty were included in the 2003 TEC Assessment (n=8 studies, 3,470 patients). (5) All 8 of these studies reported greater amounts of weight loss with open gastric bypass. These studies reported a 44–70% improvement in total weight loss, a 28–43% improvement in the percent excess weight loss (EWL), and 19–36% more patients with greater than 50% EWL for those undergoing gastric bypass compared with vertical-banded gastroplasty. Comparison of adverse events was more difficult, as the

data in these studies did not allow rigorous comparison of adverse events. Nevertheless, the data suggested that the mortality rate for both operations was low overall. Serious perioperative adverse events were also infrequently reported but were possibly somewhat higher for gastric bypass. Long-term adverse events were inconsistently reported, although it appeared that revision rates were higher for vertical-banded gastroplasty (VBG).

Relatively high rates of complications, revisions, and reoperations have led to the abandonment of VBG as a bariatric surgery procedure in the U.S. An example of these results is a large case series with long-term follow-up by MacLean and colleagues, who reported on 201 patients undergoing VBG who were followed up for a minimum of 2 years. (19) 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.

Gastric Bypass with Short Limb (<150 cm). While VBG was perhaps the dominant bariatric surgery in the 1980s, it has been surpassed in the U.S. by the gastric bypass procedure, based on a variety of studies that report improved weight loss with a gastric bypass procedure. This body of literature has been instrumental in establishing that gastric bypass should be the reference procedure to which other procedures are compared. Practice patterns in the United States have adopted this approach, with gastric bypass now composing the vast majority of all bariatric procedures performed.

Many clinical series reporting results of open gastric bypass have been published, and numerous systematic reviews of this evidence have been reported. Griffen summarized the experience of more than 10,000 gastric bypass operations from a number of bariatric surgeons. (20) Results showed that approximately 85% were able to reduce their weight to levels below 150% of their ideal weight. In about 5,000 patients who were followed up for 10 years, 80% were able to maintain this result. Pories and colleagues reported on 608 patients who underwent a gastric bypass procedure and were followed up for 1–14 years. (21) One of the unique features of this report is that only 3% of patients were lost to follow-up. The average weight loss was 75% of excess weight at 1 year, declining to 50% by the eighth year. The authors observed an immediate drop in both blood glucose and exogenous insulin requirements after surgery. Long-term observation of 298 patients with preoperative diabetes or impaired glucose intolerance revealed that 91% had normal values for blood glucose and hemoglobin A1c after surgery. The incidence of hypertension declined from 58% before surgery to 14% after gastric bypass.

Comparative trials summarized in the 2003 TEC Assessment (5) consistently report favorable outcomes for open gastric bypass when compared with vertical-banded gastroplasty, including 2 RCTs. Some nonrandomized trials that compare open gastric bypass with procedures other than VBG were also summarized in the 2003 TEC Assessment. (5) While there are fewer trials for these other procedures, comparisons of open gastric bypass to gastric banding, horizontal gastroplasty, and silastic ring gastroplasty all reported that weight loss was superior with open gastric bypass.
Metabolic abnormalities are seen more frequently in gastric bypass patients compared to those receiving a VBG. Anemia, iron deficiency, vitamin B12-deficiency, and red blood cell folate-deficiency are commonly seen. Marginal ulcerations are also seen in gastric bypasses, particularly in those whose gastric pouches are too large and include acid-secreting parietal cells.

A 2005 TEC Assessment focused on the issue of laparoscopic gastric bypass, which intends to reproduce the open procedure via minimally invasive techniques. (22) This is a technically complex operation that requires a dedicated team and a relatively high degree of skill and experience in laparoscopic surgery. This Assessment reviewed 7 comparative trials of open gastric bypass and laparoscopic gastric bypass, including 3 RCTs. In addition, 18 large clinical series of laparoscopic gastric bypass were included in the review.

The 2005 TEC Assessment (22) on laparoscopic gastric bypass concludes that weight loss at 1 year is similar between laparoscopic and open gastric bypass approaches. Weight loss at longer follow-up

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

The mini-gastric bypass has primarily been advocated by one surgeon. In 2001, Rutledge published his experience with 1,274 patients who underwent the mini-gastric bypass procedure. (23) The mean operating time was 36 minutes, and the mean hospital stay was 1.5 days. Mean excess weight loss was 51% at 6 months, 68% at 12 months, and 77% at 2 years. The overall complication rate reported was 5.2%. While this surgical approach may result in decreased surgical time, the anastomosis creates the risk of biliary reflux gastritis, one of the reasons that this anastomosis has been abandoned, in general, in favor of a Roux-en-Y anastomosis that diverts the biliary juices away from the stomach.

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

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

A 2006 TEC Assessment (25) updated the evidence on laparoscopic adjustable gastric banding (LAGB), and compared outcomes to those of gastric bypass. This Assessment concluded that for patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either open gastric bypass (GBY) or laparoscopic gastric bypass (LAGY) as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits (such as extent of weight loss and frequency and timing of potential complications) of the two procedures to allow the optimal choice to be made based on preferences and shared decision making.

Weight loss outcomes from the studies reviewed in the Assessment confirm the conclusions of previous TEC Assessments that weight loss at 1 year is less for LAGB compared with GBY. The percentage of excess weight lost (EWL) at 1 year is in the range of approximately 40%, compared to 60% or higher for GBY. At time points longer than 1 year, some of the comparative studies report that the difference in

weight loss between LAGB and GBY lessens, but others do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that the difference in weight loss between the procedures begins to lessen after 1–2 years of follow-up. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

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

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

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the benefits, as defined by the amount of weight loss, will also be less for LAGB. The patterns of long-term complications also differ between the two procedures. For LAGB, longer-term 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.

