MEDICAL POLICY

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POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, the surgical treatment of morbid obesity by open or laparoscopic Roux-en-Y gastric bypass, duodenal switch procedure (biliopancreatic diversion), and sleeve gastrectomy have been medically proven to improve health outcomes and, therefore, are considered **medically appropriate** for selected patients who meet **ALL** of the following criteria:

A. Patient is morbidly obese, which is defined as follows:

1. For adults aged 18 years and older: either having a BMI greater than or equal to 40 kg/m^2, or having a BMI greater than or equal to 35 kg/m^2 and existing comorbid condition(s) (e.g., hypertensive cardiovascular disease, coronary heart disease, pulmonary hypoventilation, hypertension, hypercholesterolemia, dyslipidemias, diabetes, sleep apnea, degenerative arthritis of weight-bearing joints, or other weight-related arthropathies, or metabolic syndrome). Documentation of the comorbid existing medical condition(s) must be submitted by the primary care physician.
2. For adolescents: either having a BMI greater than or equal to 40 kg/m2 or 140% of the 95th percentile (whichever is lower), or having a BMI greater than or equal to 35 kg/m2 or 120% of the 95th percentile (whichever is lower) with clinically significant comorbid condition(s) (e.g., hypertensive cardiovascular disease, hypertension, hypercholesterolemia, dyslipidemias, diabetes, sleep apnea, weight-related arthropathies, and metabolic syndrome). Documentation of the comorbid existing medical condition(s) must be submitted by the primary care physician.

B. A letter of support from the physician who is currently providing primary care to the patient and who is familiar with the patient's attempts at weight reduction, medical history, and current health status (including obesity issues) is also necessary for the review process.

C. History of rigorous attempts at weight reduction:
   1. There must be written evidence of a weight loss history, either by the bariatric surgeon, primary care physician or nutritionist. This documentation should include the name of the weight loss program, length of participation in the program, and any weight loss achieved**.** Continued participation in weight loss programs should be encouraged pre-operatively.
   2. A clinical evaluation by a Registered Dietician pre-operatively is mandatory, and documentation must be included.

D. There must be no significant liver, kidney, or gastrointestinal disease present. The presence of non-alcoholic steatohepatitis, or "fatty liver," which is associated with morbidly obese patients, would not be considered significant liver disease in this instance.

E. Treatable metabolic causes for obesity (e.g., adrenal or thyroid disorders) have been addressed.

F. Patients with a history of alcohol or substance use disorder will not be considered, unless there is a record of at least six months of abstinence. If there has been six months of abstinence, this condition must be addressed in a psychiatric consultation.

G. Patient must be screened by the patient's physician for major psychopathology. All patients who have current symptoms that concern the physician, or who have had a psychiatric hospitalization, must have a psychiatric evaluation. The psychiatric evaluation should be performed by a psychiatrist familiar with the implications of weight reduction surgery. If psychiatrists with this expertise are not available, an evaluation by any state-licensed, qualified mental health provider familiar with the implications of weight reduction surgery is also acceptable. A current mental health provider familiar with the implications of weight reduction surgery who is providing ongoing care for the patient may also provide this evaluation. If the patient already has an established psychiatric provider, that provider must provide a second letter of support for the proposed surgery. Psychological testing as a screening tool or as part of the psychological evaluation prior to bariatric surgery is considered **not medically necessary**.

II. Laparoscopic adjustable gastric banding (LAGB) (e.g., LAP BAND) is considered **medically appropriate** in the following circumstances:

A. The patient meets **ALL** of the criteria specified in Policy Statement I; and
B. The patient's dietary history does not include a large consumption of highly caloric liquids (e.g., milkshakes) or sweets; and
C. The patient has no significant history of esophageal or gastric disease (*please note contraindications to adjustable gastric banding listed in the rationale section*); and
D. The patient participates in a pre-operative bariatric program that requires a 5% weight loss to demonstrate commitment to behavioral and dietary changes. The 5% weight loss will be measured from the date of the patient's initial visit to the bariatric surgeon to the date of the request for pre-authorization of the adjustable gastric banding procedure.

