The GEHA guidelines 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.

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. Case series report a high rate of remission of diabetes in undergoing gastric bypass surgery, and this indication was judged to meet the BCBS 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 5 years’ post-surgery. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome. However, bariatric surgery for diabetes in patients with a body mass index less than 35 kg/m² is not currently considered standard of care and is not supported in current specialty society guidelines. Clinical input did not support the use of bariatric surgery as a stand-alone treatment for diabetes. As a result, bariatric surgery for diabetic patients with a body mass index less than 35 kg/m² is considered not medically necessary.

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

a. Body mass index (BMI) (see appendix) exceeding 40; or

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b. BMI greater than 35 in conjunction with any of the following severe co-morbidities:

   I. Clinically significant obstructive sleep apnea defined an AHI => 50

   ii. 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

   iii. Refractory Hyperlipidemia defined as unachievable acceptable levels of lipids despite maximal diet and pharmacological therapy; or

   iv. Severe arthropathy of the spine or weight bearing joints when obesity prohibits appropriate surgical management

   v. Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of 3 anti-hypertensive agents of different classes

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

a. BMI exceeding 40 with one or more of the following serious co-morbidities:

   I. Clinically significant obstructive sleep apnea; or

   ii. Type 2 diabetes mellitus; or

   iii. Pseudo tumor comorbidities

b. BMI exceeding 50 with one or more of the following less serious co-morbidities:

   I. Medically refractory hypertension; or

   ii. Dyslipidemias; or

   iii. Nonalcoholic steatohepatitis; or

   iv. Venous stasis disease; or

   v. Significant impairment in activities of daily living; or

   vi. Intertriginous soft-tissue infections; or

   vii. Stress urinary incontinence; or

   viii. Gastroesophageal reflux disease; or

   ix. Weight-related arthropathies that impair physical activity;

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

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

Conditions for which the above procedures are considered experimental and not medically necessary

Bariatric surgery as a treatment for idiopathic intracranial hypertension

Gastric bypass as a treatment for gastroparesis

Hiatal Hernia repair at time of Bariatric Surgery:

The Society of American Gastrointestinal and Endoscopic Surgeons has issued evidence-based guidelines for the management of hiatal hernia. 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
- Hiatal hernia repair performed at the time of bariatric surgery would not be reported with the hiatal hernia repair code. There is no code for this specific. Surgery, therefore it should be reported with code 43289 - Unlisted laparoscopy procedure, esophagus.

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, also known as stomach stapling (CPT 43842)

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

“Band over bypass” or LASGB revision of prior Roux-en-Y gastric bypass

“Band over sleeve" or LASGB revision of prior sleeve gastrectomy

Liposuction (suction-assisted lipectomy; ultrasonic assisted liposuction)

Loop gastric bypass

Mini gastric bypass

Natural orifice transoral endoscopic surgery (NOTES) techniques for bariatric surgery including but may not be limited to, the following:
- Gastrointestinal liners (endoscopic duodenal-jejunal bypass, endoscopic gastrointestinal bypass devices; e.g., EndoBarrier and the ValenTx Endo Bypass System); or
- Intragastric balloon ReShape Integrated Dual Balloon System); or
- Restorative obesity surgery, endoluminal (ROSE) procedure for the treatment of weight regain after gastric bypass surgery; or
- Transoral gastroplasty (TG) (vertical sutured gastroplasty; endoluminal vertical gastroplasty; endoscopic sleeve gastroplasty); or
- 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;

Open adjustable gastric banding
Roux-en-Y gastric bypass as a treatment for gastroesophageal reflux in non-obese persons

Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery

Silastic ring vertical gastric bypass (Fobi pouch)

Vagus nerve blocking (e.g., the VBLOC device, also known as the Maestro Implant or the Maestro Rechargeable System)

**Pre-surgical evaluation and preparation**

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)\(^4\) 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\(^5\) 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 Cuschi, 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 -- revisional 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.

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.

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According to a panel of experts (Inge et al) 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 multidisciplinary 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.

Rationale

Gastric Bypass with Long Limb

The Blue Cross Blue Shield 2005 TEC Assessment reviewed studies that compared outcomes of standard or “short-” limb gastric bypass with outcomes of “long-” limb gastric bypass. There were 6 comparative studies, 2 or more in which different lengths of the Roux limb were compared. However, although the categorization of patients into “standard” versus “long-limb” is based on the length of the Roux (alimentary) limb, there is not a definite cutoff for long-versus standard limbs. In these studies, there was variability in the lengths of the Roux limbs for both the standard gastric bypass and for the long-limb groups. Most comparisons of weight loss do not reveal significant differences between short- and long-limb gastric bypass. The strongest evidence in this category is from 2 RCTs.

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)

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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.

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

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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).  

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: Descriptions " 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 presented the results of a feasibility study using laparoscopic gastric plication for weight loss achieved without stapling or banding. 

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

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15 Lim RB. Bariatric surgical operations for the management of severe obesity: Descriptions. Up-to-date Inc., Waltham, MA. Last reviewed November 2015
textbook Townsend: Sabiston Textbook of Surgery (2012) this is considered an investigational bariatric procedure.

Gastrointestinal Liners: (EndoBarrier, Valen TX)

Endoscopic duodenal-jejuninal bypass is the endoscopic placement of a duodenal-jejuninal 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.

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