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

Brethauer and colleagues reviewed 36 studies (n=2,570) for a systematic review of SG as a staged and primary procedure, the largest number coming from European centers. (26) Two RCTs, one nonrandomized, matched cohort analysis, and 33 case series were examined. Thirteen studies (n=821) reported on high-risk patients having a staged approach and 24 studies (n=1,749) on SG as primary procedure. Mean percentage of excess weight loss (% EWL) was reported in 24 studies (n=1,662) and was 55.4% overall (range, 33–85%). Mean postoperative BMI was reported in 26 studies (n=1,940) and decreased from a baseline mean of 51.2 to 37.1. Other studies reported weight loss in terms of BMI decrease, percentage of BMI lost, or percentage of total weight lost, and all had significant reductions from baseline. Follow-up periods were 3–60 months. Ten studies included detailed postoperative co-morbidity data (n=754); more than 70% of patients had improvement or remission of type 2 diabetes, and significant reductions were seen in hypertension and hyperlipidemia, sleep apnea, and joint pain. The rate of major postoperative complications ranged from 0% to 23.8% for all studies and 0% to 15.3% in studies with greater than 100 patients. Leaks (2.2%), bleeding episodes requiring reoperation (1.2%), and postoperative strictures requiring endoscopic or surgical intervention (0.6%) were reported in the 33 studies reporting detailed complication data (n=2,570). All extracted studies reported mortality data with 5 deaths within 30 days of surgery (overall mortality rate 0.19%, 2 in the high-risk/staged group and 3 in the primary procedure group). The authors comment that long-term follow-up is limited.

Himpens et al. (27) report on a randomized study comparing LAGB and laparoscopic isolated SG. Eighty subjects received surgery over a period of 1 year. Median BMI was 37 (range, 30–47) in the LAGB group versus 39 in the SG group. Outcomes of weight loss, feeling of hunger, sweet-eating, gastroesophageal reflux disease (GERD), complications, and reoperations were recorded at 1 and 3 years' follow-up. Median decrease in BMI in the gastric bypass (GB) group was 15.5 (range, 5–39) after 1 year and 18 (range, 0–39) at 3 years after LAGB. One year after SG, decrease in BMI was 25 (range, 0–45) and 27.5 (range, 0–48) after 3 years. Median EWL in the LAGB group was 41.4% after 1 year and 48% at 3 years. Median EWL after SG was 58% and 66% at 1 and 3 years, respectively. More patients having SG than LAGB reported loss of craving for sweets, but the differences were not significant; GERD appeared de novo in more SG than LAGB patients at 1 year, and the relationship reversed at 3 years; between group differences were not significant at either time point. Two SG patients required reoperation for complications. Late complications requiring reoperation after LAGB included pouch dilations treated by band removal (n=2) or conversion to Roux-en-Y gastric bypass (RYGB) (n=1), 1 gastric erosion treated by conversion to RYGB, and 3 disconnections of the system were reconnected. Four patients had reoperations for inefficacy; 2 GB patients underwent conversion to RYGB, and 2 SG patients had conversion to duodenal switch (DS). The authors note that the number of reoperations was significant in both groups and that the severity of complications was greater in the SG group. (27) Karamanakos and colleagues carried out a double-blind study (28) to compare outcomes of laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic SG (LSG) on body weight, appetite, and fasting and postprandial ghrelin and peptide-YY (PYY) levels at 1, 3, 6, and 12 months after surgery. Thirty-two patients were randomized, half to each procedure. Decrease in body weight and BMI was marked and comparable in each group. Excess weight loss was greater after LSG at 6 months (55.5% vs. 50.2%, respectively; p=0.04) and 12 months (69.7% vs. 60.5%, respectively; p=0.05). Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but was greater after LSG.

An RCT comparing short-term outcomes of laparoscopic sleeve gastrectomy with gastric bypass was published in 2013. (29) The authors compared 30-day outcomes of 117 patients randomized to gastric bypass with 121 patients randomized to sleeve gastrectomy. There were no deaths in either group. The rate of major complications was 9.4% in the gastric bypass group compared to 5.8% in the sleeve gastrectomy group (p=0.29). Minor complications were more common in the gastric bypass group compared to sleeve gastrectomy (17.1% vs. 7.4%, p=0.02), as was combined major and minor complications (26.5% vs. 13.2%, p=0.01).

Several other publications report of SG compared to other bariatric procedures. In a comparative study from France, Chouillard et al. performed a comparative analysis with 200 patients who had undergone either SG or RYGB between 2005 and 2008. (30) Patients in each group were matched for age, gender, and BMI. The postoperative complications, percentage of EWL, and the resolution of co-morbidities in each group were compared at 6, 12, and 18 months postoperatively. The overall mortality rates were similar in both groups. However, the morbidity rate was significantly greater in the RYGB group (20.5%) as compared to the SG group (6.5%; $p<0.05$). The overall remission of type 2 diabetes was significantly better in the RYGB group. However, the percentage of EWL at 6, 12, and 18 months, as well as the resolution of nondiabetic comorbidities, were comparable in both groups. The authors concluded that in this study, compared with SG, RYGB was associated with a greater short-term morbidity rate and RYGB could be associated with better diabetes control. They also note that additional studies are needed to evaluate the comparative efficacy of SG and RYGB for the treatment of morbid obesity and its co-morbidities.

Leyba and colleagues reported on a series of 117 patients from Venezuela who were treated with either SG or RYGB. (31) From January 2008 to December 2008, 117 obese patients who met criteria for bariatric surgery were assigned by patient choice after informed consent to either a laparoscopic RYGB procedure (n=75) or an LSG procedure. Both groups were comparable in age, sex, BMI, and co-morbidities. Mean operative time of LSG was 82 minutes, while LRYGB was 98 minutes ($p<0.05$). Differences in length of stay, major complications, improvement in co-morbidities, and EWL were not significant ($p>0.05$). One year after surgery, average EWL was 86% in LRYGB and 78.8% in LSG

(p>0.05). The authors concluded that in the short term, both techniques are comparable regarding safety and effectiveness.

