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Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> Who are adults with morbid obesity 	Interventions of interest are: <ul style="list-style-type: none"> Gastric bypass Laparoscopic adjustable gastric banding Sleeve gastrectomy Biliopancreatic diversion with duodenal switch 	Comparators of interest are: <ul style="list-style-type: none"> Standard medical care 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Change in disease status Functional outcomes Health status measures Quality of life Treatment-related mortality Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> Who are adults or adolescents with morbid obesity 	Interventions of interest are: <ul style="list-style-type: none"> Other bariatric surgery procedures^a 	Comparators of interest are: <ul style="list-style-type: none"> Standard medical care 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Change in disease status Functional outcomes Health status measures Quality of life Treatment-related mortality Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> Who are diabetic and not morbidly obese 	Interventions of interest are: <ul style="list-style-type: none"> Any bariatric surgery procedure 	Comparators of interest are: <ul style="list-style-type: none"> Standard medical care 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Change in disease status Functional outcomes Health status measures Quality of life Treatment-related mortality Treatment-related morbidity
Individuals: <ul style="list-style-type: none"> Who are not diabetic and not morbidly obese 	Interventions of interest are: <ul style="list-style-type: none"> Any bariatric surgery procedure 	Comparators of interest are: <ul style="list-style-type: none"> Standard medical care 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Change in disease status Functional outcomes Health status measures Quality of life Treatment-related mortality Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • Who are children or adolescents with morbid obesity 	Interventions of interest are: <ul style="list-style-type: none"> • Gastric bypass • Laparoscopic adjustable gastric banding • Sleeve gastrectomy • Biliopancreatic diversion with duodenal switch 	Comparators of interest are: <ul style="list-style-type: none"> • Standard medical care 	Relevant outcomes include: <ul style="list-style-type: none"> • Overall survival • Change in disease status • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity

^a Vertical-banded gastroplasty; gastric bypass using a Billroth II type of anastomosis is (mini-gastric bypass); biliopancreatic bypass without duodenal switch; long-limb gastric bypass procedure (i.e., > 150 cm); two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion later); endoscopic procedures (including gastric balloon, endoscopic gastroplasty, or endoscopically placed duodenojejunal sleeve); laparoscopic gastric plication; single anastomosis duodenoileal bypass with sleeve gastrectomy.

Description

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

Summary of Evidence

The evidence for gastric bypass, laparoscopic gastric banding, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch in individuals who are adults with morbid obesity includes randomized controlled trials (RCTs), nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a very large body of literature on bariatric surgery, but few high-quality RCTs and no RCTs that report on long-term clinical outcomes compared to medical therapy. The available evidence, largely from nonrandomized comparative studies and case series, supports the conclusion that bariatric surgery results in greater weight loss and improvements in weight-related comorbidity than nonsurgical treatments. Gastric bypass, performed by either the open or laparoscopic approach, improves health outcomes of morbidly obese patients by leading to substantial weight loss with relatively low rates of adverse events. There is also sufficient evidence that laparoscopic gastric banding, sleeve gastrectomy, and biliopancreatic diversion with duodenal switch improve outcomes. For these procedures compared with gastric bypass, there is a tradeoff in terms of the amount of weight loss, short-term complications, and long-term complications. An informed choice between patients and surgeons should be made after a thorough consideration of the risks and benefits of each procedure. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for other bariatric surgery procedures in individuals who are adults or adolescents with morbid obesity includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is less evidence on other types of bariatric surgery. Although some comparative studies exist, the evidence is insufficient to determine whether other procedures have a favorable risk-benefit profile compared with the criterion standard procedure, gastric bypass. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for any bariatric surgery procedure in individuals who are diabetic and not morbidly obese includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are overall survival,

change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Case series report a high rate of remission of diabetes in those who have gastric bypass surgery, and this indication was judged to meet the TEC criteria in 2012. A number of small RCTs have reported that remission of diabetes is higher in patients treated with bariatric surgery and that remission is maintained in a large percentage of patients up to five years postsurgery. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

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

The evidence for bariatric surgery procedures (e.g., gastric bypass, laparoscopic adjustable gastric banding, sleeve gastrectomy, biliopancreatic diversion with duodenal switch) in children and adolescents who have morbid obesity includes nonrandomized comparative studies and case series. Relevant outcomes are overall survival, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is less evidence for bariatric surgery in adolescents, and there is a lack of RCTs reporting on clinical outcomes. The nonrandomized studies and case series report that weight loss and reduction in risk factors for adolescents is similar to that for adults. However, most experts and clinical practice guidelines recommend that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a body mass index greater than 50 kg/m². In addition, greater consideration should be placed on patient development stage, on the psychosocial aspects of obesity and surgery, and on ensuring that the patient can provide fully informed consent. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Policy

Bariatric Surgery in Adults with Morbid Obesity

The following bariatric surgery procedures may be considered **medically necessary** for the treatment of morbid obesity (see Policy Guidelines for patient selection criteria) in adults who have failed weight loss by conservative measures*. Bariatric surgery should be performed in appropriately selected patients, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up post-surgery.