III. Based upon our criteria-and assessment of the peer-reviewed literature, surgical procedures for the management of obesity for adolescents will be considered **medically appropriate**, if the patient meets all of the criteria specified in Policy Statement I. Adolescents, due to their special needs, should be referred to a Center of Excellence or other facilities specializing in bariatric surgery procedures for the adolescent population. This will allow for greater consideration to be given to psychosocial and informed consent issues.

IV. Based upon our criteria and assessment of the peer-reviewed literature, the following procedures for the primary surgical treatment of morbid obesity have not been medically proven to improve health outcomes and, therefore, are considered **investigational:**

A. Aspiration therapy (e.g., AspireAssist device);
B. Laparoscopic gastric plication;
C. Mini-gastric bypass (also called loop gastric by-pass);
D. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S);
E. Stomach-intestine pylorus-sparing surgery (SIPS); and
F. Transoral gastroplasty or endoscopic/endoluminal procedures or devices (e.g., Restorative Obesity Surgery, Endoluminal or ROSE, TOGA System, StomaphyX, EndoCinch, Overstitch device, EndoBarrier, intragastric balloon insertion, TransPyloric Shuttle Device).

V. Surgical revisions are considered **medically appropriate** for complications, such as malabsorption/malnutrition, obstruction, staple disruption, or stricture following the primary procedure. (*Refer to Policy Guideline III.)*

VI. A revision or removal of an LAGB is considered **medically appropriate** in the event of complications or a technical failure. Examples of LAGB complications reported in the literature that may warrant revision, removal or conversion to another procedure include, but are not limited to, band slippage, band erosion, infection, esophageal dilation, dysphagia, and heartburn/reflux. Technical failures of LAGB include, (but are not limited to), a displaced band, port dislocation, too tight a band (creating food passage problems), band intolerance (e.g., pain or vomiting), and port and/or catheter leakage.

VII. A revision or conversion to another medically appropriate procedure because of unsatisfactory weight loss due to technical failure of the primary bariatric procedure, such as pouch dilation or an initial pouch size that is too large (an ideal initial pouch size is approximately 20 cc), is considered **medically appropriate** if there is documentation regarding both of the following submitted with the request:
A. Primary procedure was initially successful in inducing weight loss; and
B. Patient has remained compliant for at least six months with the prescribed nutrition and exercise program. (*Refer to Policy Guideline III.)*

VIII. Placement of a second adjustable gastric band (AGB) is considered **investigational**, as there is no published literature to support the efficacy of a second AGB after failure of the first procedure to produce weight loss.

IX. Based upon our criteria and assessment of the peer-reviewed literature, use of an endoscopic/endoluminal procedure for revisional surgery (e.g., transoral outlet reduction) has not been medically proven to be effective and, therefore, is considered **investigational**.

X. Repeat surgery for morbid obesity is considered **not medically necessary** for patients who have either failed to lose weight or who have regained weight due to non-adherence with the prescribed nutrition and exercise program following their surgery.

XI. Based upon our criteria and assessment of the peer-reviewed literature, use of bariatric surgery as a treatment for either non-obese patients with type 2 diabetes mellitus or patients with type 2 diabetes and BMI between 30.0-34.9 kg/m^2 has not been medically proven to be effective and, therefore, is considered **investigational**.

XII. Based upon our criteria and assessment of the peer-reviewed literature, performing a routine liver biopsy at the time of the bariatric surgery is considered **not medically necessary** in the absence of documented signs or symptoms of liver disease (e.g., abnormal liver function tests of unknown etiology, knowledge of a specific diagnosis that will likely alter the treatment plan, known liver disease where prognostic information about fibrosis may guide subsequent treatment, the presence of a mass or lesions, or focal or diffuse abnormalities seen on imaging studies of unknown etiology).

XIII. Based upon our criteria and assessment of the peer-reviewed literature, prophylactic removal of a normal and asymptomatic gallbladder at the time of bariatric surgery is considered **not medically necessary**, unless cholelithiasis is present, or the patient will undergo biliopancreatic diversion based on a higher incidence of biliary complications.

XIV. The adjustment of a previously placed laparoscopic gastric band, beyond the global, 90-day limit, is considered **medically appropriate** to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following a medically necessary adjustable gastric banding procedure.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

Refer to Corporate Medical Policy #11.01.11 Cosmetic and Reconstructive procedures.