In a comparative study from India, Lakdawala and colleagues compared 50 patients who underwent LSG and LRYGB from 2007 to 2008. (32) Groups were matched for age, sex, and BMI. Patients were evaluated at 6 months and 1 year postoperatively. Resolution of most comorbidities such as type 2 diabetes, hypertension, dyslipidemia, sleep apnea, joint pain, and percentage of EWL in both groups was comparable at the end of 6 months and 1 year. Early resolution of type 2 diabetes was better in the LRYGB group; the results were comparable at 1 year. There was increased incidence of GERD in LSG patients. Chiu et al. reported a systematic review on the effect of SG on symptoms of GERD. (33) A total of 15 reports were retrieved; 2 reports analyzed GERD as a primary outcome, and 13 included GERD as a secondary study outcome. Of the 15 studies, 4 showed an increase in GERD after SG, 7 found reduced GERD prevalence after SG, 3 included only the postoperative prevalence of GERD, and 1 did not include data on prevalence of GERD. The authors concluded that the studies showed differing outcomes and that studies that objectively evaluate GERD after SG are needed.

A small number of clinical series also report on sleeve gastrectomy (SG) as the initial procedure of a 2-stage operation. This approach has been generally attempted in patients with “super” obesity (BMI >50), in whom a more complex initial operation may be associated with higher risk. Weight loss following SG may reduce the risk of these patients undergoing a more complex malabsorptive procedure in the future. The available series to date report only on very small numbers of patients; for example, Regan et al. (n=7) and Mognol et al. (n=10). (34, 35) The published data on outcomes following completion of both stages of a 2-stage operation are limited to case reports and case series with very small numbers of patients.

Biliopancreatic Bypass. Skroubis et al. (36) randomized 130 patients with a BMI of 35–50 to either RYGB or biliopancreatic diversion (BD) (without duodenal switch) using a variant of BPB (BPD) that included Roux-en-Y gastrectomy in place of sleeve gastrectomy. All patients were followed up for at least 2 years. Weight loss outcomes were superior for the BD group at every time period examined up to 2 years. The EWL at 1 year was 73.7% for RYGB and 83.1% for BD (p=0.0001); at 3 years, the EWL was 72.6% for RYGB and 83.1% for BD (p=0.00003). There were more early complications in the RYGB group, but this difference did not reach statistical significance (6 complications vs. 1, respectively; p=0.12). Late complications also did not differ significantly between the RYGB and BD groups (16 complications vs. 22, respectively; p=0.46).

Numerous clinical series of BPB have been published, but, as with other procedures, high-quality trials that directly compare outcomes of this procedure with gastric bypass are lacking. The largest experience with BPB is reported by Scopinaro et al., who developed the procedure. In 1996, Scopinaro et al. summarized their experience with 1,217 patients. (37) With follow-up of up to 9 years, the authors reported a durable excess weight loss of 75%, suggesting that weight loss is greater with this procedure compared to gastric restrictive procedures. In addition, the vast majority of patients reported disappearance or improvement of such complications as obstructive sleep apnea, hypertension, hypercholesteremia, and diabetes. The authors considered protein malnutrition the most serious metabolic complication, occurring in almost 12% of patients and responsible for 3 deaths. This complication may require inpatient treatment with total parenteral nutrition. To address the issue of protein malnutrition, 4% of patients underwent reoperation to either elongate the common limb (thus increasing protein absorption) or had the operation reversed, restoring normal intestinal continuity. The authors also found that protein malnutrition was strongly related to ethnicity, and presumably, eating habits of the patients,with an increased incidence among those from southern Italy where the diet contains more starch and carbohydrates than the north. Peripheral neuropathy may occur in the early postoperative period due to excessive food limitation but may be effectively treated with large doses of thiamine. Bone demineralization, due to decreased calcium absorption, was seen in about 33% of patients during the first 4 postoperative years. All patients are encouraged to maintain an oral calcium intake of 2 g/day, with monthly vitamin D supplementation.

The available evidence was reviewed in the 2006 TEC Assessment, (25) and outcomes of BPB, with or without duodenal switch, were compared with those of gastric bypass. One comparative trial and 7 single-arm series suggested that weight loss outcomes at 1 year are in the same range as for gastric bypass. While these data are not sufficient to distinguish small differences in weight loss between the two procedures, these data do not support the hypothesis that BPB results in greater weight loss than open gastric bypass.

Complication rates are poorly reported in these trials. The data suggest that mortality is low (approximately 1%) and in the same range as for open gastric bypass. However, rates of other complications, especially long-term complications, cannot be determined from these data. Limited data suggest that long-term nutritional and vitamin deficiencies occur at a high rate following BPB. Slater et al. (38) focused specifically on vitamin and calcium deficiencies following BPB. These authors reported high rates of vitamin and calcium abnormalities in their population over a 4-year period. By year 4, approximately half (48%) of the patients were found to have low calcium, and 63% had low levels of vitamin D. Other fat-soluble vitamins showed similar patterns of abnormalities. Low vitamin A was found in 69% of patients at 4 years, low vitamin K in 68%, and low zinc in 50%. Dolan et al. (39) reported similar data in a study that compared several technical variations of BPB. These authors reported low calcium levels in 12–34% of patients, low vitamin D in 22.2–70.6%, low vitamin A in 53–67%, and low vitamin K in 44–59%. In addition, this study reported high rates of iron deficiency (11–47%) and anemia (11–40%). The rates of nutritional deficiencies and the consequences of these deficiencies require further investigation.

The bulk of the experience with biliopancreatic bypass appears to be in Europe, particularly Italy, with fewer case series reported in the U.S. According to Murr and colleagues, (40) BPB has not been widely accepted in the U.S. due to unacceptable serious long-term morbidities. For example, BPB has largely been abandoned at the Mayo Clinic due to the occurrence of steatorrhea, diarrhea, foul-smelling stools, severe bone pain, and the need for a life-long commitment to supplemental vitamins and minerals. In addition, there have been scattered case reports of liver damage, resulting either in death or liver transplant. (40-42) In addition, Murr et al. hypothesized that the incidence of protein malnutrition may be higher in the U.S. compared to Scopinaro's Italian series, since the North American diet has a higher percentage of fat and lower amounts of carbohydrates.

Biliopancreatic Bypass with Duodenal Switch. Biliopancreatic diversion (BD) may be performed with or without the duodenal switch (DS) procedure. In the DS procedure, a sleeve gastrectomy is performed, preserving the pyloric sphincter. Preservation of the pyloric sphincter is intended to ameliorate the dumping syndrome and decrease the incidence of ulcers at the duodenoileal anastomosis by providing a more physiologic transfer of stomach contents to the duodenum.

