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

The first treatment of morbid obesity is dietary and lifestyle changes. Although this strategy may be effective in some patients, only a few morbidly obese individuals can reduce and control weight through diet and exercise. 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/m2, or greater than 35 kg/m2 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 may be involved. Gastrointestinal peptides, glucagon-like peptide-1 (GLP-1), glucose -dependent insulinotropic peptide (GIP), and peptide YY (PYY) are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. GLP-1 is secreted by the L cells of the distal ileum in response to ingested nutrients and acts on pancreatic islets to augment glucose-dependent insulin secretion. It also slows gastric emptying, which delays digestion, blunts postprandial glycemia, and acts on the central nervous system to induce satiety and decrease food intake. Other effects may improve insulin sensitivity. GIP acts on pancreatic beta-cells to increase insulin secretion through the same mechanisms as GLP-1, although it is less potent. PYY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

Surgery for morbid obesity, termed bariatric surgery, falls into 2 general categories: 1) gastric-restrictive procedures that create a small gastric pouch, resulting in weight loss by producing early satiety and thus decreasing dietary intake; and 2) malabsorptive procedures, which produce weight loss due to malabsorption by altering the normal transit of ingested food.
through the intestinal tract. Some bariatric procedures may include both a restrictive and a malabsorptive component. The following summarizes the different restrictive and malabsorptive procedures.

**Gastric Restrictive Procedures**

1. **Vertical-Banded Gastroplasty (CPT code 43842)**

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

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

   Adjustable gastric banding involves placing a gastric band around the exterior of the stomach. The band is attached to a reservoir that is implanted subcutaneously in the rectus sheath. Injecting the reservoir with saline will alter the diameter of the gastric band; therefore, the rate-limiting stoma in the stomach can be progressively narrowed to induce greater weight loss, or expanded if complications develop. Because the stomach is not entered, the surgery and any revisions, if necessary, are relatively simple. Complications include slippage of the external band or band erosion through the gastric wall. Adjustable gastric banding has been widely used in Europe; currently, 1 such device is approved by the U.S. Food and Drug Administration (FDA) for marketing in the United States, Lap-Band (BioEnterics, Carpentiera, 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 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 or 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 post-gastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in
association with a Roux-en-Y procedure (i.e., a gastrojejunal anastomosis). Thus, the flow of food bypasses the duodenum and proximal small bowel. The procedure may also be associated with an unpleasant “dumping syndrome,” in which a large osmotic load delivered directly to the jejunum from the stomach produces abdominal pain and/or vomiting. The dumping syndrome may further reduce intake, particularly in “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 does not accurately describe the mini-gastric bypass, since CPT code explicitly describes a Roux-en-Y gastroenterostomy, which is not used in the mini-gastric bypass.

6. **Sleeve gastrectomy (no specific CPT code)**

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 by the open or laparoscopic technique. Some surgeons have proposed this 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.

**Malabsorptive Procedures**

The multiple variants of malabsorptive procedures differ in the lengths of the alimentary limb, the biliopancreatic limb, and the common limb, in which the alimentary and biliopancreatic limbs are anastomosed. These procedures also may include an element of a restrictive surgery based on the size of the stomach pouch. The degree of malabsorption is related to the length of the alimentary and common limbs. For example, a shorter alimentary limb (i.e., the greater the amount of intestine that is excluded from the nutrient flow) will be associated with
malabsorption of a variety of nutrients, while a short common limb (i.e., the biliopancreatic juices are allowed to mix with nutrients for only a short segment) will primarily limit absorption of fat.

1. 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.

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

2. A 200-cm long “alimentary tract” consists of 200 cm of ileum connecting the stomach to a common distal segment.

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

4. 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.

5. 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.

2. Biliopancreatic Bypass with Duodenal Switch (CPT code 43845—gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenooileostomy 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 here. 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 duodenoleal 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.

3. 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.

4. 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.

Policy

Benefits are subject to all terms, limitations and conditions of the subscriber contract.

Prior approval may be required subject to all terms, limitations and conditions of the subscriber contract.

For New England Health Plan (NEHP) members an approved referral authorization is required.

One psychiatric diagnostic interview examination (CPT code 90801) is eligible under the medical benefit when billed preoperatively with the morbid obesity diagnosis (278.01)

When service or procedure is covered

1. Gastric Restrictive Procedures

Open gastric bypass using a Roux-en-Y anastomosis with an alimentary or “Roux" limb of 150 cm or less, or vertical-banded gastroplasty, may be considered medically necessary in the treatment of morbid obesity that has not responded to conservative measures. Further, 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.

Laparoscopic gastric bypass using a Roux-en-Y anastomosis is considered medically necessary in the treatment of morbid obesity that has not responded to conservative measures. Further, 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.
Adjustable gastric banding, consisting of an adjustable external band placed around the stomach, is considered medically necessary in the treatment of morbid obesity that has not responded to conservative measures. Further, 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.

Gastric bypass using a Billroth II type of anastomosis, popularized as the mini-gastric bypass, is considered investigational as a treatment of morbid obesity.

Sleeve gastrectomy, either as the sole procedure or as one step in a staged procedure, is considered investigational as a treatment for morbid obesity.

2. Malabsorptive Procedures

Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro procedure) with duodenal switch may be considered medically necessary for treatment of morbidly obese patients with BMI of 50 kg/m² or greater that has not responded to conservative measures.

Biliopancreatic bypass without duodenal switch is considered investigational as a treatment of morbid obesity.

Long-limb gastric bypass procedure (i.e., >150 cm) is considered investigational as a treatment of morbid obesity.

3. Endoscopic Procedures for Weight Gain after Bariatric Surgery

Endoscopic procedures (e.g., insertion of the StomaphyX™ device) to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches are considered investigational.

4. Bariatric Surgery in Treatment of Type 2 Diabetes Mellitus

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

Policy Guidelines

Patient Selection Criteria

Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m² or a BMI greater than 35 kg/m² 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/m²) 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 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 ages 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/m². Malabsorptive procedures, though they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

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

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

When service or procedure may not be covered
- When prior approval has not been obtained and is required
- When the above medical necessity criteria has not been met.

