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<b>Preauthorization</b>	No	<b>Review Dates:</b> 04/07, 05/08, 05/09, 03/10, 03/11, 07/11, 07/12, 9/12, 05/13, 01/14, 01/15, 11/15, 11/16, 11/17, 11/18, 11/19, 11/20, 11/21	

**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.*

### RELATED PROTOCOLS

Gastric Electrical Stimulation

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>Who are adults with morbid obesity</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Gastric bypass</li> <li>Laparoscopic adjustable gastric banding</li> <li>Sleeve gastrectomy</li> <li>Biliopancreatic diversion with duodenal switch</li> <li>Biliopancreatic diversion without duodenal switch</li> <li>Vertical-banded gastroplasty</li> <li>Laparoscopic gastric plication</li> <li>Single anastomosis duodenoileal bypass with sleeve gastrectomy</li> <li>Duodenojejunal sleeve</li> <li>Intragastric balloon devices</li> <li>Aspiration therapy device</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are adults with morbid obesity</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Two-stage bariatric surgery procedures</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>One-stage bariatric surgery procedure</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>Who are adults with morbid obesity and failed bariatric surgery</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Revision bariatric surgery</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are diabetic and not morbidly obese</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Gastric bypass</li> <li>Sleeve gastrectomy</li> <li>Biliopancreatic diversion</li> <li>Adjustable gastric banding</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are not diabetic and not morbidly obese</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Any bariatric surgery procedure</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are adolescent children with morbid obesity</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Gastric bypass, laparoscopic adjustable gastric banding, or sleeve gastrectomy</li> <li>Bariatric surgery other than gastric bypass, laparoscopic adjustable gastric banding or sleeve gastrectomy</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are preadolescent children with morbid obesity</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Bariatric surgery</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Standard medical care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>With morbid obesity and a preoperative diagnosis of hiatal hernia</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Hiatal hernia repair with bariatric surgery</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Bariatric surgery alone</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Overall survival</li> <li>Change in disease status</li> <li>Functional outcomes</li> <li>Health status measures</li> <li>Quality of life</li> <li>Treatment-related mortality</li> <li>Treatment-related morbidity</li> </ul>

**DESCRIPTION**

Bariatric surgery is a treatment for morbid obesity in patients who fail to lose weight with conservative measures. There are numerous gastric and intestinal surgical techniques available. While these techniques have heterogeneous mechanisms of action, the result is a smaller gastric pouch that leads to restricted eating. However, these surgeries may lead to malabsorption of nutrients or eventually to metabolic changes.