The largest case series of this procedure is by Marceau et al., who reported their 15-year experience with DS in 1,423 patients from 1992–2005. Follow-up evaluation was available for 97% of patients. Survival rate was 92%. After a mean of 7 years (range 2–15 years), 92% of patients with an initial BMI equal to or less than 50 obtained BMI less than 35, and 83% of patients with BMI greater than 50 achieved a BMI of less than 40. Diabetes medication was discontinued in 92% and decreased in others. The use of continuous positive airway pressure (CPAP) was discontinued in 92% of patients, and the prevalence of cardiac risk index greater than 5 was decreased by 86%. Operative mortality was 1%; the revision rate was 0.7%, and the reversal rate was 0.2%. Revision for failure to lose sufficient weight was needed in only 1.5%. Severe anemia, vitamin deficiency, or bone damage were preventable or easily treated and without documented permanent damage. (43)

In a 2009 evidence-based review of literature, Farrell et al. summarized data on BPD with or without DS, RYGB (proximal), and adjustable gastric band (AGB) and report that at the mean of 1-year follow-up, EWL for BPD with or without DS (outcomes with and without DS not reported separately) was 72% (4 studies, aggregate n=896), 67% for RYGB (7 studies, n=1,627), and 42% for AGB (11 studies, n=4,456). At mean follow-up of 5 years, EWL for BPD with or without DS was 73% (3 studies, aggregate n=174), 58% for RYGB (3 studies, n=176), and 55% for AGB (5 studies, n=640). The

authors note that “given the marked paucity of prospectively collected comparative data among the different bariatric operations, it remains impossible to make definitive recommendations for one procedure over another.” (44)

In summary, the comparative studies provide evidence that weight loss at 1 year following BPD is superior to RYGB. The difference in EWL at 1 year is approximately 10% in favor of BPD. Evidence of long-term weight loss is limited, and comparisons between techniques are more difficult. Long-term nutritional complications such as protein, iron, or vitamin D deficiency are common after malabsorptive procedures, and careful monitoring and compliance with dietary advice and supplementation are required. The impact of these and other long-term nutritional/metabolic complications of BPD cannot be determined from the current evidence. Some studies combine data for BPD with and without DS so that the outcomes of one or the other technique cannot be directly compared. The more recent literature describes BPD with DS. Though RCTs with mid- to long-term outcomes are lacking, BD with DS appears to produce weight loss at least comparable to that with RYGB. Thus, the policy statement is revised related to BPD with DS.

Prachand et al. (45) published the largest comparative series of 350 super-obese patients with BMI greater than 50 who underwent either RYGB (n=152) or Scopinaro BD combined with the DeMeester duodenal switch (DS-BPD) (n=198). In this retrospective study, the decision for surgery was made by the surgeon and/or patient. The DS-BPD patients differed from RYGB patients on weight and BMI; mean weight in pounds was 368.2 ± 52.3 (range, 267.4–596.5) in DS-BPD patients versus 346.3 ± 55.2 (range, 239.8–504.9) in the RYGB group, and mean BMI was 58.8 ± 6.7 (range, 50–96) in DS-BPD patients versus 56.4 ± 6.8 (range, 49.5–84.2) in the RYGB group. At 1 year, data were reported for 143 DS-BPD patients and 81 RYGB patients. The EWL was greater for BPD versus RYGB (64.1% vs. 55.9%, respectively; $p<0.01$), and the reduction in BMI was also greater for BPD versus RYGB (23.6 vs. 19.4, respectively; $p<0.001$). Complications and data on resolution of comorbidities were not reported in this study. Strain et al. published a smaller comparative study of 72 patients who underwent either RYGB (n=50) or BPD (n=22). Choice of surgery was per surgeon and/or patient, and the patient populations differed in age and time since surgery. Weight loss at 1 year was greater for BPD, with a reduction in BMI of 23.3 for BPD compared to 16.5 for RYGB ($p<0.001$). (46)

Gastric Bypass with Long Limb (>150 cm). As discussed in the Description section, the degree of malabsorption associated with long-limb gastric bypass will vary with the length of the alimentary and biliary limbs. These modifications have been developed in an effort to decrease the metabolic side effects associated with BPB. However, there has been limited published evidence on outcomes from this procedure and a large degree of variability in the technical aspects of the procedure among the published literature. Murr et al. reported on 26 patients who underwent a “very very long-limb Roux-en-Y gastric bypass.” (39) In comparison to a case series of 11 patients who underwent BPB, the authors reported similar weight loss but decreased metabolic or nutritional abnormalities, attributed in part to the increased length of the common segment, 100 cm compared to 50 cm used in BPB. Sugerman et al. also attribute increasing the length of the common segment to decreasing metabolic morbidities. (47)

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

The majority of comparisons of weight loss do not reveal significant differences between short- and long-limb gastric bypass. The strongest evidence in this category is from 2 RCTs. (48, 49) In both of these trials, there were no significant differences in weight loss between groups. Brolin et al. (50) compared 3 limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at 1 year, while the other two groups had similar decrease in BMI. MacLean et al. (51)

examined morbidly obese and super-obese patients separately and reported a significant difference in favor of the long-limb gastric bypass group. However, this analysis compared the final BMI of the two groups and did not report the actual change in BMI or the initial BMI for each group.

Adverse events were poorly reported by these studies, with only 3 reporting data on adverse events. Mason et al. (52) reported the percent of patients with "major post-op complications," which was 2.3% for standard gastric bypass and 1.2% for long-limb gastric bypass. There was no further breakdown of the types of major complications recorded and no statistical testing for this outcome. In the remaining 2 studies, the rates of short-term adverse events reported by Inabnet et al. (49) were higher for standard gastric bypass, while the rates reported by Brolin et al. (50) were higher for the long-limb gastric bypass. Data on long-term complications were scant and did not reveal any apparent differences between short- and long-limb procedures.

