Corporate Medical Policy

Bariatric Surgery

Description of Procedure or Service

A variety of surgical procedures are performed with intention to aid in weight loss for morbid obesity. Procedures include those that restrict stomach volume and/or cause malabsorption of nutrients. Weight loss occurs by the decreased size or malabsorption or by the combination of both gastric restriction and malabsorption. The goal is to cause significant weight loss and thereby avoid or reduce the development of obesity-related comorbidities (Fisher & Barber, 1999).

Benefit Application

This medical policy relates only to the services or supplies described herein. Please refer to the member’s benefit booklet for availability of benefits. Benefit eligibility may be limited by specific criteria designated in the member’s benefit booklet.

Policy Statement

GEHA will provide coverage for bariatric weight loss surgery when it is determined to be medically necessary because the medical criteria and guidelines as documented below have been demonstrated and criteria within the GEHA member brochure benefit description has been met. 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.

Repair of a hiatal hernia that is diagnosed preoperatively or at the time of bariatric surgery in members who have not demonstrated signs and/or symptoms for repair, is considered incidental and not separately payable.

Guidance in this policy relates specifically to the determination of medical necessity. Please note that payment for specific services will always be dependent upon additional factors including, correct coding, contractual requirements, GEHA payment policy, etc. The fact that a service is determined to be clinically necessary does not dictate payment processes.

When bariatric weight loss surgery is covered:

To be eligible for coverage of any primary bariatric procedure, the individual must show documentation of:

A. Psychological clearance of the member’s ability to understand and adhere to pre- and post-operative program based on a psychological assessment performed by a licensed professional mental health practitioner; and

B. Documentation that the member has been nicotine free the six months prior to surgery; and
C. Member has not been treated for substance/alcohol use for one year prior to surgery and there is no evidence of substance use or harmful/hazardous drinking within the one-year period prior to surgery; and

D. Failure to lower the body mass index within a medically supervised program of at least 6 months duration immediately preceding surgical authorization, that includes a low calorie diet, increased physical activity, behavioral modification. Documentation of compliance to the program is required; and

E. Demonstration of clinically significant obesity as defined below:

For adults aged 18 years or older, presence of persistent severe obesity, documented in concurrent clinical records, defined as any of the following:

1. Initial Body mass index (BMI) (see appendix) exceeding 40; or
2. Initial BMI greater than 35 in conjunction with any of the following severe co-morbidities:
   a. Clinically significant obstructive sleep apnea (AHI >15 events/hour); or
   b. Coronary heart disease, with objective documentation (by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT angiography, coronary angiography, heart failure or prior myocardial infarction); or
   c. Unmanaged Hyperlipidemia defined as unachievable normal levels of lipids despite prescribed diet and pharmacological therapy; or
   d. Obesity Induced Cardiomyopathy; or
   e. Severe Arthropathy of the spine or weight bearing joints where joint replacement has been recommended but obesity prohibits appropriate surgical management; or
   f. Medically unmanaged hypertension defined as blood pressure > 140 mmHg systolic and/or 90 mmHg diastolic despite medical treatment with maximal dose of three antihypertensive medications; or
   g. Type II Diabetes Mellitus as diagnosed by the American Diabetes Association Diagnostic criteria of A1C greater than 6.5%, or fasting blood glucose of 126 mg/dl or greater, or oral glucose tolerance test of 200 mg/dl or greater or random (casual) plasma glucose test of 200 mg/dl.

For adolescents who have documented completed bone growth and the presence of obesity with severe co-morbidities:

1. Preoperative preparatory program BMI exceeding 40 with one or more of the following serious co-morbidities:
   (1) Clinically significant obstructive sleep apnea; or
   (2) Type 2 diabetes mellitus (defined above); or
   (3) Pseudo tumor comorbidities; or
   (4) Hypertension.