**SUMMARY OF EVIDENCE****ADULTS WITH MORBID OBESITY**

For individuals who are adults with morbid obesity who receive gastric bypass, the evidence includes randomized controlled trials (RCTs), observational studies, and systematic reviews. Relevant outcomes are overall survival (OS), change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. TEC Assessments and other systematic reviews of RCTs and observational studies found that gastric bypass improves health outcomes, including weight loss and remission of type 2 diabetes (T2D). A TEC Assessment found similar weight loss with open and laparoscopic gastric bypass. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive laparoscopic adjustable gastric banding (LAGB), the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that LAGB is a reasonable alternative to gastric bypass. There is less weight loss with LAGB than with gastric bypass, but LAGB is less invasive and is associated with fewer serious adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive sleeve gastrectomy (SG), the evidence includes RCTs, observational studies (evaluating SG alone and comparing SG with gastric bypass), as well as systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that SG results in substantial weight loss and that this weight loss is durable for at least five years. A meta-analysis found that short-term weight loss was similar after SG compared with gastric bypass. Long-term weight loss was greater after gastric bypass, but SG is associated with fewer adverse events. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive biliopancreatic diversion (BPD) with duodenal switch (DS), the evidence includes nonrandomized comparative studies, observational studies, and a systematic review. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Nonrandomized comparative studies have found significantly higher weight loss after BPD with DS compared with gastric bypass at one year. A large case series found sustained weight loss after seven years. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive BPD without DS, the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment reviewed the available observational studies and concluded that weight loss was similar after BPD without a DS or gastric bypass. However, concerns have been raised about complications associated with BPD without DS, especially long-term nutritional and vitamin deficiencies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive vertical-banded gastroplasty (VBG), the evidence includes observational studies and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A TEC Assessment identified eight nonrandomized comparative studies evaluating VBG, and these studies found that weight loss was significantly greater with open gastric bypass. Moreover, VBG has relatively high rates of complications, revisions, and reoperations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive two-stage bariatric surgery procedures, the evidence includes a small RCT, observational studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is a lack of evidence that two-stage bariatric procedures improve outcomes compared with one-stage procedures. The small RCT compared intragastric balloon (IGB) plus gastric bypass with the standard of care plus gastric bypass and did not detect a difference in weight loss at six months postsurgery. Case series have shown relatively high complication rates in two-stage procedures, and patients are at risk of complications in both stages. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive laparoscopic gastric plication, the evidence includes two RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A 2014 systematic review only identified a small nonrandomized comparative study comparing laparoscopic gastric plication with other bariatric surgery procedures. Since the systematic review, two RCTs have been published, one comparing laparoscopic gastric plication with a sham procedure and another comparing laparoscopic gastric plication with SG. Laparoscopic gastric plication was more effective than sham at one-year follow-up and equally effective as SG at two-year follow-up. Additional comparative studies and RCTs with longer follow-up are needed to permit conclusions about the safety and efficacy of laparoscopic gastric plication. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive single anastomosis duodeno-ileal bypass with SG (SADI-S), the evidence includes a systematic review of observational studies and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of 12 observational studies concluded that SADI-S was associated with promising weight loss and comorbidity resolution. A comparative chart review found that patients without diabetes experienced significantly better weight loss and lipid profiles with SADI-S than with RYGB and patients who had diabetes experienced significantly higher rates of remission with SADI-S than with RYGB. Comparative studies and especially RCTs are needed to permit conclusions about the safety and efficacy of SADI-S. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive duodenojejunal sleeve, the evidence includes RCTs and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. A systematic review of duodenojejunal sleeves included five RCTs and found significantly greater short-term weight loss (12 to 24 weeks) with the sleeves compared with medical therapy. There was no significant difference in symptoms associated with diabetes. All RCTs were small and judged by systematic reviewers to be at high-risk of bias. High-quality comparative studies are needed to permit conclusions on the safety and efficacy of the procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive IGB devices, the evidence includes RCTs, systematic reviews, and case series. Relevant outcomes are OS, change in disease status, functional outcomes,

health status measures, quality of life, and treatment-related mortality and morbidity. RCTs assessing the two IGB devices approved by the U.S. Food and Drug Administration have found significantly greater weight loss with IGB than with sham treatment or lifestyle therapy alone after six months (maximum length of device use). Some adverse events were reported, mainly related to accommodation of the balloon in the stomach; in a minority of cases, these adverse events were severe. One RCT followed patients for an additional six months after IGB removal and found sustained weight loss. There are limited data on the durability of weight loss in the long-term. Comparative data are lacking. A large case series found that patients gradually regained weight over time. Moreover, it is unclear how six months of IGB use would fit into a long-term weight loss and maintenance intervention. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are adults with morbid obesity who receive an aspiration therapy device, the evidence includes an RCT and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. The RCT found significantly greater weight loss with aspiration therapy than lifestyle therapy at one year. Forty of 58 patients (69%) achieved at least 10% total weight loss at four years or at time of study withdrawal; however, only 15/111 initial aspiration therapy patients completed the study through four years. In addition to a high degree of missing data, the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study noted a potentially large number of adverse events related to A-tube malfunction, an element of the therapy which is expected to require replacement within approximately 3.5 years postgastrostomy in 50% of cases. The impact of this on health outcomes compared to existing surgical approaches is unknown. One small case series reported on 15 patients at two years. The total amount of data on aspiration therapy remains limited and additional studies are needed before conclusions can be drawn about the effects of treatment on weight loss, metabolism, safety, nutrition, and long-term durability of treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### REVISION BARIATRIC SURGERY

For individuals who are adults with morbid obesity and failed bariatric surgery who receive revision bariatric surgery, the evidence includes case series and registry data. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Case series have shown that patients receiving revision bariatric surgery experienced satisfactory weight loss. Data from a multinational bariatric surgery database has found that corrective procedures following primary bariatric surgery are relatively uncommon but generally safe and efficacious. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