Two-stage procedures. Bariatric surgeries that are performed in 2 stages have been proposed as a treatment option, particularly for patients with "super-obesity" defined as a BMI greater than 50. The rationale for a 2-stage procedure is that the risk of an extensive surgery is prohibitive in patients with extreme levels of obesity. Therefore, an initial procedure with low risk, usually a sleeve gastrectomy, is performed first. After a period of time in which the patient loses some weight, thus lowering the surgical risk, a second procedure that is more extensive, such as a biliopancreatic diversion (BD), is performed.

The evidence on 2-stage procedures consists of case-series of patients undergoing sleeve gastrectomy as the initial procedure. Many of these case series do not report on the second-stage operation, and in those that do, only a minority of patients undergoing the first stage actually proceed to the second-stage surgery. For example, Cottam et al. (53) reported on 126 patients with a mean BMI of 65 who underwent laparoscopic SG as the first portion of a planned 2-stage procedure. The incidence of major perioperative complications for laparoscopic SG was 13%. After one year, the mean EWL was 46%. A total of 36 patients (29%) proceeded to the second-stage procedure, which was laparoscopic gastric bypass. The incidence of major complications following the second procedure was 8%. In a similar study, Alexandrou et al. (54) reported on 41 patients who underwent SG as the first stage of a planned 2-stage procedure. After 1-year follow-up, 12 patients (29%) achieved a BMI less than 35 and were not eligible for the second-stage procedure. Of the remaining 28 patients, 10 (24% of total) underwent the second-stage procedure. The remaining 18 patients (44% of total) were eligible for, but had not undergone, the second-stage procedure at the last follow-up.

Patients who undergo 2-stage procedures are at risk for complications from both procedures. Silecchia et al. (55) described the complication rates in 87 patients undergoing a stage I SG followed by a BPD in 27 patients. For the first stage of the operation, 16.5% of patients had complications of bleeding, fistula, pulmonary embolism, acute renal failure, and abdominal abscess. For the 27 patients who underwent the second-stage BPD, major complications occurred in 29.6% including bleeding, duodenoileal stenosis, and rhabdomyolysis.

This evidence does not indicate that a 2-stage bariatric surgery procedure improves outcomes for patients with extreme levels of obesity. There is no evidence to suggest that weight loss is improved or that complications are reduced, by this approach. A majority of patients who receive SG as the initial procedure lose sufficient weight during the first year such that a second procedure is no longer indicated. In addition, patients undergoing a 2-stage procedure are at risk for complications from both procedures; therefore, it is possible that overall complications are increased by this approach.

Section Summary. The evidence on the comparative efficacy of different bariatric surgery approaches consists largely of low-quality evidence, with a lack of long-term, high-quality RCTs. Compared with gastric bypass, the evidence is sufficient to conclude that laparoscopic adjustable gastric banding is associated with lower short-term complications and lower medium- to long-term weight loss. The evidence is also sufficient to conclude that sleeve gastrectomy has similar or lower short-term complications, with medium- to long-term weight loss that is somewhat less than for gastric bypass. The evidence on other types of bariatric surgery procedures is insufficient to form conclusions on the

impact on health outcomes. For biliopancreatic bypass, the weight loss is similar or greater than gastric bypass but the complications rates, especially for nutritional complications, may also be higher. The evidence base for other types of procedures is insufficient to form conclusions.

Revision Bariatric Surgery

There are a number of reasons why patients who are treated with accepted forms of bariatric surgery may not lose weight or may regain weight that is initially lost. These reasons include issues of adherence (compliance), as well as technical (structural) issues. Some patients who regain weight after bariatric surgery, e.g., after RYGB, are found to have enlarged gastric stoma and/or enlarged gastric pouches. Correction of these abnormalities has been reported to again result in successful weight loss. However, some have questioned whether the association with enlarged stoma is as important as it is for enlarged pouches. (56)

A number of studies have evaluated the efficacy of revision procedures after failed bariatric surgery and reported satisfactory weight loss and resolution of co-morbidities with somewhat higher complication rates than for primary surgery. Mognol et al. reported on conversion of adjustable gastric banding (AGB) to Roux-en-Y in 70 patients. (57) Indications for conversion were insufficient weight loss or weight regain after band deflation for gastric pouch dilatation in 34 patients (49%), inadequate weight loss in 17 patients (25%), symptomatic proximal gastric pouch dilatation in 15 patients (20%), intragastric band migration in 3 patients (5%), and psychological band intolerance in 1 patient. Median excess body weight loss was 70%. Sixty percent of patients achieved a BMI of less than 33 with mean follow-up 18 months. The early complication rate was 14.3% (10/70). Late major complications occurred in 6 patients (8.6%). Brolin and Cody, reporting on a series of 151 revision surgeries, observed that “Weight loss after revision of pure restrictive operations is significantly better than after revision of operations with malabsorptive components. Improvement of comorbidities in the great majority of patients justifies revision of all types of bariatric operations for unsatisfactory weight loss.”(58) Bueter et al. reported that of 172 patients who underwent adjustable gastric band placement between May 1997 and June 2006, 41 had one or more revision procedures. (59) There were no deaths following the reoperations. Band replacement (n=18), band repositioning (n=7), conversion to SG (n=2) and Roux-en-Y gastric bypass (RYGBP, n=2) or band removal without any further substitution (n=12) were performed as first reoperation. Seven patients had a second reoperation. Median follow-up since reoperation was 56 months (range 7–113). Excess weight loss (EBWL %) of patients was 59.4% after RYGBP (n=5), 45.1% after re-banding (n=18), and 33.4% after SG (n=2). Comorbidities were further reduced or even resolved after reoperation.

While these abnormalities can be revised using standard operative approaches, novel endoscopic procedures are being publicized as an option for these patients. Some of these procedures use devices that are also being evaluated for endoscopic treatment of gastroesophageal reflux (GERD) (referenced in another policy). The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate). (60) Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron et al. reported on a feasibility study in animals. (61) Thompson et al. reported on a pilot study with changes in anastomotic diameter and weight loss in 8 patients who had weight regain and dilated gastrojejunal anastomoses after RYGB. (62) 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 the 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 summary, the published scientific literature on use of these devices in patients who regain weight after bariatric surgery is very limited. No comparative studies were identified. These endoscopic procedures are considered investigational.