Benefit Application

BlueCard/National Account Issues
State mandates and contractual exclusions may apply to coverage eligibility of bariatric surgery in general.
State or federal mandates (e.g., FEP) may dictate that all devices approved by the U.S. Food and Drug Administration (FDA) (i.e., the Lap-Band device) may not be considered investigational and thus coverage eligibility of these devices may be assessed only on the basis of their medical necessity.

Eligible Providers
Surgeons (MD or DO)

Billing and Coding/Physician Documentation Information
See Attachment I

Rationale

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 2 procedures were the focus of the 1991 National Institutes of Health (NIH) Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass. (1)
A 2003 TEC Assessment (2) 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. (3) 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 biliopancreatic bypass 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.

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

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.)

Surgical Procedures

The following discussion provides a representative summary of the literature on bariatric surgery, focusing on improvements in comorbidities of obesity.

Vertical-Banded Gastroplasty

Numerous clinical series report substantial amounts of weight loss following vertical-banded gastroplasty. As a representative example of a large case series with long-term follow-up, MacLean and colleagues reported on 201 patients who underwent vertical-banded gastroplasty and were followed up for a minimum of 2 years. (4) Staple line perforation occurred in 48% of patients, and 36% underwent reoperation either to repair the perforation or to repair a stenosis at the rate-limiting orifice. However, the more than 50% of patients who maintained an intact staple line had durable weight loss of 75% to 100% of excess weight.

In another case series of 305 patients undergoing vertical-banded gastroplasty, there was a mean weight loss of 60% of excess weight at 2-year follow-up. (5) In contrast to MacLean’s report, there was only a 1.3% incidence of staple line disruption. Significant decreases in cardiovascular risk factors and incidence of diabetes and sleep apnea were also reported in this trial and other case series. (6-8) For example, Melissa and colleagues evaluated obesity’s comorbid conditions in 62 patients who had undergone a vertical-banded gastroplasty. (8) All patients were followed up for 12 to 48 months, with 84% of patients losing at least 50% of their excess weight. Of the 218 weight-related pathologic conditions existing before the operation, 83% were either cured or improved.

A smaller body of literature compares outcomes between vertical-banded gastroplasty and open gastric bypass. The most rigorous of these comparative trials, the Adelaide Study (9), randomized 310 morbidly obese patients to gastric bypass, vertical-banded gastroplasty, or horizontal gastroplasty. The percent of patients with greater than 50% 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. (10) 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) (2). 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, and 19%–36% more patients with >50% excess weight loss for patients 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.

Gastric Bypass with Short Limb (<150 cm)

While vertical-banded gastroplasty was perhaps the dominant bariatric surgery in the 1980s, it has been surpassed in this country 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. Griffen summarized the experience of over 10,000 gastric bypass operations from a number of bariatric surgeons. (11) It was estimated that 85% of patients reduced their weight to at least 50% above the 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. (12) 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. Flickinger and colleagues reported on the incidence of diabetes and hypertension in a case series of 397 patients. (13) Prior to surgery, 22% had diabetes mellitus and 13% had impaired glucose intolerance. After surgery, all but 1 of the patients remained euglycemic. A total of 57% of patients were hypertensive before surgery compared to only 18% after surgery. Similarly, Pories and colleagues (12) reported that of 163 obese patients with diabetes or impaired glucose tolerance, only 5% remained with inadequate control after gastric bypass surgery and associated weight loss. Other studies have reported that gastric bypass surgery and weight loss are associated with improvements in the lipid profile. (14)

As discussed previously, comparative trials summarized in the 2003 TEC Assessment (2) consistently report favorable outcomes for open gastric bypass when compared with vertical-banded gastroplasty, including 2 randomized, controlled trials. Some nonrandomized trials that compare open gastric bypass with procedures other than vertical-banded gastroplasty were also summarized in the 2003 TEC Assessment. (2) 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 vertical-banded gastroplasty. 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. (15) 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 randomized, controlled trials. In addition, 18 large clinical series of laparoscopic gastric bypass were included in the review.

The 2005 TEC Assessment (15) 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 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 been primarily advocated by 1 surgeon. In 2001, Rutledge published his experience with 1,274 patients who underwent the mini-gastric bypass procedure. (16) 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.

Adjustable Gastric Banding

Adjustable gastric banding, using an externally adjustable band placed around the stomach, has been extensively used in Europe, and 1 such device, the Lap-Band, has received approval from the FDA in this country. 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. (17) 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 (18) 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 reasonable 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 in order 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, reoperations are reported in approximately 25% of patients, while in the single-arm studies the composite rate for re-operations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable, for example, the range of rates for band slippage is 1%–36% and the range for port access problems is 2%–20%. These data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. 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 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.

As a stand-alone procedure, there are limited data to evaluate outcomes and/or compare efficacy to other procedures. A small number of clinical series have been published that report on outcomes after sleeve gastrectomy alone. Moon et al (19) reported on a series of 60 patients who had undergone sleeve gastrectomy and who had at least 1-year follow-up. These authors reported an 83% EWL at 12 months. Diabetes resolved in 100% of patients in this series, and hypertension resolved in 93%. In a smaller series of 23 patients, Langer et al (20) reported a 56% EWL at 1 year.