2. Preoperative preparatory program BMI exceeding 50 with one or more of the following less serious co-morbidities:
   a. Medically refractory hypertension (defined above); or
   b. Dyslipidemias; or
   c. Nonalcoholic steatohepatitis; or
   d. Venous stasis disease; or
When bariatric weight loss surgery revision is covered:

GEHA considers revision bariatric surgery eligible for coverage when one of the following medical necessity criteria have been demonstrated:

A. Revision surgery to address perioperative or late complications of the original bariatric procedure. These include, but are not limited to, staple-line failure, obstruction, stricture, erosion, non-absorption resulting in hypoglycemia or malnutrition, weight loss of 20% or more below ideal body weight, band herniation, and band slippage that cannot be corrected with manipulation or adjustments.

B. Revision of a primary bariatric procedure that has failed due to dilation of the gastric pouch or dilation proximal to an adjustable gastric band or other restrictive procedure (documented by upper gastrointestinal examination or endoscopy), but only when the initial procedure was successful in inducing weight loss prior to dilation and the patient has objectively demonstrated compliance with a prescribed nutrition and exercise program.

C. Repeat surgical procedures for revision or conversion to another surgical procedure (that is also considered medically necessary within this document) for inadequate weight loss, (that is, unrelated to a surgical complication of a prior procedure) when all the following criteria are met:
   1. The individual continues to meet all the medical necessity criteria for bariatric surgery, including current pre-operative nutritional assessment; and
   2. There is objective documentation of compliance with the previously prescribed postoperative dietary and exercise program (this must include medical records demonstrating compliance with recommended post-surgical protocols); and
   3. The maximum weight loss following the original surgery was less than 50% of pre-operative excess body weight and current weight remains at least 30% over ideal body weight (taken from standard tables for adult weight ranges based on height, body frame, gender and age).

When bariatric weight loss surgery is not covered:

1. The above criteria is not met, or
2. The treatment regime and/or procedure is considered experimental or investigational, or
3. The treatment regime and/or procedure is listed as a non-covered service per this policy.

GEHA considers the following bariatric weight loss surgeries experimental and investigational and therefore not covered. This includes, but is not limited to, the following:

1. Bariatric surgery as a treatment for idiopathic intracranial hypertension
2. Bariatric surgery for diabetes in patients with a body mass index less than 35 kg/m²
3. Gastric bypass as a treatment for gastroparesis
4. Vertical-banded gastroplasty, also known as stomach stapling
5. Gastric bypass using a Billroth II type of anastomosis (mini-gastric bypass)
6. Biliopancreatic bypass without duodenal switch
7. Long-limb gastric bypass procedure (i.e., >150 cm)
8. Two-stage bariatric surgery procedures (e.g., sleeve gastrectomy as initial procedure followed by biliopancreatic diversion at a later time)
9. 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-jejunal sleeve) as a primary bariatric procedure or as a revision procedure to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches.
10. Laparoscopic gastric plication
11. Single anastomosis duodenal ileal bypass with sleeve gastrectomy
12. Natural orifice transanal endoscopic surgery (NOTES) techniques for bariatric surgery including:
   a. Gastrointestinal liners (endoscopic duodenal-jejunal bypass, endoscopic gastrointestinal bypass devices; e.g., EndoBarrier and the ValenTx Endo Bypass System); or
   b. Intragastric balloon ReShape Integrated Dual Balloon System); or
   c. Restorative obesity surgery, endoluminal (ROSE) procedure for the treatment of weight regain after gastric bypass surgery; or
   d. Transoral gastroplasty (TG) (vertical sutured gastroplasty; endoluminal vertical gastroplasty; endoscopic sleeve gastroplasty); or
   e. Use of any endoscopic closure device (Over the Scope clip [OTSC] system set, Apollo OverStitch endoscopic suturing system, StomaphyX endoluminal fastener and delivery system) in conjunction with NOTES;
13. Open adjustable gastric banding
15. Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery
16. Silastic ring vertical gastric bypass (Fobi pouch)
17. Vagus nerve blocking (e.g., the VBLOC device, also known as the Maestro Implant or the Maestro Rechargeable System)