A survey of members of the American Society for Metabolic and Bariatric Surgery (ASMBS) bariatric surgeons indicates different risk tolerance and weight loss expectations for primary and revisional endoscopic procedures. (63) 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.

Bariatric Surgery as a Treatment for Type 2 Diabetes

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

Morbidly obese patients. The Stampede trial (64) was an unblinded RCT of 150 patients with a BMI between 27-43 and uncontrolled diabetes. The majority of patients in this trial had a BMI greater than 35, but approximately one-third of patients had a BMI of less than 35. Patients were randomized to 1 of 3 arms: medical treatment, Roux-en-Y gastric bypass, or sleeve gastrectomy. Patients were followed for 1 year with the primary outcome being remission of diabetes, defined as a hemoglobin A1c (HgbA1c) of 6.0% or less. There was improvement in glycemic control for all groups. Starting from an Hgb baseline of 9.2%, the final value was 7.5% for the medical group, 6.6% in the sleeve gastrectomy group ($p=0.003$ compared to medical therapy), and 6.4% in the gastric bypass group ($p<0.001$ for comparison with medical therapy). The primary endpoint was reached by12% of patients in the medical therapy group, 37% in the sleeve gastrectomy group ($p=0.008$ compared to medical therapy), and 42% in the gastric bypass group ($p=0.002$ compared to medical therapy). The use of anti-diabetic medications increased in the medical therapy group and decreased in both the surgical groups. All patients in the gastric bypass group who achieved the primary endpoint did so without medications, while 28% of patients in the sleeve gastrectomy group who reached the primary endpoint required continued medication use.

A second RCT published in 2012 compared bariatric surgery to medical therapy. (65) This trial randomized 60 patients to 1 of 3 arms: medical therapy, Roux-en-Y gastric bypass, and biliopancreatic diversion. Patients were followed for at least 1 year, with the primary endpoint being remission of diabetes, defined as a fasting glucose less than 100, HgbA1c less than 6.5%, and off all diabetic medications. There was a significant decrease in HgbA1c for all groups. The HgbA1c decreased by 8.9% in the medical group, 25% in the gastric bypass group, and 43% in the biliopancreatic diversion group, with the differences between the medical and surgical groups reaching statistically significance. At 2 years of follow-up, remission was achieved in 0% of the medical therapy group, 75% of patients undergoing gastric bypass, and 95% of patients undergoing biliopancreatic diversion.

Two RCTs of bariatric surgery compared to medical therapy enrolled diabetic patients with a BMI between 30-40 kg/m^2. Ikramuddin et al. performed an unblinded RCT of gastric bypass versus intensive medical therapy on 120 patients with type II diabetes for at least 6 months and an HgbA1C of at least 8.0%. (66) Patients were followed for 12 months with the primary endpoint being a composite of HgbA1C less than 7.0%, low-density lipoprotein (LDL) cholesterol less than 100 mg/dL and systolic blood pressure less than 130 mm Hg. A total of 28 patients in the surgery group achieved the primary outcome compared to 11 patients in the medical therapy group (odds ratio [OR]: 4.8, 95% CI: 1.9-11.7). The percent of patients achieving HgbA1C of less than 7.0% was 75% in the surgery group compared to 32% of patients in the medical therapy group (OR: 6.0, 95% CI: 2.6-13.9). There were 22 serious complications in the surgery group, including 4 perioperative complications, compared to 15 serious complications in the medical group.

Dixon et al. (67) performed an RCT designed to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI of greater than 30 kg/m^2 and less than 40 kg/m^2. (Results were not reported separately for patients with BMI <35 or >35, and 47/60 patients had BMI >35.) Sixty patients were enrolled, and 30 were randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the 2-year follow-up. Remission of diabetes was achieved by 22 (73%) in the laparoscopic adjustable gastric banding (LAGB) group and 4 (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was less than 6.2% at baseline in 2 surgically and 4 conventionally treated patients versus 24 and 6 patients, respectively, at 2 years. At baseline, 2 surgically treated and 4 conventionally treated patients were using no pharmacotherapy versus 26 and 8, respectively, at 2 years. One surgical patient developed a wound infection, 2 developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band.

The remaining evidence at the present time consists of small case series and case reports with short follow-up from non-U.S. centers employing procedures considered investigational in this policy. For example, Lee et al. retrospectively identified 44 patients with type 2 diabetes and BMI less than 35 kg/m^2, 114 patients with BMI between 35 and 45, and 43 patients with BMI greater than 45 in a large series (68) of patients who underwent laparoscopic mini-gastric bypass. One year after surgery, fasting plasma glucose levels returned to normal in 89.5% of patients with BMI less than 35 and in 98% of those with BMI greater than 35. The treatment goal of hemoglobin A1c less than 7%, low-density lipoprotein (LDL) less than 150 mg/dL and triglyceride less than 150 mg/dL, was met in 76.5% of patients with BMI less than 35 and in 92.4% of those with BMI greater than 35.

Diabetic patients without morbid obesity. A TEC Assessment was completed in 2012 on bariatric surgery in diabetic patients with a BMI less than 35 kg/m^2. (69) The evidence consisted mainly of case series. This Assessment made the following conclusions:

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

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

DePaula et al. report on 39 patients with BMI less than 35 who underwent 1 of 2 laparoscopic procedures comprising different combinations of ileal interposition into the proximal jejunum via a sleeve or diverted sleeve gastrectomy. Mean BMI was 30.1 (range, 23.4–34.9). All had type 2 diabetes for at least 3 years (mean duration, 9.3 years, range 3–22 years) and evidence of stable treatment with oral hypoglycemic agents or insulin for at least 12 months. Mean follow-up was 7 months (range, 4–16 months). Mean postoperative BMI was 24.9 (range, 18.9–31.7). Adequate glycemic control was achieved for 86.9% of patients, and 13.1% had important improvement. Four major complications occurred within 30 days of surgery, and mortality was 2.6%. (70) Scopinaro et al. reported outcomes at mean follow-up of 13 years (range, 10–18 yrs) on 7 patients with BMI less than 35 who underwent BPD. In all patients, serum glucose levels were normalized at 1, 2, and 3 years. In 5 patients, a slight increase above 123 mg/dL was observed at or around 5 years. The values were maintained at all subsequent times with no one value higher than 160 mg being recorded. The other 2 patients had full resolution of diabetes at all follow-up times. Serum cholesterol and triglyceride values fell to normal 1 year after BPD and remained within the normal range. Blood pressure normalized in 6 cases and improved in 1. No patient had excessive weight loss at any postoperative time. (9) Kakoulidis and colleagues investigated the role of SG for patients with BMI 30–35. Fifteen of the 79 patients in the study had type 2 diabetes. At a follow-up of 6 months or more, diabetes was resolved in 2 patients and improved in one. (71)