A small number of clinical series also report on sleeve gastrectomy 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 sleeve gastrectomy 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). (21, 22) 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**

Numerous clinical series of biliopancreatic bypass 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 biliopancreatic bypass is reported by Scopinaro, who developed the procedure. In 1996, Scopinaro summarized his experience with 1,217 patients. (23) 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 2005 TEC Assessment, (15) and outcomes of biliopancreatic bypass, 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 2 procedures, these data do not support the hypothesis that biliopancreatic bypass 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 biliopancreatic bypass. Slater et al (24) focused specifically on vitamin and calcium
deficiencies following biliopancreatic bypass. 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 (25) reported similar data in a study that compared several technical variations of biliopancreatic bypass. 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 this country. According to Murr and colleagues (26), biliopancreatic bypass has not been widely accepted in this country due to unacceptable serious long-term morbidities. For example, biliopancreatic bypass 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. (26-28) In addition, Murr hypothesizes that the incidence of protein malnutrition may be higher in this country compared to Scopinaro’s Italian series, since the North American diet has a higher percentage of fat and lesser amounts of carbohydrates. (26)

Biliopancreatic Bypass with Duodenal Switch

Biliopancreatic diversion may be performed with or without the duodenal switch procedure. In the duodenal switch 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, who reported on 465 patients who underwent the duodenal switch procedure compared to 252 who underwent the biliopancreatic bypass. (29) It should be noted that in addition to the preservation of the duodenum, the common segment was elongated to 100 cm. The authors noted similar weight loss in the 2 groups. Also, in the duodenal switch group, there was a lower incidence of metabolic abnormalities such as protein malnutrition, which prompted reversal of the procedure in 1.7% of those undergoing biliopancreatic bypass versus only 0.1% after the duodenal switch procedure. However, it is not known whether this outcome is attributed to the lengthening of the common segment versus retention of the pylorus. Hess reported on a case series of 440 patients with variable lengths of the common channel. (30) The EWL varied between 60% and 90%, depending on the length of the common segment and alimentary limb. There were 2 late deaths, 1 due to septic shock secondary to an infected panniculus and 1 related to liver failure. A total of 10 patients underwent revision to lengthen the common segment secondary to low protein or excessive diarrhea. Seven patients underwent shortening of the common segment due to inadequate weight loss. Baltasar and colleagues reported on a case series of 60 patients undergoing the duodenal switch procedure with a common segment length of 75 cm. (31) One patient succumbed to liver failure and another to malnutrition. The authors questioned the safety of the procedure.

The malabsorptive component of biliopancreatic bypass with duodenal switch is essentially identical to biliopancreatic bypass alone; therefore, the incidence of metabolic and nutritional deficiencies between the procedures is likely to be very similar.

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 biliopancreatic bypass. However, there has been limited published evidence on outcomes from this procedure, and a large amount of variability in the technical aspects of the procedure among the published literature. Murr reported on 26 patients who underwent a "very very long-limb Roux-en-Y gastric bypass." (26) In comparison to a case series of 11 patients who underwent biliopancreatic bypass, 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 biliopancreatic bypass. Sugerman also attributes increasing the length of the common segment to decreasing metabolic morbidities. (32)

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 in which 2 or more 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 cut-off 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 randomized, controlled trials (33, 34). In both of these trials, there were no significant differences in weight loss between groups. Brolin et al (35) compared 3 limb lengths, with the longest limb (distal gastric bypass) group having a significantly larger decrease in BMI at 1 year, while the other 2 groups had similar decrease in BMI. MacLean et al (36) examined morbidly obese and super obese patients separately, and reported a significant difference in favor of the long-limb gastric bypass group. However, this analysis compared the final BMI of the 2 groups, and did not report the actual change in BMI or the initial BMI for each group.

Adverse events were poorly reported by these studies, with only 3 reporting data on adverse events. Mason et al (37) 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 (33) were higher for standard gastric bypass, while the rates reported by Brolin et al (35) 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.

**Summary**

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. The degree of weight loss following gastric bypass is associated with improvement in weight-related morbidities for these patients. Gastric bypass accounts for over 80% of bariatric operations performed in the United States, and is considered the reference standard to which other procedures should be compared. There is sufficient evidence for patients considering bariatric surgery to make an informed choice between gastric bypass and adjustable gastric banding. An informed patient may choose either approach as the preferred procedure based on assessment of comparative risks and benefits.

As noted in the Policy section, some bariatric procedures for treatment of morbid obesity remain investigational. This interpretation of the term investigational may be questioned by those who would point out some procedures, for example, biliopancreatic bypass, have been performed for some 20 years with results of large case series reported in the peer-reviewed literature. However, one criterion used to define the term investigational in the Introduction to
the Medical Policy Reference Manual is whether the malabsorptive procedures are at least as good as the alternatives.

For biliopancreatic diversion, the comparison involves a judgment as to whether the increased metabolic risks are more than outweighed by an increased benefit associated with potentially greater weight loss. Some experts contend that the percent of excess weight loss following biliopancreatic bypass is at or above 70%, higher than that reported with gastric restrictive procedures. However, the recent 2005 TEC Assessment (26), which included comparative studies and the largest clinical series, did not find that the evidence was sufficient to conclude that weight loss following biliopancreatic bypass was greater than for gastric bypass. In addition, the TEC Assessment found that rates of nutritional and metabolic complications appear to be very high following biliopancreatic bypass.

The duodenal switch procedure is often performed in conjunction with biliopancreatic diversion. This modification of biliopancreatic bypass affects the gastric restrictive portion of the surgery but not the malabsorptive component. The evidence is not sufficient to determine whether this modification leads to important differences in health outcomes. Limited evidence suggests that weight loss is similar between the procedures. The metabolic and nutritional deficiencies reported following biliopancreatic diversion are expected to be the same whether or not the duodenal switch is included in the procedure.

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 pre-operative 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.

Other Issues

It should be noted that all bariatric surgeries require a high degree of patient compliance. For gastric-restrictive procedures, the weight loss is primarily due to reduced caloric intake, and thus the patient must be committed to eating small meals, reinforced by early satiety. For example, gastric restrictive surgery will not be successful in patients who consume high volumes of calorie-rich liquids. In patients undergoing biliopancreatic bypass, reduced intake may not be as much of an issue, but patients must adhere to a balanced diet to avoid metabolic complications. In addition, the high potential for metabolic complications requires life-long follow-up. Therefore patient selection is a critical process, often requiring psychiatric evaluation and a multidisciplinary team approach. Given these factors, bariatric surgery should be approached very cautiously in adolescents.

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. (3) 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.