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

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

- Vertical-banded gastroplasty

- Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., greater than 150 cm)
- Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
- Endoscopic procedures (including but not limited to insertion of the StomaphyX™ device, insertion of a gastric balloon, endoscopic gastroplasty, or use of an endoscopically placed duodenal/jejeunal sleeve) as a primary bariatric procedure or as a revision procedure, (i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches).
- Laparoscopic gastric plication
- Single anastomosis duodenoileal bypass with sleeve gastrectomy.

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

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

Revision Bariatric Surgery

Revision surgery to address perioperative or late complications of a bariatric procedure is considered **medically necessary**. These include, but are not limited to, staple-line failure, obstruction, stricture, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, and band slippage that cannot be corrected with manipulation or adjustment (see Policy Guidelines).

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

Bariatric Surgery in Adolescents

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

Concomitant Hiatal Hernia Repair with Bariatric Surgery

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

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

*Conservative measures are defined as non-surgical treatment including dietary counseling and some amount of exercise under the supervision of a physician. (If, in the opinion of the physician, the patient's condition precludes the ability to exercise, this will be taken into consideration under individual medical director review on a case by case basis.) Conservative measures need to be documented as refractory for at least six months. There should be a failure to sustain a five to 10% or more reduction in body weight prior to consultation for bariatric surgery. The patient should be screened carefully by the appropriate mental health professional with regard to their ability to follow up with post op requirements. There should be no evidence of alcohol or drug abuse and it is strongly recommended that the bariatric surgeon urge the patient to remain nicotine free for six weeks prior to surgery.

Policy Guidelines

Patient Selection Criteria

Morbid obesity is defined as a body mass index (BMI) greater than or equal to 40 kg/m² or a BMI greater than or equal to 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 younger than age 18 years, very severely obese (BMI greater than or equal to 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. FDA premarket approval for the LAP-BAND^R System indicates it is for use only in severely obese adult patients.

Patients should have documented failure to respond to conservative measures for weight reduction, prior to consideration of bariatric surgery, and these attempts should be reviewed by the practitioner prior to seeking approval for the surgical procedure. As a result, some centers require active participation in a formal weight reduction program that includes frequent documentation of weight, dietary regimen, and exercise. However, there is lack of evidence on the optimal timing, intensity and duration of non-surgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Patients with BMI of 50 kg/m² or more 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 a procedure used for patients with BMI less than 50 kg/m². Malabsorptive procedures, although they produce more dramatic weight loss, potentially result in nutritional complications, and the risks and benefits of these procedures must be carefully weighed in light of the treatment goals for each patient.

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

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

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

Bariatric surgery in children and adolescents

The evidence for bariatric surgery in patients younger than age 18 years consists primarily of studies of adolescents, with a lack of evidence for younger children. Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 kg/m² with comorbidities to a BMI of 50 kg/m². Most guidelines use weight-based criteria that parallel those for adult patients.

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

The Endocrine Society:

- The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- Psychological evaluation confirms the stability and competence of the family unit.

- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits (August et al, 2008).

Institute for Clinical Systems Improvement:

- Recommendations for adolescents apply to “mature adolescents”, which is defined as having reached skeletal maturity.
- Bariatric surgery in the adolescent patient is controversial and should be undertaken on a case-by-case basis in a high-volume bariatric surgery center. (Institute for Clinical Systems Improvement, 2009).

The choice of procedure in adolescents may also differ from adults, but there is a lack consensus in guidelines or expert opinion as to the preferred procedure(s) for adolescents. The following factors should be considered in the choice of bariatric surgery in adolescents (Aikenhead et al, 2011):

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

Hiatal Hernia Repair Guidelines

The Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia. (Kohn et al, 2013). The society noted that the general methodologic quality of available studies is low. Recommendations for indications for repair are as follows:

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

Medicare Advantage

Individuals who may be considered **medically necessary** as candidates for gastrointestinal surgery include those with a body mass index (BMI) $\geq 35 \text{ kg/m}^2$, who suffer from Type II diabetes or other comorbidities related to obesity and have previously been unsuccessful with medical treatment for obesity.