#### ADULTS WITH TYPE 2 DIABETES

For individuals who are diabetic and not morbidly obese who receive gastric bypass, SG, BPD, or LAGB, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of RCTs and observational studies have found that certain types of bariatric surgery are more efficacious than medical therapy as a treatment for type 2 diabetes in obese patients, including those with a body mass index (BMI) between 30 and 34.9 kg/m<sup>2</sup>. The greatest amount of evidence is on gastric bypass. Systematic reviews have found significantly greater remission rates of diabetes, decrease in hemoglobin A1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. The efficacy of surgery is balanced against the short-term risks of the surgical procedure. Most RCTs in this population have one to three years of follow-up; with a few having five-year follow-up data. There are clinical concerns about durability and long-term outcomes at five to ten years as well as potential variation in observed outcomes in community practice versus clinical trials. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

#### NONDIABETIC AND NONOBESE ADULTS

For individuals who are not diabetic and not morbidly obese who receive any bariatric surgery procedure, the evidence includes RCTs, nonrandomized comparative studies, and case series. Relevant outcomes are OS, 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 are not diabetic or morbidly obese. A few small RCTs and case series have reported a loss of weight and improvements in comorbidities for this population. However, the evidence does not permit conclusions on the long-term risk-benefit ratio of bariatric surgery in this population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### ADOLESCENT CHILDREN WITH MORBID OBESITY GASTRIC BYPASS, LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING, OR SLEEVE GASTRECTOMY

For individuals who are adolescent children with morbid obesity who receive gastric bypass, or LAGB, or SG, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Systematic reviews of studies on bariatric surgery in adolescents, who mainly received gastric bypass or LAGB or SG, found significant weight loss and reductions in comorbidity outcomes with bariatric surgery. For bariatric surgery in the adolescent population, although data are limited on some procedures, studies have generally reported that weight loss and reduction in risk factors for adolescents are similar to that for adults. Most experts and clinical practice guidelines have recommended that bariatric surgery in adolescents be reserved for individuals with severe comorbidities, or for individuals with a BMI greater than 50 kg/m<sup>2</sup>. Also, greater consideration should be placed on the patient developmental 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 that the technology results in an improvement in the net health outcome.

#### BARIATRIC SURGERY OTHER THAN GASTRIC BYPASS, LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING, OR SLEEVE GASTRECTOMY

For individuals who are adolescent children with morbid obesity who receive bariatric surgery other than gastric bypass, or LAGB, or SG, the evidence includes systematic reviews and a cohort study. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Studies using bariatric surgery other than gastric bypass, LAGB, or SG, have small sample sizes. Results from a meta-analysis including patients using other procedures have shown significant improvements in BMI reduction, fasting blood insulin, and total cholesterol, although the estimates have wide confidence intervals, limiting interpretation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### PREADOLESCENT CHILDREN WITH MORBID OBESITY

For individuals who are preadolescent children with morbid obesity who receive bariatric surgery, the evidence includes no studies focused on this population. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Several studies of bariatric surgery in adolescents have also included children younger than 12 years old, but findings were not reported separately for preadolescent children. Moreover, clinical practice guidelines have recommended against bariatric surgery for preadolescent children. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

#### HIATAL HERNIA REPAIR WITH BARIATRIC SURGERY

For individuals with morbid obesity and a preoperative diagnosis of a hiatal hernia who receive hiatal hernia repair with bariatric surgery, the evidence includes cohort studies and case series. Relevant outcomes are OS, change in disease status, functional outcomes, health status measures, quality of life, and treatment-related

mortality and morbidity. Results from the cohort studies and case series have shown that, when a preoperative diagnosis of a hiatal hernia has been present, repairing the hiatal hernia during bariatric surgery resulted in fewer complications. However, the results are limited to individuals with a preoperative diagnosis. There was no evidence on the use of hiatal hernia repair when the hiatal hernia diagnosis is incidental. The evidence is sufficient to determine that the technology results in an 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\*:

- 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.

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.

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 diversion 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)
- Laparoscopic gastric plication
- Single anastomosis duodenoileal bypass with sleeve gastrectomy.

The following endoscopic procedures are **investigational** 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):

- Insertion of the StomaphyX™ device
- Endoscopic gastroplasty
- Use of an endoscopically placed duodenojejunal sleeve
- Intra-gastric balloons
- Aspiration therapy device.

## BARIATRIC SURGERY IN PATIENTS WITH A BODY MASS INDEX LESS THAN 35 KG/M<sup>2</sup>

Bariatric surgery is considered **not medically necessary** for patients with a body mass index less than 35 kg/m<sup>2</sup>.