**Physician Documentation**

Provide the following documentation with your request for members age 18 and older:

a. Current history and physical including BMI;

b. Clinical records documenting progress during a physician supervised weight, dietary and exercise regimen for the immediate previous 6 months prior to your request for authorization. Note – the documentation must reflect that the physician was participative in this process;
c. For members with a preoperative preparatory program BMI between 35 and 39 include clinical records documenting one or more of the comorbidities identified within this policy and the corresponding treatment. (i.e. lab and diagnostic findings)

For members less than 18 years of age, you will need to provide the above in addition to:

- Documentation of completed bone growth
- For members less than 18 years of age with a preoperative preparatory program BMI exceeding 40 or 50, include clinical records documenting one or more of the comorbidities identified per BMI within this policy and the corresponding treatment.

Provide the following documentation with your request for a weight-loss revision surgery:

- All of the above requested documents as applicable per the age and BMI group; and
- Clinical records documenting the indications for revision listed within this policy.

**Policy Guidelines**

The GEHA coverage policy pertaining to consideration of bariatric surgery is based on the NIH Consensus Conference on Surgical Treatment of Morbid Obesity (1998) which state that obesity surgery should be reserved only for patients who have first attempted medical therapy: “Weight loss surgery should be reserved for patients in whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity.” Surgery for severe obesity is usually considered an intervention of last resort with patients having attempted other forms of medical management (such as behavior change, increased physical activity and drug therapy) but without achieving permanent weight loss (Colquitt et al, 2002; NIH, 1995). Surgery is indicated for persons with severe obesity (BMI of 40 kg/m2 or more) or for persons with a BMI of 35 kg/m2 or more and serious co-morbidities such as diabetes, coronary heart disease, or obstructive sleep apnea. Ideally patients selected for surgery should have no major perioperative risk factors, a stable personality, no eating disorders, and have lost some weight prior to surgery. The patient’s ability to lose weight prior to surgery makes surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restriction imposed on patients following surgery.

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

- Repair of a type I hernia [sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm] in the absence of reflux disease is not necessary.

- All symptomatic paraesophageal hiatal hernias should be repaired (high quality evidence, strong recommendation), particularly those with acute obstructive symptoms or which have undergone volvulus
The SAGES recommendation is for repair of all hiatal hernias when present at the time of bariatric surgery (weak evidence and rating).

Anderin et. al. (2015) collected data on over 22,000 patients undergoing primary gastric bypass from Jan 2008 to June 30, 2012. It was found that weight loss before bariatric surgery is associated with marked reduction of risk of postoperative complications. Moreover, the degree of risk reduction seems to be related to amount of weight lost and patients in the higher range of BMI are likely to benefit most from preoperative weight reduction.

Kohn, et. al., (2013) presented guidelines for the management of hiatal hernia based upon a systematic review of published literature and supporting evidence. Repair of a type I hernia in the absence of reflux disease is not necessary. All symptomatic paraesophageal hiatal hernias should be repaired, particularly those with acute obstructive symptoms or which have undergone volvulus. A weak recommendation for repair of all detected hiatal hernias during operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands.

**Background**

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, hypertension, or obstructive sleep apnea. The evidence for bariatric surgery procedures in individuals who have diabetes without 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. Other carriers report a high rate of remission of diabetes in patients undergoing gastric bypass surgery. 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 5 years’ post-surgery. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Revision Bariatric Surgery is defined as the surgical adjustment or alteration of a prior bariatric procedure. Generally, such intervention may be warranted for proven complications of the original weight loss surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when the complication causes abdominal pain, inability to eat or drink, or causes unmanageable vomiting of prescribed meals. Revisions are sometimes desired by a member or provider when an original procedure has not led to the desired impact. In such cases, while surgical revision might be considered feasible, it does not necessarily mean that such a service would be considered medically necessary: in many cases the procedure was appropriately performed and remains functional, but other factors have adversely impacted the response to surgery, such as poor compliance with dietary and exercise recommendations, inadequate surgical follow-up, etc.