Refer to Corporate Medical Policy #7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy.

Refer to Corporate Medical Policy #7.01.64 Gastric Electrical Stimulation.

POLICY GUIDELINES

I. Patients considering surgery must participate in an integrated pre- and post-surgery program consisting of dietary therapy, physical activity, and behavioral and social support programs. Post-surgically, patients must be involved in a formal program for at least one year.

II. Gastric bypass surgery affects the absorption of medication and may lead to irregular blood levels of medication. Where drug level maintenance is critical, bypass surgery may be contraindicated. Examples include patients with seizure disorders requiring anti-seizure medications, and patients with mental illness who require maintenance medication.

III. Some post-bariatric surgery patients regain lost weight or never lose sufficient weight. Other patients may develop unacceptable post-operative symptoms (e.g. de novo gastroesophageal reflux disease (GERD) that does not respond to medical therapies). These failures may warrant reversal surgery or revision surgery (e.g., conversion to Roux-en-Y). Failures due to patient noncompliance reflect poor patient selection and do not warrant revision procedures. A clue to this is gastric pouch dilation in a patient not adhering to the recommended eating protocols. These patients are likely to fail again. Patients must demonstrate compliance for at least six months before a revision will be considered for failure to lose adequate weight and/or weight regain. A revision due to medical complications does not require six months of demonstrated compliance.

IV. Coverage is limited to physicians who have been properly trained in performing a bariatric procedure at facilities with the diagnostic and support services necessary for the care of morbidly obese patients.

V. Any device used for bariatric surgery must be used in accordance with the approved indications of the United States Food and Drug Administration (FDA).

VI. An expected outcome of successful bariatric surgery is redundant/excessive skin. Surgery to remove this skin is generally not considered medically necessary and, therefore not covered.

Refer to Corporate Medical Policy # 7.01.53 Abdominoplasty and Panniculectomy.

DESCRIPTION

Obesity is a complex, multifactorial, chronic condition that substantially raises an individual's risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary artery disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, respiratory problems, and a variety of cancers.

The 1998 National Heart Lung Blood Institute (NHLBI) expert panel defined Class I obesity as a body mass index (BMI) of 30-34.9 kg/m^2; Class II obesity as a BMI of 35-39.9 kg/m^2; and extreme obesity or Class III as a BMI greater than or equal to 40 kg/m^2.

In 2017, in a new position statement , the American Association of Clinical Endocrinologists (AACE) replaced the word obesity for the diagnostic terminology Adiposity-Based Chronic Disease (ABCD) because obesity is not about weight itself, but the health threats it causes due to the effects of excess weight or adipose tissue on your body. ABCD looks at the science of the disease and destigmatizes the term "obesity".

Bariatric surgery can be divided into two categories: gastric restrictive procedures and malabsorptive procedures. Gastric restrictive procedures mechanically prevent the patient from overeating; malabsorptive procedures interfere with the absorption of ingested nutrients. Examples of gastric restrictive procedures include vertical and horizontal banded gastroplasty and adjustable gastric banding. Malabsorptive procedures include biliopancreatic bypass, long-limb gastric

bypass, and biliopancreatic bypass with duodenal switch. The Roux-en-Y gastric bypass is actually a combination of a gastric restrictive and malabsorptive procedure. A bariatric procedure is usually considered a success when at least 50% of excess body weight is lost or when the patient returns to within 30% of his/her ideal body weight.

The intragastric balloon has been proposed as a temporary, non-surgical obesity treatment for short-term weight loss in patients who have had unsatisfactory results with their diet and exercise programs. The intragastric balloon has also been proposed for weight loss in the super-obese patient, prior to a permanent, invasive surgical procedure. The saline-filled intra-gastric balloon, placed endoscopically, is intended to reduce gastric capacity, creating satiety and reducing food intake.