### REVISION BARIATRIC SURGERY

Revision surgery to address perioperative or late complications of a bariatric procedure is considered **medically necessary**. They 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-approved indications.

### BARIATRIC SURGERY IN PREADOLESCENT CHILDREN

Bariatric surgery is considered **investigational** for the treatment of morbid obesity in preadolescent children.

### 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).

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) of 40 kg/m<sup>2</sup> or more or a BMI of 35 kg/m<sup>2</sup> or more 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, severely obese (BMI greater than or equal to 40 kg/m<sup>2</sup> or 140% of the 95<sup>th</sup> percentile for age and sex, whichever is lower) adolescents with commonly present though not required comorbidities, or who have a BMI of 35 kg/m<sup>2</sup> or greater (or 120% of the 95<sup>th</sup> percentile for age and sex, whichever is lower) with clini-



cally significant disease may be considered for bariatric surgery according to the American Academy of Pediatrics.<sup>1</sup> U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND® System indicates it is intended for 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 nonsurgical attempts at weight loss, and whether a medical weight loss program immediately preceding surgery improves outcomes.

Patients with a BMI of 50 kg/m<sup>2</sup> 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 for patients with a BMI less than 50 kg/m<sup>2</sup>. 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.

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 PROCEDURE CONSIDERATIONS

Of note, VBG is a purely restrictive procedure that is largely not performed in the U.S. and has been replaced by LAGB or SG. Weight loss with VBG is substantial, but there are high rates of revisions and reoperations due to staple line disruption, perforation, band erosion or disruption, and stenosis at the band site. Overall rates of revisions and reoperations at up to 10 years may be as high as 50%.<sup>2,3</sup> VBG is not included on the list of endorsed procedures by the American Society for Metabolic and Bariatric Surgery.<sup>4</sup>

#### CONSIDERATIONS FOR BARIATRIC SURGERY IN ADOLESCENTS

Guidelines for bariatric surgery in adolescents are not uniform, with variability in weight-based criteria, ranging from a BMI of 35 kg/m<sup>2</sup> with comorbidities to a BMI of 50 kg/m<sup>2</sup>. Most guidelines use weight-based criteria that parallel those for adults.

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 2013 that address issues of maturity and psychosocial status.

#### 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.<sup>5</sup>

#### INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

The Institute for Clinical Systems Improvement's 2013 obesity guidelines have indicated that bariatric surgery should only be considered in the pediatric population under the following conditions.<sup>6</sup>

- "The child has attained Tanner 4 or 5 pubertal development or has a bone age  $\geq 13$  years in girls or  $\geq 15$  years in boys."
- "Failure of  $\geq$  six months of organized attempts at weight management..."

- “The adolescent should have decisional capacity and also demonstrate commitment to comprehensive medical and psychological evaluation before and after surgery.”
- “A supportive family environment....”

#### BARIATRIC PROCEDURE GUIDELINES

The choice of procedure in adolescents may also differ from adults, but there is a lack of 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<sup>7</sup>:

- 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 United States 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.

In 2018, the American Society for Metabolic and Bariatric Surgery published an updated guideline on pediatric metabolic and bariatric surgery.<sup>8</sup> With regard to choice of procedure, the guideline stated:

- “Vertical sleeve gastrectomy has become the most used and most recommended operation in adolescents with severe obesity for several reasons, near-equivalent weight loss to RYGB in adolescents, fewer reoperations, better iron absorption, and near-equivalent effect on comorbidities as RYGB in adolescents. However, given the more extensive long-term data available for RYGB, we can recommend the use of either RYGB or VSG in adolescents.”

#### HIATAL HERNIA REPAIR GUIDELINES

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery.<sup>9</sup> The guideline contained the following conclusions and summary recommendations:

- “There is a significant link between obesity and hernia formation both after abdominal surgery and de novo. There is also evidence that abdominal wall hernia can more commonly present with obstruction or strangulation in patients with obesity.”
- “There is a higher risk for complications and recurrence after hernia repair in patients with obesity.”
- “In patients with severe obesity and ventral hernia, and both being amenable to laparoscopic repair, combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection. There is a relative lack of evidence, however, about the use of synthetic mesh in this setting.”
- “In patients with severe obesity and abdominal wall hernia that is not amenable to laparoscopic repair, a staged approach is recommended. Weight loss prior to hernia repair is likely to improve hernia repair outcomes. Metabolic/bariatric surgery appears to provide far more significant and rapid weight loss than other modalities and would be a good option for selected patients with severe obesity and large, symptomatic abdominal wall hernia.”