**Open or Laparoscopic gastric bypass using a Roux-en-Y anastomosis**

Roux-en-Y gastric bypass, the typical form of gastric bypass, causes weight loss through both restricting stomach size and malabsorption. There is good evidence that patients see significant weight loss following RYGB, although weight loss below the obesity threshold is not typical. There is weak evidence...
for weight loss lasting for as long as 10 years. Complications are frequent with RYGB but treatable. Some do experience serious complications, death or limited weight loss. Laparoscopic may be chosen to minimize surgical complications and recovery time.

**Laparoscopic adjustable gastric banding (LASGB)**

The LASGB causes weight loss by restriction only. LASGB is considered a simpler and reversible procedure with fewer deadly complications but with a higher rate of complications occurring later in recovery, many of which require an additional operation. LASGB require band adjustments and need sometimes frequent post procedure visits with professional staff experienced in bad adjustments.

**Open or laparoscopic biliopancreatic bypass (i.e., the Scopinaro procedure) with duodenal switch**

Biliopancreatic bypass or diversion (BPD)/(BPD-DS) uses both restriction and malabsorption to induce weight loss. Limited to moderate evidence is available for BPD and BPD-DS. The evidence available shows significant and long-term weight loss from this procedure. Evidence is weak in determining short and long term impact on comorbidities, overall survival, and side effects (Hayes report, 2012).

**Sleeve gastrectomy**

A "sleeve" gastrectomy is an alternative approach to gastrectomy that can be performed on its own, or in combination with malabsorptive procedures (most commonly biliopancreatic diversion with duodenal switch). In this procedure, the greater curvature of the stomach is resected from the angle of His to the distal antrum, resulting in a stomach remnant shaped like a tube or "sleeve". The pyloric sphincter is preserved, resulting in a more physiologic transit of food from the stomach to the duodenum, and avoiding the "dumping syndrome" (overly rapid transport of food through stomach into intestines) that is seen with distal gastrectomy. This procedure can be done by the open or laparoscopic technique.

**Gastric Bypass with Long Limb**

Choban & Flancbaum (2002) reviewed studies that compared outcomes of standard or "short-" limb gastric bypass with outcomes of "long-" limb gastric bypass. There were 6 comparative studies, 2 or more in which different lengths of the Roux limb were compared. However, although the categorization of patients into "standard" versus "long-limb" is based on the length of the Roux (alimentary) limb, there is not a definite cutoff for long- versus standard limbs. In these studies, there was variability in the lengths of the Roux limbs for both the standard gastric bypass and for the long-limb groups. Most comparisons of weight loss do not reveal significant differences between short- and long-limb gastric bypass.

In 2005, Inabnet et. al., conducted a prospective randomized trial comparing short and long limb lengths in relationship to laparoscopic Roux-en-Y gastric bypass (LRYGBP) in patients with a BMI <50. There was no difference in demographic data, preoperative BMI, presence of co-morbidities, or duration of surgery. The overall complication rate was not different between the 2 groups; however, the incidence of internal hernias was significantly higher in the long limb group. The length of hospital stay was longer for the short limb group compared to the long limb group. When comparing the short limb to the long limb patients, the BMI decreased equally in both groups at the following time intervals: preoperative (44.6 vs 44.9), 3 weeks (40.3 vs 40.9), 3 months (35.5 vs 35.2), 6 months (31.2 vs 31.8), and 12 months (27.7 vs 28.3). There were no significant nutritional deficiencies in either group. It was concluded that
patients with BMI <50 undergoing LRYGBP, increasing the length of the Roux limb does not improve weight loss and may lead to a higher incidence of internal hernias

**Vertical Banded Gastroplasty (VBG)**

VBG has fallen into disfavor because of inadequate long-term weight loss. VBG is one of the early types of bariatric surgery developed in the 1980s. This is a purely restrictive procedure that has been largely replaced by laparoscopic adjustable gastric banding (LAGB) or sleeve gastrectomy (SG). Weight loss with VBG is substantial, but there is a high rate of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site.