The following procedures are **medically necessary** when the above criteria have been met:

- Laparoscopic Adjustable Gastric Banding,
- Gastric Bypass Surgery (open and laparoscopic Roux-en-Y),
- Open and laparoscopic Biliopancreatic Diversion with Duodenal Switch or Gastric Reduction Duodenal Switch, and
- Stand-alone laparoscopic sleeve gastrectomy (LSG).

The following are **investigational** for Medicare Advantage:

- Open vertical banded gastroplasty,
- Laparoscopic vertical banded gastroplasty,
- Open sleeve gastrectomy,
- Laparoscopic sleeve gastrectomy, not as a stand-alone service,
- Open adjustable gastric banding,
- Gastric balloon, and
- Intestinal bypass.

Medicare Advantage Policy Guidelines

The operation must be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of management, assessment and follow-up.

Background

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

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

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

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

The following summarizes the different types of bariatric surgery procedures.

Vertical-Banded Gastroplasty

Vertical-banded gastroplasty (VGB) was formerly one of the most common gastric restrictive procedures performed in the United States, but has now been replaced by other restrictive procedures due to high rates of revisions and reoperations. In this procedure, the stomach is segmented along its vertical axis. To create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of stomach is removed, and a propylene collar is placed through this hole and then stapled to itself. Because the normal flow of food is preserved, metabolic complications are uncommon.

Complications include esophageal reflux, dilation, or obstruction of the stoma, with the latter two requiring reoperation. Dilation of the stoma is a common reason for weight regain. VGB may be performed using an open or laparoscopic approach.

Adjustable Gastric Banding

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

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

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

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

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

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

Open Gastric Bypass

The original gastric bypass surgeries were based on the observation that postgastrectomy patients tended to lose weight. The current procedure involves both a restrictive and a malabsorptive component, with horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal

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

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

Laparoscopic Gastric Bypass

Laparoscopic gastric bypass is the same procedure as open gastric bypass, but performed laparoscopically.

Mini-Gastric Bypass

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.

Sleeve Gastrectomy

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

Endoluminal Bariatric Procedures

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

Biliopancreatic Bypass Procedure

The biliopancreatic bypass (BPB) procedure (also known as the Scopinaro procedure), developed and used extensively in Italy, was designed to address drawbacks of the original intestinal bypass procedures that have been abandoned due to unacceptable metabolic complications. Many complications were thought to be related to bacterial overgrowth and toxin production in the blind, bypassed segment. In contrast, BPB consists of a

subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure. The procedure consists of the following components:

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

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

Biliopancreatic Bypass With Duodenal Switch

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

Long-Limb Gastric Bypass (i.e., > 150 cm)

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 (e.g., resection or stapling along the horizontal or vertical axis). Unlike the traditional gastric bypass, which is a gastric restrictive procedure, these very long-limb Roux-en-Y gastric bypasses combine gastric restriction with some element of malabsorptive procedure, depending on the location of the anastomoses.

Laparoscopic Malabsorptive Procedure

Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption.

Laparoscopic Gastric Plication

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

Regulatory Status

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

Several gastric bands for use in bariatric surgery have been approved by FDA through the premarket approval process and are summarized in Table 1 (FDA Product Code: LTI).

Table 1: FDA-Approved Gastric Band Devices

Device	Manufacturer	Original PMA Date	Labeled Indications
REALIZE Adjustable Gastric Band (Curved Adjustable Gastric Band)	Ethicon Endosurgery, Somerville, NJ, and Cincinnati, OH	Nov 2007	Intended for use in weight reduction for morbidly obese patients and indicated for individuals with a BMI of at least 40 kg/m ² , or a BMI of at least 35 kg/m ² with ≥ 1 comorbid conditions, or those who are ≥ 45.4 kg over their estimated ideal weight. The band is indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).
LAP-BAND Adjustable Gastric Band	Apollo Endosurgery, Austin TX (original applicant: Allergan)	Jun 2001	Indicated for use in weight reduction for severely obese patients with a BMI of at least 40 kg/m ² or a BMI of at least 30 kg/m ² with ≥ 1 severe comorbid conditions, or those who are ≥ 100 lb 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 (e.g. supervised diet, exercise, behavior modification programs).

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

Related Protocol

Gastric Electrical Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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