The Society of American Gastrointestinal and Endoscopic Surgeons issued evidence-based guidelines for the management of hiatal hernia.<sup>4</sup> 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

The following procedures may be considered **medically necessary** when the individual has a body mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>, has at least one comorbidity related to obesity (including type 2 diabetes mellitus) and has previously been unsuccessful with medical treatment for obesity:

- 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 considered **not medically necessary** 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.

### BACKGROUND

#### BARIATRIC SURGERY

Bariatric surgery is performed to treat morbid (clinically severe) obesity. Morbid obesity is defined as a body mass index (BMI) greater than 40 kg/m<sup>2</sup> or a BMI greater than 35 kg/m<sup>2</sup> 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, rectal, prostate; for women: breast, uterine, ovarian), and a shortened lifespan. 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.

Resolution (cure) or improvement of type 2 diabetes 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 the treatment of type 2 diabetes. 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, glucose-dependent insulinotropic peptide, and peptide YY, are secreted in response to contact with unabsorbed nutrients and by vagally mediated parasympathetic neural mechanisms. Glucagon-like peptide-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. Glucose-dependent insulinotropic peptide acts on pancreatic beta cells to increase insulin secretion through the same mechanisms as glucagon-like peptide-1, although it is less potent. Peptide YY is also secreted by the L cells of the distal intestine and increases satiety and delays gastric emptying.

#### TYPES OF BARIATRIC SURGERY PROCEDURES

##### 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 the horizontal or vertical partition of the stomach performed in association with a Roux-en-Y procedure (i.e., a gastrojejunal). 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.

##### 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 U.S. Food and Drug Administration (FDA) for marketing in the United States. The first to receive the 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 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, the FDA-labeled indications for the LAP-BAND were expanded to include patients with a BMI from 30 to 34 kg/m<sup>2</sup> with at least one obesity-related comorbid condition.

The second adjustable gastric banding device approved by the 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 BMI of at least 40 kg/m<sup>2</sup>, or a BMI of at least 35 kg/m<sup>2</sup> 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.”

#### Sleeve Gastrectomy

A sleeve gastrectomy (SG) is an alternative approach to gastrectomy that can be performed on its own or in combination with malabsorptive procedures (most commonly biliopancreatic diversion [BPD] 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 the 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 SG as the first in a two-stage procedure for very high-risk patients. Weight loss following SG may improve a patient’s overall medical status and, thus, reduce the risk of a subsequent more extensive malabsorptive procedure (e.g., BPD).

#### Biliopancreatic Diversion

The biliopancreatic diversion (BPD) 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, BPD 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 distal gastrectomy induces temporary early satiety and/or the dumping syndrome in the early postoperative period, both of which limit food intake.
- A 200-cm long “alimentary tract” consists of 200 cm of ileum connecting the stomach to a common distal segment.
- A 300- to 400-cm “biliary tract” connects the duodenum, jejunum, and remaining ileum to the common distal segment.
- 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, creating selective malabsorption. The length of the common segment will influence the degree of malabsorption.

Because of the high incidence of cholelithiasis associated with the procedure, patients typically undergo an associated cholecystectomy.

Many potential metabolic complications are related to BPD, including, most prominently, iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization. Protein malnutrition may require treat-

ment with total parenteral nutrition. Also, several case reports have noted liver failure resulting in death or liver transplant.

#### Biliopancreatic Diversion With Duodenal Switch

The duodenal switch procedure is a variant of the BPD previously described. In this procedure, instead of performing a distal gastrectomy, a SG 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 BPD, 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 duodeno-ileal by providing a more physiologic transfer of stomach contents to the duodenum. The SG 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 BPD, i.e., producing selective malabsorption by limiting the food digestion and absorption to a short common ileal segment.

#### Vertical-Banded Gastroplasty

Vertical-banded gastroplasty (VBG) 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. In order to create a durable reinforced and rate-limiting stoma at the distal end of the pouch, a plug of the 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. VBG may be performed using an open or laparoscopic approach.

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

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.