**Gastroplasty (Stomach Stapling)**

Overall, clinical studies have shown that about 40% of persons who have this operation do not achieve loss of more than half of their excess body weight. In the long-term, 5 or more years after surgery, only about 30% of patients have maintained a successful weight loss. Studies have reported that many patients must undergo another revisional operation to obtain the results they seek.

**Loop Gastric Bypass**

Although patients can have increased frequency of bowel movements, increased fat in their stools, and impaired absorption of vitamins, recent studies have reported good results. The loop gastric bypass developed years ago has generally been abandoned by most bariatric surgeons as unsafe. Although easier to perform than the RYGB, it has been shown to create a severe hazard in the event of any leakage after surgery, and seriously increases the risk of ulcer formation, and irritation of the stomach pouch by bile.

**Mini Gastric Bypass**

The "mini gastric bypass" has been promoted as a new surgical treatment for severe obesity. It involves laparoscopic construction of a large and elongated gastric pouch and a loop gastric bypass with distal diversion) to reduce food absorption. This is a major surgical procedure. The evidence for the mini gastric bypass has come from a single investigator, thus raising questions about the generalization and validity of the reported findings. The mini-gastric bypass has not been subjected to a prospective clinical outcome study in peer-reviewed publication.

**Silastic Ring Vertical Gastric Bypass (Fobi Pouch)**

The Fobi pouch, developed by California surgeon Mathias A.L. Fobi, is a modification of gastric bypass surgery. The modifications to gastric bypass surgery are designed to prevent post-surgical enlargement of the gastric pouch and stoma, there is a paucity of direct comparative studies of the Fobi pouch to traditional gastric bypass surgery. All of the published literature has been limited to descriptive articles, case series, and a prospective non-randomized controlled study. These studies were from a single group of investigators, raising questions about the generalization of the findings (Davis, J. 2000).

In 2018 a case report was presented discussing a 56 year old female 10 years postoperatively Fobi-pouch. An enteroscopy revealed several marginal ulcers and erosion of the silastic ring marker in the excluded stomach. A partial gastric sleeve resection including the silastic ring was performed without any complications, preventing further bleeding due to the eroded ring. Gastric ulceration and bleeding
related to the presence of a foreign body have been previously described; however, this is the first article reporting the concomitant erosion and bleeding of the silastic marker in the excluded stomach (Franco-Martinez et. al., 2018).

**Intragastric Balloon (Silicone Intragastric Balloon)**

Intragastric balloon is intended to reduce gastric capacity, causing satiety, making it easier for patients to take smaller amounts of food. Randomized, controlled clinical studies, however, have found no increase in weight loss with the intragastric balloon plus dieting versus dieting alone (Rigaud et al, 1995; Geliebter et al, 1991; Mathus-Vliegen et al, 1990; Lindor et al, 1987).

The majority of weight loss occurs within the first 3 months and mean percentage excess weight loss (EWL) at 6 months is 14% but almost half of patients may return to their initial weight at 12 months after removal of the device [12, 24]. For a large proportion of patients, the weight loss is not sustained making it a less favourable intervention as a long-term solution for weight loss (Aruchuna et. al., 2019)

**Reshape Balloon**

There is a lack of data on the durability of the results with the ReShape Integrated Dual Balloon System. It is unclear what benefit there is from a temporary reduction in weight. Furthermore, an Up-to-date review on Bariatric surgical operations for the management of severe obesity by Lim et. al. (2019) lists intragastric balloon as an investigational procedure. It states that as much as 33 % excess weight loss has been reported in trials conducted outside of the United States with devices not approved by the FDA. After 5 years of surveillance, however, only 23 % of patients maintained more than 20 % of their excess weight loss

**Stomaphyx**

This is an endoluminal fastener and delivery system used to tighten esophageal tissue. There is only limited evidence on the effectiveness of the StomaphyX in bariatric surgery repair/revision. In a prospective, single-center, randomized, single-blinded study examined the safety and effectiveness of endoscopic gastric plication with the StomaphyX device versus a sham procedure for revisional surgery in RYGB (performed at least 2 years earlier) patients to reduce regained weight. The authors concluded that StomaphyX treatment failed to achieve the primary efficacy target and resulted in early termination of the study.