High-volume bariatric programs are likely to be more successful in achieving optimal outcomes. Accumulating evidence supports a correlation between increasing volume and positive outcomes for bariatric surgery. Nguyen et al (38) compared outcomes of low- and high-volume academic medical centers. The authors reported that higher-volume hospitals (more than 100 cases/year) had lower rates of mortality (0.3% vs. 1.2%, p<0.01) and overall complication rates (10.2% vs. 14.5%, p<0.01), when compared with lower volume hospitals. Liu et al (39) examined complication rates from bariatric surgery in California, classifying programs as very low (<50 cases/year), low (50–99 cases/year), or high (>200 cases/year) volume. After adjusting for differences in case-mix, patients at very low-volume hospitals were
2.72 times more likely to experience perioperative complications, and patients at low-volume hospitals were 2.7 times more likely to experience complications, compared with high-volume hospitals. Courcoulas et al (40) examined mortality and complications in Pennsylvania bariatric surgery programs by individual surgeon and hospital volume. This study reported that low-volume surgeons had higher rates of adverse events (28% vs. 5%, p<0.05), and a trend toward higher mortality (5% vs. .03%, p=0.06), when compared to high-volume surgeons.

Some states and health systems have instituted internal regulations to address these programmatic concerns. Blue Cross and Blue Shield Association (BCBSA) has an ongoing initiative that attempts to identify high performing bariatric surgery centers that meet programmatic requirements and, ultimately, that achieve pre-specified outcomes (BCBSA Bariatric Surgery Workgroup). This initiative identifies numerous indicators including institutional factors, characteristics of individual surgeons, the availability of ancillary services, patient selection procedures, and follow-up plans. It also outlines data collection and management procedures that can be used in the future to track patient outcomes, such as mortality, complications, and re-admission rates.

This policy does not apply to patients under the age of 18 years. There is limited long-term follow-up information for bariatric surgery in these patients and a need for clinical trials. Studies are needed to assess the relative benefits and harms of bariatric surgery for these individuals. In particular, the impact on growth and development needs further study. Of note, the FDA PMA for the LAP-BAND system indicates that it is for use only in severely obese adult patients. (41) (The clinical study submitted to the FDA for LAP-BAND approval involved adults ages 18–55 years.)

February 2008 Update

The policy was updated following a MEDLINE search in January 2008. One area of focus was use of adjustable gastric banding in those with a BMI above 50 kg per meter-squared. Overall, the data concerning this use of gastric banding are quite limited, in that they are focused on reporting duration of surgery, complications, and percentage of EWL. While weight loss is important, data about impact on comorbid conditions such as diabetes, hypertension, and obstructive sleep apnea are of equal importance. Comparative data, but not from a randomized trial, were reported by Bowne. (42) Using a prospectively maintained database, the authors identified patients who underwent operative treatment for morbid obesity between February 2001 and June 2004. The study group included super morbidly obese patients (BMI above 50) who received LAGB or laparoscopic Roux-en-Y gastric bypass (LRYGB). Among 106 patients with super morbid obesity, 60 (57%) and 46 (43%) underwent LAGB and LRYGB, respectively. The overall median follow-up was 16.2 months (range, 1–40 months). Compared with LRYGB, patients who underwent LAGB experienced a greater incidence of late complications and reoperations. Likewise, patients who underwent LRYGB had a greater resolution of concomitant diabetes mellitus and sleep apnea compared with the LAGB group. The EWL was 52% in the LRYGB group compared to 31% in the LAGB group. Other studies identified (43-46) did not report on the impact of the surgery on co-morbid conditions and/or did not provide comparative data with other techniques. For example, Parikh conducted a retrospective comparative review of super-obese patients (BMI greater than 50) who underwent LAGB, LRYGB, or biliopancreatic diversion. At 1 year, EWL was 35% for LAGB and 58% for LRYGB. (43) This study also noted that LAGB had the shorter operative times and lowest morbidity; however, it did not report outcomes on comorbid disease. Because of the limited data, concerns exist that the LAGB will not produce sufficient long-term weight loss to impact important comorbid conditions such as diabetes, hypertension, and sleep apnea. Thus, the policy guideline statement concerning adjustable banding in those with a BMI above 50 is unchanged.

Another area of focus for this update was to review endoscopic procedures for patients who gain weight after 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. (47) 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 (policy No. 2.01.38). The published data concerning use of these devices for treatment of regained weight is quite limited. Published case series have reported results using a number of different devices and procedures (including sclerosing injections) as treatment for this condition. The largest series found involved 28 patients treated with a sclerosing agent (sodium morrhuate). (48) Reported trials that used one of the suturing devices had fewer than 10 patients. For example, Herron reported on a feasibility study in animals. (49) Thompson 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. (50) 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 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.

Recently another adjustable gastric banding device has been approved by the FDA through the PMA process. The REALIZE device was approved in September 2007. The results of a multicenter study with 3-year follow-up that enrolled 276 adults submitted to the FDA show outcomes with this device that are similar (weight loss, reoperation, complications) to other studies reviewed in this policy for adjustable gastric banding. (51) Thus, this device is another option that can be used in adjustable gastric banding.

Physician Specialty Society and Academic Medical Center Input

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.

2009 Update

This update is based on a search of the MEDLINE database to January 2009.

Mini-gastric Bypass

Although largely abandoned because of concerns about biliary regurgitation with bile gastritis and esophagitis, the mini-gastric bypass procedure continues to have its proponents, mainly outside the United States. An RCT compared mini-gastric bypass with LRYGP in 80 patients randomized to 40 patients in each group. At 2 years, the EWL was not significantly different (64% vs. 60%, respectively). The rate of major early postoperative complications was 5% in the LRYGP group and none in the mini-gastric bypass group, but the incidence of marginal
ulcer was 5% in the mini-gastric bypass group and 3% in the LRYGP group. (52) A number of case series with short outcomes are reported in the recent literature. Wang and colleagues report results in 423 patients. Mean preoperative BMI was 44.2 and decreased to 29.2 and 28.4 at 1- and 2-year follow-up. Mean EWL at 1 and 2 years was 69% and 72%, respectively. Seven major and 18 minor complications occurred. Marginal ulcers were noted in 34 patients and anemia in 41 during follow-up. (53) Two case series had 100 or more patients but report only 6-month or 1-year outcomes. (54, 55) Johnson and colleagues identified 32 mini-gastric bypass patients who require or required surgical revision after the procedure. Complications requiring surgery included gastrojejunostomy leak (3), bile reflux (20), intractable marginal ulcer (54), malabsorption/malnutrition (8), and weight gain (2). Twenty-one patients underwent conversion to RYGB, and 5 more have planned revisions in the future. The authors propose a national registry to record complications and revisions performed after non-traditional bariatric procedures. (56) This evidence does not prompt reconsideration of the policy statement.