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

Bariatric Surgery in Nondiabetic Patients With BMI Less Than 35 kg/m ^{2} (Other Than Diabetes)

A TEC Assessment was completed in 2012 concerning laparoscopic gastric banding in nondiabetic individuals with a BMI less than 35. (72) This Assessment was prompted by FDA approval of Lap-Band™ for this indication in 2011. The TEC Assessment concluded that laparoscopic adjustable gastric banding does not meet the TEC criteria in these patients and made the following summary statements:

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

Bariatric Surgery in Children and Adolescents

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

Treadwell and colleagues conducted a systematic review and meta-analysis of the published evidence on bariatric surgery in adolescents. (73) Their analysis included English language articles on currently performed procedures when data were separated by procedure and there was a minimum 1-year follow-up for weight and BMI. Studies must have reported outcome data for 3 or more patients aged 21 years or younger, representing at least 50% of pediatric patients enrolled at that center. Nineteen studies reported on from 11 to 68 patients who were 21 years or younger. Eight studies of LAGB reported data on 352 patients (mean BMI 45.8, median age range 15.6–20 years); 6 studies on RYGB included 131 patients (mean BMI 51.8, median age range 16–17.6 years); 5 studies of other procedures included 158 patients (mean BMI 48.8, median age range 15.7–21 years). Meta-analyses of BMI at longest follow-up indicated sustained and clinically significant reductions for both LAGB and RYGB. Comorbidity resolution was sparsely reported, but surgery appeared to resolve some medical conditions including diabetes and hypertension; 2 studies of LAGB showed large rates of diabetes resolution but low patient enrollment, and only 1 study of RYGB reporting relevant data. No in-hospital or postoperative death was reported in any LAGB study. The most frequently reported complications for LAGB were band slippage and micronutrient deficiency with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. More severe complications were reported for RYGB such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition. No in-hospital death was reported; however, 1 patient died 9 months after the study with severe *Clostridium difficile* colitis; 3 more died of causes that were not likely to have been directly related to the bariatric surgeries. No LAGB studies reported data on the impact of surgery on growth and development. One study of RYGB reported pre- and postoperative heights and concluded that there was no evidence of growth retardation at an average follow-up of 6 years, but it could not be determined from the data whether expected growth was achieved.

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

There are many case series of bariatric surgery in adolescents, and these generally report weight loss that is in the same range seen for adult patients For example, Nadler et al. (74) reported on 73 patients aged 13 to 17 years who have undergone LAGB since 2001 at the authors' institution. Mean preoperative BMI was 48. The EWL at 6 months, 1 year, and 2 years postoperatively was 35% ± 16%, 57% ± 23%, and 61% ± 27%, respectively. Six patients developed band slippage, and 3 developed symptomatic hiatal hernias. Nutritional complications included asymptomatic iron deficiency in 13 patients, asymptomatic vitamin D deficiency in 4 patients, and mild subjective hair loss in 14. In the 21 patients who entered the authors' FDA-approved study and had reached 1-year follow-up, 51 comorbid conditions were identified, 35 of which completely resolved, 9 were improved, 5 were unchanged, and 2 were aggravated after 1 year. (The FDA approval of the LapBand device is unchanged as of this writing.)

The Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Adolescent Bariatrics: Assessing Health Benefits and Risk study is an ongoing longitudinal study.

A number of guidelines for bariatric surgery in adolescents have been published in the U.S. (see clinical practice guidelines section). (1, 2, 75) These all include recommendations for BMI thresholds of 40, or

35 with weight-related comorbidities. The Institute for Clinical Systems Improvement (ICSI) recommendations apply to “mature adolescents”, (2) which is defined as those who have reached skeletal maturity. They acknowledge that bariatric surgery in the adolescent is controversial and should be approached on a case-by-case basis in conjunction with experts in obesity management. Guidelines from the Society of Gastrointestinal and Endoscopic Surgeons (75) state that bariatric surgery has been proven effective in adolescents and that patient selection criteria should be the same as used for adult bariatric surgery. The Endocrine Society guidelines on prevention and treatment of pediatric obesity (1) recommends bariatric surgery for adolescents who have a BMI greater than 50, or in adolescents with a BMI greater than 40 with severe comorbidities. They also state that adolescents should be psychologically stable and expected to be able to adhere to lifestyle modifications.

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

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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

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

Summary

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

Limited evidence is available on bariatric surgery in patients with a body mass index (BMI) of less than 35 kg/m^2. Case series report a high rate of remission of diabetes in undergoing gastric bypass surgery, and this indication was judged to meet the TEC criteria in 2012. However, bariatric surgery for diabetes in patients with a BMI less than 35 is not currently considered standard of care and is not supported in current specialty society guidelines. For patients without diabetes, there is limited evidence on

outcomes of surgery and no evidence that health outcomes are improved. As a result, bariatric surgery for patients with a BMI less than 35 is investigational.

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

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

Practice Guidelines and Position Statements

Joint Guidelines were published by AACE/ASM/Obesity Society in 2013. (76) 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 co-morbidities
- 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.

In November 2009**,** the ASMBS updated its position on sleeve gastrectomy to state that it has accepted sleeve gastrectomy as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients. They cite the need for long-term data to confirm the effectiveness of the procedure as a stand-alone intervention. (77)

In January 2009, the ASMBS Emerging Technologies and Clinical Issues Committee issued a Position Statement on Emerging Endosurgical Interventions for Treatment of Obesity. (78) The committee stated that “use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention.” It calls for trials to generate data for risk-benefit analysis, assessments of disability, durability, and resource utilization and notes that dramatic reduction in risk may allow for acceptance of interventions that do not provide durable benefits comparable to currently accepted bariatric procedures.