**Laparoscopic Gastric Plication**

Brethauer (2011) presented the results of a feasibility study using laparoscopic gastric plication for weight loss achieved without stapling or banding. The initial experience has suggested that a reduction in gastric capacity can be achieved by way of plication of the anterior stomach and greater curvature. The early weight loss results have been encouraging, with better weight loss in patients who underwent greater curvature plication (GCP). The use of laparoscopic GCP warrants additional investigation as a primary bariatric procedure.

**Sclerotherapy for Dilated Gastrojejunostomy**

Surgeons have tried endoscopic injection of sclerosing agents to create scar and a smaller anastomosis, with variable effects.” For patients with have inadequate weight loss or significant weight regain and
who have a dilated gastrojejunostomy after Roux-en-Y gastric bypass (RYGB) who. It is thought that these patients lose restriction because of the dilated gastrojejunostomy and thus overeat. In the textbook Townsend: Sabiston Textbook of Surgery (2012) this is considered an investigational bariatric procedure.

**Gastrointestinal Liners**

Endoscopic duodenal-jejunal bypass is the endoscopic placement of a duodenal-jejunval bypass sleeve (DIBL) which lines the first section of the small intestine causing food to be absorbed further along the intestine. Once implanted, the device is purported to influence gastrointestinal hormones and satiety. While these procedures look promising in several studies, they suffer from small size, short follow up duration, and lack of blinding. Most authors have called for larger studies with long term follow before wide acceptance.

The pre-operative surgical preparatory regimen should include cessation counseling for smokers. The National Institutes of Health Consensus Statement (1998) states that all smokers should be encouraged to quit, regardless of weight. Smoking cessation is especially important in obese persons, as obesity places them at increased risk for cardiovascular disease. Severely obese persons are at increased risk of surgical complications.

The surgical center where surgery is to be performed should be accomplished in bariatric surgery with a demonstrated commitment to provide adequate facilities and equipment. A number of studies have demonstrated a relationship between surgical volumes and outcomes of obesity surgery. Most recently, an assessment by the Canadian Agency for Drugs and Technologies in Health (CADTH) stated that their volume-outcome review found that higher surgical volumes were associated with better clinical outcomes. CADTH was not, however, able to identify specific thresholds for surgical volume that were associated with better clinical outcomes.

A Multidisciplinary Care Task Group conducted a systematic review of the literature to provide evidence-based guidelines for patient selection and to recommend the medical and nutritional aspects of multi-disciplinary care required to minimize peri-operative and post-operative risks in patients with severe obesity who undergo weight loss surgery. The Task Group recommended multi-disciplinary screening of weight loss surgery patients to ensure appropriate selection; pre-operative assessment for cardiovascular, pulmonary, gastrointestinal, endocrine, and other obesity-related diseases associated with increased risk for complications or mortality; pre-operative weight loss and cessation of smoking; peri-operative prophylaxis for deep vein thrombosis and pulmonary embolism (PE); pre-operative and post-operative education and counseling by a registered dietitian; and a well-defined post-surgical diet progression.

Anderin et al found that weight loss before bariatric surgery is associated with marked reduction of risk of postoperative complications. The investigators reported that the degree of risk reduction seems to be related to amount of weight lost and patients in the higher range of BMI are likely to benefit most from pre-operative weight reduction.