Biliopancreatic Diversion

Literature search since the last policy update identified 3 comparative studies of biliopancreatic diversion (BD) versus gastric bypass, 1 of which was randomized, and a retrospective comparison of BD with distal gastrectomy versus BD with duodenal switch. A fourth study compared the impact of BD (with or without duodenal switch), gastric bypass, and adjustable gastric band on diabetes. In addition, several case series of BD that included at least 100 patients were found.

Skroubis et al (44) randomized 130 patients with a BMI of 35–50 to either RYGB or BD (without duodenal switch) using a variant of 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, p=0.12). Late complications also did not differ significantly between the RYGB and BD groups (16 complications vs. 22, p=0.46). (57)

Prachand et al (45) published the largest comparative series of 350 super-obese patients with BMI >50 who underwent either RYGB or BD. 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). (59)
had lost >50% of the initial excess weight. During 10-year follow-up, 46 of 248 BPD-DG patients required revision surgery versus 6 of 431 BPD-DS patients. Most revisions after BPD-DG were for malnutrition and diarrhea and consisted of lengthening the common channel. Information regarding side effects was collected in questionnaires; 90 of 178 BPD-DG and 44 of 185 BPD-DS responders reported vomiting during the last month, and diarrhea was reported by 14% of BPD-DG versus 20% of BPD-DS responders. Heartburn was reported more frequently by BPD-DS patients (67 of 185 vs. 32 of 178) and was manageable without revision. One ulcer was documented by gastroscopy and cured with medical treatment. Long-term complications (fractures, urolithiasis) and rates of reoperation for obstruction were not significantly different between groups. At 10 years, albumin levels were comparable; however, the common channel had been lengthened in 20% of BPD-DG patients for hypoalbuminemia. Mortality at 10 years was 4.8% in the BPD-DG group and 8.4% in the BPD-DS group, although the difference was mainly attributed to causes unrelated to operative technique (trauma and suicide). (60)

Parikh and colleagues compared 3 types of bariatric surgery for outcomes on resolution of diabetes: LAGB, n=218; RYGB, n=53; and BPD (with or without DS), n=11. Outcomes with and without DS were not reported separately. Patient preference played a large part in choice of surgery type. Data on the 282 diabetic patients came from a registry of 1,293 patients collected from July 2001 through December 2004 at a U.S. center. Diabetes diagnosis was based on requirement for diabetes medication or diagnosis of diagnosis or glucose intolerance by the primary physician. Resolution was defined as discontinuation of oral hypoglycemic agents or insulin. Preoperative BMIs were LAGB, 49.8 +/- 11; RYGB, 46.1 +/- 9.6; and BPD with or without DS, 46 +/- 10.6. The EWL at 1 year was 43% for LAGB (87% follow-up), 66% for RYGB (72% follow-up), and 68% for BPD with or without DS (55% follow-up). At 3 years, the EWL was 45% (65% follow-up), 66% (65% follow-up), and 82% (56% follow-up). At 1 year, 39% of LAGB patients, 22% of RYGB patients, and 11% of BPD patients required oral hypoglycemics, and at 2 years 34%, 13%, and 13%, respectively, did. At 1 year, 14% of LAGB patients, 7% of RYGB patients, and 11% of BPD patients required insulin, and at 2 years, 18%, 13%, and 13%, respectively, did. A subgroup analysis revealed that LAGB patients who still required medications at 2 years had longer duration of diabetes before surgery and a lower EWL. (61)

One single-arm case series provided further evidence on long-term outcomes from BPD (47). In this study, 343 consecutive patients who underwent the Larrad variation of BPD were followed for up to 10 years (n=65). (The Larrad 50-50 BPD consists of lengthening the alimentary channel preserving most of the jejunum-ileum, by creating a short biliopancreatic limb (50 cm) and maintaining 50 cm of common limb.) Weight loss was maintained for up to 10 years, with a 77.8% EWL reported at 10 years. Diarrhea was reported in 10.8% of patients, with severe diarrhea in 2.5%. Anemia or iron deficiency was experienced by 30% of patients, and vitamin D deficiency was experienced by 30% of patients. (62)

Marceau et al 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 (2–15), 92% of patients with an initial BMI < 50 obtained BMI <35, and 83% of patients with BMI >50 achieved a BMI <40. Diabetes medication was discontinued in 92% and decreased in others. The use of continuous positive airway pressure was discontinued in 92% of patients, and the prevalence of cardiac risk index >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. (60)

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 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. (63)

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.

Limb-Length

Interest in improving weight loss outcomes, increasing control of comorbidities, and minimizing complications, particularly long-term nutritional deficiencies, has resulted in continuous evolution of bariatric surgical procedures including modification of limb lengths. Two comparative studies that evaluated long-limb gastric bypass were identified. Christou et al reported the results of a study comparing long-term weight loss between short-limb (standard) and long-limb gastric bypass. This retrospective study obtained data on 228 of 272 (83.8%) consecutive patients undergoing one of the two procedures at one institution. Short-limb gastric bypass was performed on 140 patients (61%), and 69 (39%) underwent long-limb bypass; the mean follow-up for all patients was 11.4 years. The decision on which operation to perform was made according to time, as this institution used the short-limb bypass until 1993 and then switched to the long-limb bypass afterward. The results of this study showed no difference between groups in weight loss or percent of patients categorized as ‘failures’. (64)