#### WEIGHT LOSS OUTCOMES

There is no uniform standard for reporting results of weight loss or for describing a successful procedure. Common methods of reporting the amount of body weight loss are the percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. Excess body weight is defined as actual weight minus "ideal weight" and "ideal weight" and is based on 1983 Metropolitan Life Insurance height-weight tables for "medium frame."

These two reporting methods are generally preferred over the absolute amount of weight loss because these methods reflect the ultimate goal of surgery: to reduce weight to a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. Table 1 summarizes the variations in reporting weight loss outcomes.

Table 1. Weight Loss Outcomes

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

BMI: body mass index; EBW: excess body weight.

### DURABILITY OF WEIGHT LOSS

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

### SHORT-TERM COMPLICATIONS (OPERATIVE AND PERIOPERATIVE COMPLICATIONS <30 DAYS)

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications (e.g., pneumonia, myocardial infarction).

### REOPERATION RATE

Reoperation may be required to “take down” or revise the original procedure. Reoperation may be particularly common in VBG due to pouch dilation.

### LONG-TERM COMPLICATIONS (METABOLIC ADVERSE EVENTS, NUTRITIONAL DEFICIENCIES)

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

### IMPROVED HEALTH OUTCOMES IN TERMS OF WEIGHT-RELATED COMORBIDITIES

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

### REGULATORY STATUS

Forms of bariatric surgery performed without specific implantable devices are surgical procedures and, as such, are not subject to regulation by the FDA.

Table 2 shows forms of bariatric surgery with implantable devices approved by the FDA through the premarket approval process.

Table 2. FDA-Approved Bariatric Surgery Devices

Device	Manufacturer	PMA Date	Labeled Indications
AspireAssist	Aspire Bariatrics	Jun 2016	For long-term use in conjunction with lifestyle therapy and continuous

Device	Manufacturer	PMA Date	Labeled Indications
System®			medical monitoring in obese adults >22 y, with a BMI of 35.0 to 55.0 kg/m <sup>2</sup> and no contraindications to the procedure who have failed to achieve and maintain weight loss with nonsurgical weight loss therapy.
ORBERA® intra-gastric balloon system	Apollo Endosurgery	Aug 2015	For use in obese adults (BMI, 30-40 kg/m <sup>2</sup> ) who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon placed endoscopically and inflated with saline.
ReShape® Integrated Dual Balloon System	ReShape Medical	Jul 2015	For use in obese adults (BMI, 30-40 kg/m <sup>2</sup> ) and ≥1 comorbid conditions who have failed weight reduction with diet and exercise, and have no contraindications. Maximum placement time is 6 mo. Balloon delivered transorally and inflated with saline.
LAP-BAND® Adjustable Gastric Banding System	Apollo Endosurgery (original applicant: Allergan)	Apr 2010	For use in weight reduction for severely obese adults with BMI of at least 40 kg/m <sup>2</sup> or a BMI of at least 30 kg/m <sup>2</sup> with ≥1 severe comorbid conditions who have failed more conservative weight-reduction alternatives (e.g., supervised diet, exercise, behavior modification programs).
REALIZE® Adjustable Gastric Band	Ethicon Endosurgery	Nov 2007	For use in weight reduction for morbidly obese patients and for individuals with BMI of at least 40 kg/m <sup>2</sup> , or a BMI of at least 35 kg/m <sup>2</sup> with ≥1 comorbid conditions, or those who are ≥45.4 kg over their estimated ideal weight. Indicated for use only in morbidly obese adults 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.

In February 2017, the FDA issued a letter to health care providers discussing the potential risks with liquid-filled intra-gastric balloons in response to reports of two types of adverse events related to the balloons. Several dozen reports concerned spontaneous overinflation of the balloons, which caused pain, swelling, and vomiting. The second set of adverse event reports indicated that acute pancreatitis developed in several patients due to compression of gastrointestinal structures. These reports involved both ReShape and ORBERA brands. The adverse events may require premature removal of the balloons.

In August 2017, the FDA issued a second letter to health care providers informing them of five unanticipated deaths occurring from 2016 through the time of the letter, due to intra-gastric balloons. The FDA recommended close monitoring of patients receiving these devices.

In April 2020, the FDA provided an update on risks and continued to recommend that healthcare providers “instruct patients about the symptoms of life-threatening complications such as balloon deflation, gastrointestinal obstruction, and gastric and esophageal perforation and monitor patients closely during the entire duration of treatment for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications.”

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