Candidates for obesity surgery should begin a weight reduction diet prior to surgery. The purpose of a pre-operative nutrition program prior to obesity surgery are to test patient motivation, to reduce perioperative morbidity, to accustom patients to the restriction of food intake after surgery, and to
increase total weight loss (van de Weijgert et al, 1999; Jung and Cusciheri, 2000; Pekkarinen et al, 1997; Martin et al, 1995). Even super obese patients (BMI greater than 50) may benefit from initiating a nutrition and exercise program prior to surgery. For maximal benefit, dieting should occur proximal to the time of surgery, and not in the remote past to reduce surgical risks and improve outcomes.

Contraindications to Obesity Surgery

A Multidisciplinary Care Task Group (Saltzman et al, 2005) identified contraindications to weight loss surgery, including unstable or severe coronary artery disease, severe pulmonary disease, portal hypertension with gastric or intestinal varices, and/or other conditions thought to seriously compromise anesthesia or wound healing. The Task Group also noted that weight loss surgery is contraindicated in those who are unable to comprehend basic principles of weight loss surgery or follow operative instructions. The Task Group stated that any combination of the following factors -- revision surgery, male, greater than 50 years of age, BMI greater than 50 kg/m2, and obstructive sleep apnea, hypertension, and type 2 diabetes -- indicates high risk.

Requirement that Obesity be Persistent

Obesity surgery is not indicated for persons with transient increases in weight (Collazo-Clavell, 1999). Guidelines of the American Association of Clinical Endocrinologists and the American College of Endocrinology (1998) and guidelines on obesity surgery from the Massachusetts Department of Health and Human Services (2006) state that surgery candidates should be severely obese for a period of time.

Adolescent considerations

Obesity Surgery in Children and Adolescents: According to available guidelines, obesity surgery is generally indicated for persons age 18 and older (AACE, 1998). Children and adolescents are rapidly growing, and are therefore especially susceptible to adverse long-term consequences of nutritional deficiencies from the reduced nutrient intake and malabsorption that is induced by obesity surgery. It is not known whether the benefits of obesity surgery in children and adolescents outweigh the increased risks.

According to a panel of experts (Inge et. al., 2014) bariatric surgery may be an appropriate treatment for severe obesity in adolescents who have completed bone growth. According to the recommendations by the expert panel, potential candidates for bariatric surgery should be referred to centers with multi-disciplinary weight management teams that have expertise in meeting the unique needs of overweight adolescents. Consideration for bariatric surgery is generally warranted only when adolescents have experienced failure of 6 months of organized weight loss attempts and have met certain criteria: severe obesity (a BMI of 40) and severe co-morbidities, or super obesity (BMI of 50) and less severe co-morbidities that may be remedied with weight loss; and have attained a majority of skeletal maturity (generally 13 years of age for girls and 15 years of age for boys). Surgery should only be performed at facilities that are equipped to collect long-term data on clinical outcomes. The panel recommended the Roux-en-Y gastric bypass method of surgery over the simpler, newer technique of implanting an adjustable gastric band since gastric bands are less effective and younger patients would probably need replacement as they age.

Zeinoddini et. al. (2014), conducted a prospective study evaluating the safety and efficacy of laparoscopic gastric plication (LPG) on adolescents. A prospective study was performed on adolescents
who underwent LGP from 2007-2013. Measured parameters included the percentage of excess weight (%EWL), percentage of body mass index loss (%BMIL), obesity related co-morbidities, operative time, and length of hospitalization and complications. LGP was performed in 12 adolescents (9 female and 3 male). Mean (SD) age of the patients was 13.8±1 year. Mean preoperative weight and BMI were 112.4±19.7 kg and 46.0±4 kg/m², respectively. Mean (SD) %EWL and %EBMIL were 68.2±9.9% and 79.0±9.0%, respectively after 2 years. All medical co-morbidities were improved after LGP. There were no deaths. One patient required replication 4 days postoperatively due to obstruction at the site of the last knot. No other major complications were observed. No patient required rehospitalization. It was concluded that LGP has the potential of being an ideal weight loss surgery for adolescents, resulting in excellent weight loss and minimal psychological disruption. It is associated with a minimal risk of leakage, bleeding, and nutritional deficiency. However, large well-designed studies with long-term follow-up are needed.