In a study by Pinheiro et al, 105 patients with BMI of 50 or greater who were diabetic or had insulin resistance were randomly assigned to RYGB with a biliary limb of 50 cm and a Roux limb of 150 cm (group 1, n=57) or RYGB with a biliary limb of 100 cm and a Roux limb of 250 cm (group 2, n=48). Co-morbidities were considered controlled if patients required no medications and had normal blood test results during follow-up and improved if they required less medication or had improved blood test results. Mean follow-up was 48 months (range, 6–56 months). Preoperatively, 55 patients in group 1 had a mean fasting glucose of 154 mg/dL and a mean hemoglobin A1c of 7.7%; 34 used oral hypoglycemic drugs, 11 used oral drugs and insulin, and 10 used only insulin. In group 2, 45 patients had a mean fasting glucose of 174 mg/dL and a mean hemoglobin A1c of 8.3%; 23 used only oral agents, 14 used oral agents and insulin, and 8 used only insulin. In group 1, 32 of 55 (58%) patients achieved control of diabetes (mean fasting glucose 104 mg/dL), 22 improved (mean fasting glucose 118 mg/dL), and 1 had no response. In group 2, 42 of 45 (93%) patients achieved control, 1 improved, and 2 had no improvement (p<.05). Control was achieved within 1–12 weeks in both groups. With respect to lipid disorders (present in 52 of the 57 group 1 patients and in 41 of the 48 group 2 patients), 30 (57%) in group 1 and 29 (70%) in group 2 improved (p<.05). Rates of improvement in hypertension, sleep apnea, and gastroesophageal reflux disease were not significantly different between groups. Excess weight loss was faster in group 2, but not significantly different at 48 months. The authors cite total and subgroup sample size as limitations of their study and note that larger studies are needed to better assess the differences between the techniques. (65)
One case series was identified in the recent literature. Hamoui et al divided their series of 1,001 patients with mean BMI of 52 +/- 9 who underwent BBP with DS into 2 groups according to the ratio of the biliopancreatic limb length to the total small bowel length: a biliopancreatic limb length 45% or less of the small bowel length versus a biliopancreatic limb length more than 45% of the small bowel length. They compared nutritional parameters and EWL at 1, 2, and 3 years’ follow-up. In patients with a BMI of 60 or less, EWL was not clinically significant at any time point. For patients with BMI greater than 60, the EWL was 56.8% in patients with a biliopancreatic limb length 45% or less of the small bowel length versus 61.4% in those with a biliopancreatic limb length more than 45% of the small bowel length (p=.07). At 2 years, the EWL was 62.2% versus 77.5% (p=.04), and at 3 years, it was 59.8% versus 77.5% (p=.05).

This evidence does not prompt reconsideration of the policy statement, which remains unchanged.

Sleeve Gastrectomy

Two trials and a large number of reports of case series were identified in the literature search, most from centers outside the United States. Sleeve gastrectomy as a stand-alone procedure dominates the recent literature. Himpens et al report on a randomized study comparing LAGB and laparoscopic isolated sleeve gastrectomy (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, complications, and reoperations were recorded at 1 and 3 years’ follow-up. Median decrease in BMI in the 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) after 1 year 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; gastroesophageal reflux disease 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 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. 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. (67) Karamanakos and colleagues carried out a double-blind study to compare outcomes of 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%, p=0.04) and 12 months (69.7% vs. 60.5%, p=0.05). Fasting PYY levels increased after both surgical procedures. Appetite decreased in both groups but was greater after LSG. (68)

Case series with at least 100 subjects and at least 1-year follow-up are summarized here. All report on LSG as a stand-alone procedure. Lee et al report on a comparison of outcomes of 4 different laparoscopic bariatric procedures, RYGB (303 patients), adjustable gastric band (AGB, 271 patients), vertical banded gastrectomy also known as sleeve gastrectomy (VG, 216 patients), Hess’ BPD and DS (56 patients) performed between November 2002 and August 2005. Choice of operation was based on a combination of insurance coverage, patient preference, and physician recommendations. Preoperative and 1-year outcomes are shown below.
Preop BMI

<table>
<thead>
<tr>
<th></th>
<th>n=216</th>
<th>n=271</th>
<th>n=303</th>
<th>n=56</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>49+/-11</td>
<td>42+/-5</td>
<td>46+/-6</td>
<td>47+/-6</td>
</tr>
</tbody>
</table>

1-yr BMI

<table>
<thead>
<tr>
<th></th>
<th>n=216</th>
<th>n=271</th>
<th>n=303</th>
<th>n=56</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37+/-9</td>
<td>32+/-5</td>
<td>28+/-5</td>
<td>27+/-4</td>
</tr>
</tbody>
</table>

1-yr EWL, %

<table>
<thead>
<tr>
<th></th>
<th>n=216</th>
<th>n=271</th>
<th>n=303</th>
<th>n=56</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>59+/-17</td>
<td>47+/-20</td>
<td>75+/-16</td>
<td>79+/-12</td>
</tr>
</tbody>
</table>

BMI at 2 years (from graph)

|       | 27.7    | 31.4    | 27.8    | 25.1    |

Complication rates are as follows:

<table>
<thead>
<tr>
<th></th>
<th>VG</th>
<th>AGB</th>
<th>RYGB</th>
<th>BPD-DS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonoperative readmissions (%)</td>
<td>5 (2.3)</td>
<td>4 (1.5)</td>
<td>12 (4.0)</td>
<td>4 (7.1)</td>
</tr>
<tr>
<td>Reoperations (%)</td>
<td>6 (2.8)</td>
<td>13 (4.8)</td>
<td>26 (8.6)</td>
<td>18 (32.1)</td>
</tr>
<tr>
<td>Deaths (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Major complications (%)</td>
<td>10 (4.6)</td>
<td>13 (4.8)</td>
<td>32 (10.6)</td>
<td>22 (39.3)</td>
</tr>
<tr>
<td>Total complications (%)</td>
<td>6 (7.4)</td>
<td>18 (6.6)</td>
<td>69 (22.8)</td>
<td>27 (48.2)</td>
</tr>
</tbody>
</table>