Recommendations from the National Institutes of Health stress the importance of a multidisciplinary approach to bariatric surgery patients, including such ancillary services as nutritional and psychological support. (4) It is also recommended that bariatric surgery programs provide lifelong follow-up for treated patients. However, no regulatory mechanisms ensure that these resources are present in all programs.

The Endocrine Society published recommendations for the following for prevention and treatment of pediatric obesity in 2008. These guidelines contained the following recommendations for bariatric surgery (1):

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The child has a BMI 50 kg/m^2 or has BMI above 40kg/m^2 and significant, severe comorbidities.
- Severe obesity and comorbidities persist, despite a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit.
- There is access to an experienced surgeon in a medical center employing a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family, and the institution is either participating in a study of the outcome of bariatric surgery or sharing data.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.
- Bariatric surgery is not recommended for preadolescent children, for pregnant or breast-feeding adolescents, and for those planning to become pregnant within 2 years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved eating disorder, untreated psychiatric disorder, or Prader-Willi syndrome.

Medical National Coverage

Medicare has published a national coverage decision regarding bariatric surgery that concluded the following (79):

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

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

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

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

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Billing Coding/Physician Documentation Information

S2083 Adjustment of gastric band diameter via subcutanous port by injection or aspiration of saline
43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43659 Unlisted laparoscopy procedure, stomach
43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
43771 Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only
43772 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only
43773 Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only
43774 Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components
43775 Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43842 Gastric restrictive procedure, without gastric bypass for morbid obesity vertical banded gastroplasty
43843 Gastric restrictive procedure, with gastric bypass for morbid obesity; other than vertical banded gastroplasty
43845 Gastric restrictive procedure with partial gastrectomy, pylorus preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846 Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb Roux-en-Y gastroenterostomy
43847 Gastric restrictive procedure with gastric bypass for morbid obesity; with small bowel

reconstruction

43848 Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)

43886 Gastric restrictive procedure, open; revision of subcutaneous port component only

43887 Gastric restrictive procedure, open; removal of subcutaneous port component only

43888 Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

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 co-morbidities. 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.
3/1/2014	Language added to policy statement on revision surgery to include complications of laparoscopic adjustable gastric banding.

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)

Surgery	Year of Surgery

Medical History:

(check all that apply and indicate the year diagnosed)

Abnormal EKG	☐ Yes	☐ No	Year:
Alcohol abuse	☐ Yes	☐ No	Year:
Anemia	☐ Yes	☐ No	Year:
Angina (chest pain)	☐ Yes	☐ No	Year:
Arthritis	☐ Yes	☐ No	Year:
Asthma	☐ Yes	☐ No	Year:
Cirrhosis	☐ Yes	☐ No	Year:
Colitis/Inflammatory Bowel/Crohn's	☐ Yes	☐ No	Year:
Congestive heart failure (CHF)	☐ Yes	☐ No	Year:
COPD	☐ Yes	☐ No	Year:
Coronary artery bypass graft (CABG)	☐ Yes	☐ No	Year:
Deep vein thrombosis (DVT)	☐ Yes	☐ No	Year:
Depression	☐ Yes	☐ No	Year:
Diabetes Last HgA1C value: Date:	☐ Yes	☐ No	Year:
Drug abuse	☐ Yes	☐ No	Year:
Fatty liver	☐ Yes	☐ No	Year:
Fibromyalgia	☐ Yes	☐ No	Year:
Gallbladder disease	☐ Yes	☐ No	Year:
Heart defibrillator placement	☐ Yes	☐ No	Year:
Heart disease	☐ Yes	☐ No	Year:

Heartburn/Reflux	☐ Yes	☐ No	Year:
Hepatitis	☐ Yes	☐ No	Year:
Hiatal hernia	☐ Yes	☐ No	Year:
High blood pressure	☐ Yes	☐ No	Year:
High cholesterol	☐ Yes	☐ No	Year:
High triglycerides	☐ Yes	☐ No	Year:
Hyperthyroid	☐ Yes	☐ No	Year:
Hypothyroid	☐ Yes	☐ No	Year:
IVC filter	☐ Yes	☐ No	Year:
Lupus	☐ Yes	☐ No	Year:
Myocardial infarction (heart attack)	☐ Yes	☐ No	Year:
Palpitations	☐ Yes	☐ No	Year:
Pneumonia	☐ Yes	☐ No	Year:
Psychiatric disorder	☐ Yes	☐ No	Year:
Pulmonary embolism (PE)	☐ Yes	☐ No	Year:
Sleep Apnea Syndrome On CPAP? ☐ Yes ☐ No	☐ Yes	☐ No	Year:
Stress incontinence	☐ Yes	☐ No	Year:
Use of Coumadin or Heparin	☐ Yes	☐ No	Year:
Venous leg ulcers	☐ Yes	☐ No	Year:

Drugs, Medications, Vitamins, or Herbal Supplements:

Name	**Dose**	**Frequency**

☐ Taking no medications

Social History:

Marital Status (check one):

☐ Single ☐ Divorced

☐ Married ☐ 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:

Activity (walking, swimming, etc.)	**Frequency**

Weight loss programs/diets/medications:

Diet	Dates	Length of time	Amt. of weight loss	Form of Proof
Acutrim®				
Atkins Diet®				
Calorie Counting				
Dexatrim®				
Diet Pills from physician				
Grapefruit Diet®				
Health Spa Program				
Hypnosis				
Jenny Craig®				
Low fat diets				
Meridia®				
Nutri-System®				
Orlistat®				
Overeaters Anonymous®				
Phen Fen®				
Physicians Weight Loss®				
Redux®				
Richard Simmons®				
Slim Fast®				
Supervised calorie counting by registered dietician				
Weight Watchers®				
Xenical®				
Other:				
Other:				
Other:				
Other:				
Other:				
Other:				
Other:				