**Regulatory Status**

Bariatric weight loss surgeries are surgical procedures and, as such, are not regulated by the FDA. However, the FDA does regulate manufacturing practices, distribution and use of devices for such procedures.

The following codes are for reference purposes only and do not imply that the service is covered or non-covered. Applicable codes include but are not limited to:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<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>
</tr>
<tr>
<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)</td>
</tr>
<tr>
<td>43771</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43772</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43773</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components</td>
</tr>
<tr>
<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)</td>
</tr>
<tr>
<td>43845</td>
<td>Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)</td>
</tr>
<tr>
<td>43846</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy</td>
</tr>
<tr>
<td>43855</td>
<td>Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy</td>
</tr>
</tbody>
</table>
S2083  Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

CPT or HCPCS not covered for indications listed in this coverage policy:

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
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</tr>
<tr>
<td>43620</td>
<td>Gastrectomy, total; with esophagoenterostomy</td>
</tr>
<tr>
<td>43621</td>
<td>Gastrectomy, total; with Roux-en-Y reconstruction</td>
</tr>
<tr>
<td>43622</td>
<td>Gastrectomy, total; with formation of intestinal pouch, any type</td>
</tr>
<tr>
<td>43631</td>
<td>Gastrectomy, partial, distal; with gastroduodenostomy</td>
</tr>
<tr>
<td>43632</td>
<td>Gastrectomy, partial, distal; with gastrojejunostomy</td>
</tr>
<tr>
<td>43633</td>
<td>Gastrectomy, partial, distal; with Roux-en-Y reconstruction</td>
</tr>
<tr>
<td>43634</td>
<td>Gastrectomy, partial, distal; with formation of intestinal pouch</td>
</tr>
<tr>
<td>43635</td>
<td>Vagotomy when performed with partial distal gastrectomy (List separately in addition to code[s] for primary procedure)</td>
</tr>
<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty</td>
</tr>
<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty</td>
</tr>
<tr>
<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43848</td>
<td>Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)</td>
</tr>
<tr>
<td>0312T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming</td>
</tr>
<tr>
<td>0313T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>43886</td>
<td>Gastric restrictive procedure, open; revision of subcutaneous port component only</td>
</tr>
<tr>
<td>43887</td>
<td>Gastric restrictive procedure, open; removal of subcutaneous port component only</td>
</tr>
<tr>
<td>43888</td>
<td>Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only</td>
</tr>
<tr>
<td>47000</td>
<td>Biopsy of liver, needle; percutaneous (In the absence of signs or symptoms of liver disease such as elevated liver enzymes or enlarged liver)</td>
</tr>
<tr>
<td>47001</td>
<td>Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (In the absence of signs or symptoms of liver disease such as elevated liver enzymes or enlarged liver), (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>
Biopsy of liver, wedge, (In the absence of signs or symptoms of liver disease such as elevated liver enzymes or enlarged liver)

Other CPT codes related to this coverage policy when billed or requested with a bariatric surgery:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>43280</td>
<td>Laparoscopy, surgical, esophagogastric fundoploasty (eg, Nissen, Toupet procedures)</td>
</tr>
<tr>
<td>43281</td>
<td>Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoploasty, when performed; without implantation of mesh</td>
</tr>
<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
</tr>
<tr>
<td>43830</td>
<td>Gastrostomy, open; without construction of gastric tube (eg, Stamm procedure) (separate procedure)</td>
</tr>
<tr>
<td>43840</td>
<td>Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury</td>
</tr>
<tr>
<td>43999</td>
<td>Unlisted procedure, stomach</td>
</tr>
</tbody>
</table>

Scientific References


Policy implementation and updates

12/2017 Revised coverage criteria and updated.
06/2018 Technical correction and reformatting: Preauthorization Requirements
12/2018 Clarification of physician documentation needs. Added clarification with the benefit application language.
12/2019 Updated background content and referencing. Clarification of benefit application language, no changes in benefit coverage