The authors conclude that while long-term efficacy of sleeve gastrectomy is not clear, the data are promising. (69) Nocca and colleagues report EWL, mortality, and morbidity for 163 patients who underwent LSG. The EWL was 48.97% at 6 months, 59.45% at 1 year (120 patients), 62.02% at 18 months, and 61.52% at 2 years (98 patients). No statistical difference was noticed in EWL between obese and extremely obese patients. There was no operative mortality. Perioperative complications occurred in 12 cases (7.4%). The reoperation rate was 4.90%, and the postoperative morbidity was 6.74% due to 6 gastric fistulas (3.66%), in which 4 patients (2.44%) had a previous LAGB. Long-term morbidity was caused by esophageal reflux symptoms (11.80%). The authors noted that LSG may be proposed for volume-eater patients; however, weight regained, quality of life, and obesity-related morbidities need to be evaluated in longer-term studies. (70) Fuks et al reviewed experience with 135 patients who had stand-alone LSG. Mean preoperative BMI was 48.8 (range, 37–72) and decreased to 39.8 at 6 months (p < .001). Average excess body weight loss was 38.6% and 49.4% at 6 months and 1 year, respectively. There was no mortality, and the major complication rate, corresponding to gastric fistula in every case, was 5.1% (n = 7). (71)

Hamoui et al (50) reported on 118 high-risk patients undergoing sleeve gastrectomy by the open approach. There was 1 perioperative death (0.85%) and 18 postoperative complications (15.3%). Median EWL was 49.4% at 12 months and 47.3% at 24 months. (72) Cottam et al 2006 (51) reported on 126 high-risk patients (ASA class III or IV) who underwent LSG as the first stage of a two-stage operation. There was 1 death that occurred after the immediate postoperative period (0.8%), and major postoperative complications occurred in 16 patients (13%). Mean EWL at 1 year was 46%; 36 patients proceeded to the second stage operation, LRYGP, after a mean interval of 12.6 months. (73)

Two papers report on complications of sleeve gastrectomy. Lalor et al retrospectively reviewed data from 164 patients who underwent LSG as a primary or revision bariatric surgery. The major complication rate was 2.9% in the 148 patients who had LSG as a primary procedure. Complications were 1 leak and 1 case of hemorrhage requiring reoperation, 1 postoperative
abscess, 1 sleeve stricture requiring endoscopic dilation, and late choledocholithiasis and bile duct stricture requiring a Whipple procedure. Of the 16 patients undergoing revision surgery, 1 developed a leak and an abscess requiring reoperation, 1 case was aborted, and 2 were converted to an open procedure due to dense adhesions. No patient in either group died. (74) Frezza and colleagues reported their patients’ complications after LSG and compared them to 17 other published series. The mean complication rate for the 17 articles was 4.5%, the most common being reoperation, which occurred after 3.6% of procedures. (75) The additional evidence on sleeve gastrectomy indicates that this procedure is associated with early mortality of <1% and a risk of postoperative complications in the range of 13%–15%. The RCT suggests that weight loss at 1 year may be greater than for LAGB, while the case series report weight loss at 1 year that may be less than that reported for RYGP. This new evidence does not prompt reconsideration of the policy statement, which remains unchanged.

Bariatric surgery for children and adolescents

Published data on pediatric and adolescent patients undergoing bariatric procedures are limited. Treadwell and colleagues conducted a systematic review and meta-analysis of the published evidence. They included in their analysis 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. (76) Nadler et al report 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 improved, 5 were unchanged, and 2 were aggravated after 1 year. (The FDA approval of the LapBand device is unchanged as of this writing.) (77) The Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) Adolescent Bariatrics: Assessing Health Benefits and Risk study is currently recruiting participants. (78) A 2004 guideline developed by an expert panel discusses concerns and recommendations regarding evaluation, selection, choice of surgery type, timing of surgery, post-operative concerns, and long-term monitoring of severely overweight (BMI>40) adolescents considered
for bariatric surgery. The authors emphasize 3 important considerations: whether the patient’s health is compromised by severe obesity; whether conservative options have been tried and failed; and whether the patient is capable of decision making and providing informed consent. They recommend that patients must have failed >6 months of organized attempts at weight management, have attained or nearly attained physiologic maturity, have a BMI of 40 or more with serious obesity-related comorbidities, or a BMI of 50 or more with less severe comorbid conditions. (79) Although data are limited, outcomes of bariatric surgery in adolescents, in terms of weight loss, improvement in obesity-related comorbid conditions, and adverse events, appear to be similar to those reported in adults and are sufficient to consider bariatric surgery medically necessary for severely overweight adolescents with serious, uncontrolled comorbid conditions.

Bariatric Surgery for Treatment of 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 with a BMI in this range whose disease is under control and in patients with lower BMI. Dixon et al 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 >30 and <40. (Results were not reported separately for patients with BMI < or >35.) Sixty patients were enrolled and 30 were randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the 2-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and 4 (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was <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. (80)

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. Lee et al retrospectively identified 44 patients with type 2 diabetes and BMI <35, 114 patients with BMI between 35 and 45, and 43 patients with BMI >45 in a large series (820) 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 <35 and in 98% of those with BMI >35. The treatment goal of hemoglobin A1c <7%, LDL<150 mg/dl, and triglyceride <150 mg/dl was met in 76.5% of patients with BMI <35 and in 92.4% of those with BMI >35. (81) DePaula et al report on 39 patients with BMI <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%. (82) Scopinaro reported outcomes at mean follow-up of 13 years (range, 10–18 yrs) on 7 patients with BMI < 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. (83) Kakoulidis and colleagues investigated the role of sleeve gastrectomy 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 1. (84) Ramos et al reported preliminary results for 20 patients with BMI <30 who underwent duodenal-jejunal exclusion for treatment of type 2 diabetes. Outcomes measured preoperatively and at 3 and 6 months were BMI and fasting glycemia, glycosylated hemoglobin, and C-peptide levels. BMI decreased to the third month and stabilized between 3 and 6 months. Fasting glycemia was reduced by 43.8% (mean preoperative value, 171.3 [127–242], 107.1 [82–145] at 3 months, and 96.3 [78–118]) at 6 months, and hemoglobin A1c was lowered by 22.8% up to the sixth month (mean preoperative level, 8.8% [7.5–10.2], 7.8% [6.7–9.6] at 3 months, and 6.8% [5.8–7.9] at 6 months). C-peptide levels decreased 25% between the third and sixth months. (p<0.001). Two (20%) patients remained on oral medication after the sixth month. Longer follow-up of a larger number of patients is required before conclusions can be drawn regarding a potential role for this procedure. Clinical trials are underway in South America. (85)

The data are insufficient to allow conclusions regarding the efficacy of expanding the surgical approach in the treatment or cure of type 2 diabetes.

**Medicare Policy**

Medicare has published a national coverage decision regarding bariatric surgery that concluded the following (86):

“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 (87), 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.

References:


15. 2005 TEC Assessments; Tab 15. Laparoscopic gastric bypass surgery for morbid obesity.


47. Morton JM. Weight gain after bariatric surgery as a result of large gastric stoma: endotherapy with sodium morrhuate to induce stomal stenosis may prevent the need for surgical revision (editorial). Gastrointest Endosc 2007; 66(2): 246-7.

58. Prachand VN, DaVee RT, Alverdy JC. Duodenal switch provides superior weight loss in the super-obese (BMI≥50 kg/m²) compared with gastric bypass. Ann Surg 2006;244:611-19.


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/31/96</td>
<td>Add to Surgery section</td>
<td>New policy</td>
</tr>
<tr>
<td>08/18/00</td>
<td>Replace policy</td>
<td>Policy updated to include expanded discussion of biliopancreatic bypass and gastric banding. Policy statement unchanged</td>
</tr>
<tr>
<td>05/31/01</td>
<td>Replace policy</td>
<td>Policy revised to include mini-gastric bypass</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
<td>Details</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>02/15/02</td>
<td>Replace policy</td>
<td>Policy revised to include further information on laparoscopic banding. Policy statement unchanged</td>
</tr>
<tr>
<td>07/17/03</td>
<td>Replace policy</td>
<td>Policy revised to include the conclusions of the 2003 TEC Assessment. Policy statement added stating laparoscopic gastric bypass is investigational</td>
</tr>
<tr>
<td>11/9/04</td>
<td>Replace policy</td>
<td>Policy revised to include revised CPT code 43846; no other aspects of policy reviewed at this time. Coding updated in code table</td>
</tr>
<tr>
<td>12/14/05</td>
<td>Replace policy</td>
<td>Policy revised to include the results of the two 2005 TEC Assessments; policy statement regarding laparoscopic gastric bypass changed to medically necessary. Coding updated</td>
</tr>
<tr>
<td>07/20/06</td>
<td>Replace policy</td>
<td>Policy updated with sleeve gastrectomy. Sleeve gastrectomy is considered investigational</td>
</tr>
<tr>
<td>12/12/06</td>
<td>Replace policy</td>
<td>Policy updated with recent TEC Assessment; policy statement changed to indicate that adjustable gastric banding can be considered for those needing bariatric surgery. New references 18 (TEC Assessment) and 41 added. Information added to guidelines section that this policy does not apply to those under the age of 18.</td>
</tr>
<tr>
<td>02/14/08</td>
<td>Replace policy</td>
<td>Policy updated with literature review and clinical vetting. Policy statement added that endoscopic procedures for those who regain weight are investigational. Reference numbers 42 to 50 added</td>
</tr>
<tr>
<td>9/16/08</td>
<td>Policy Adopted by BCBSVT</td>
<td>Approved by Clinical Advisory Committee</td>
</tr>
<tr>
<td>03/12/09</td>
<td>Replace policy</td>
<td>Policy update with literature review. Reference numbers 51-87 added. 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 Guidelines updated related to indications for surgery in adolescents and to further clarify definition of morbid obesity. Policy re-titled “Bariatric Surgery.”</td>
</tr>
<tr>
<td>5/14/09</td>
<td>Replace policy/correction only</td>
<td>Policy History for 3/12/09 corrected to say “Policy statement added which states that this surgery is investigational as a cure for type 2 diabetes mellitus.”</td>
</tr>
</tbody>
</table>
Robert F. Griffin, M.D
Chairman, Medical Policy Committee

APPROVED FOR IMPLEMENTATION:

Allen J. Hinkle, M.D.  
Chief Medical Director  
Date Approved:_______________
## Attachment I: Bariatric (Obesity) Surgery

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Eligible for Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT Codes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43770 – 43774;</td>
<td>Laparoscopic placement of adjustable gastric restrictive device and laparoscopic and open revision/removal code ranges</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43842 – 43843</td>
<td>Gastric restrictive procedure (e.g., vertical-banded gastroplasty); code range</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43845</td>
<td>Biliopancreatic diversion with duodenal switch</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43846 – 43847</td>
<td>Gastric bypass code range</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43848</td>
<td>Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>43886-43888</td>
<td>Gastric restrictive device procedure, open revisions code range</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td>90801</td>
<td>Psychiatric diagnostic interview examination NOTE: 1 visit allowed pre operatively under the medical benefit when billed with diagnosis code 278.01</td>
<td>Yes, with Prior Approval</td>
</tr>
<tr>
<td><strong>ICD-9 Codes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43.7</td>
<td>Partial gastrectomy with anastomosis to jejunum (biliopancreatic diversion)</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>43.89</td>
<td>Other partial gastrectomy (biliopancreatic diversion with duodenal switch)</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>44.31</td>
<td>High gastric bypass</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Approval Required</td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>44.68</td>
<td>Laparoscopic gastroplasty</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>44.69</td>
<td>Other repair of stomach</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>44.95 – 44.98</td>
<td>Laparoscopic gastric restrictive procedures (adjustable gastric band and port)</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td>278.01</td>
<td>Morbid obesity</td>
<td>Yes, for BlueCard home with Prior Approval</td>
</tr>
<tr>
<td></td>
<td><strong>HCPCS Codes</strong></td>
<td></td>
</tr>
<tr>
<td>S2083</td>
<td>Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline</td>
<td>Yes, Prior Approval not required</td>
</tr>
</tbody>
</table>