The TOGA and StomaphyX Systems consist of a set of transoral, endoscopically guided staples that are used to create a restrictive pouch along the lesser curvature of the stomach. The EndoCinch was initially devised for the endoscopic treatment of (GERD). With EndoCinch, sutures are deployed in a continuous and cross-linked fashion from the proximal fundus to the distal body. Once the suture is fixed, distention of the stomach is significantly limited, thus providing a method of restricting food intake. The Overstitch device allows for full-thickness endoscopic suturing, compared to the superficial-thickness suturing provided by other devices. These endoscopic procedures may offer lower morbidity than other current bariatric procedures and are adjustable and reversible. They are being investigated as the primary bariatric surgery and as a revisional procedure to treat weight gain (e.g., large gastric pouch, large gastric stoma/dilated gastrojejunal anastomosis).

Laparoscopic gastric plication is a relatively new restrictive technique that involves sewing one or more folds in the stomach. Gastric plication reduces stomach volume by approximately 70% and is potentially reversible.

Aspiration therapy as a treatment for obesity involves a surgically placed tube to drain a portion of the stomach contents after every meal. The tube is inserted in the stomach with an endoscope via a small incision in the abdomen. A disk-shaped port valve that lies outside the body, flush against the skin of the abdomen, is connected to the tube and remains in place. Approximately 20 to 30 minutes after meal consumption, the patient attaches the device's external connector and tubing to the port valve, opens the valve, and drains the contents. Once opened, it takes approximately five to 10 minutes to drain food matter through the tube and into the toilet. The device removes approximately 30 percent of the calories consumed.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) has a restrictive component when reducing the greater curvature of the stomach, but especially a malabsorptive component, as the common channel is also reduced. The objective of this surgical technique is to lessen the intestinal loop where nutrients are absorbed. The procedure is based on biliopancreatic diversion, in which a sleeve gastrectomy is followed by an end-to-side duodeno-ileal diversion. The preservation of the pylorus makes possible the reconstruction in one loop.

Stomach-intestine pylorus-sparing surgery (SIPS) is a modified version of the duodenal switch procedure. SIPS involves the creation of a 300 cm common channel, with a single-anastomosis duodenal enterostomy. It involves the formation of a sleeve gastrectomy that is slightly larger than our usual sleeve, with an attachment placed beneath the pyloric valve that controls emptying of the stomach into the mid-gut, located three meters from the terminal ileum. A proposed benefit of SIPS is that it does not cause abrupt rise and fall of blood glucose, thus preserving the pyloric valve. Also, by not bypassing as much intestine, it may reduce the complications of short bowel syndrome.

Post-bariatric surgery patients who regain lost weight, do not lose sufficient weight, or develop unacceptable post-operative symptoms due to structural complications may warrant reversal or revision surgery. Reversal or revision of bariatric procedures is usually not warranted in patients whose failure is due to noncompliance (e.g., gastric pouch dilation from 20cc to greater than 100cc in a patient who is not adhering to the recommended eating protocols). Conversely, revisional surgery for complications, such as those related to malabsorption resulting in hypoglycemia, malnutrition, or weight loss of 20% below ideal body weight, may be warranted, particularly after malabsorptive procedures. Examples of laparoscopic adjustable gastric banding complications reported in the literature that may warrant revision, removal or conversion to another procedure include, but are not limited to, band slippage, band erosion, infection, esophageal dilation, dysphagia, and heartburn/reflux. Technical failures of LAGB include (but are not limited to) a displaced band, port dislocation, too tight a band (creating food passage problems), band intolerance (e.g., pain, vomiting), and port and/or catheter leakage.

RATIONALE

The hallmark piece of published literature supporting the safety and effectiveness of bariatric surgery is the National Institutes of Health (NIH) Consensus Statement. The following recommendations were included among the findings: (1) gastric restrictive or bypass procedures could be considered for well-informed and motivated individuals with acceptable operative risks; (2) patients who are candidates for surgical procedures should be selected carefully after evaluation by a multi-disciplinary team with medical, surgical, psychiatric, and nutritional expertise; (3) the operation should be performed by a surgeon substantially experienced with appropriate procedures and working in a clinical setting with adequate support for all aspects of management and assessment; and (4) lifelong medical surveillance after surgical therapy is necessary.

The NIH Consensus Conference on the Surgical Management of Morbid Obesity (1998) stated that obesity surgery should be reserved only for patients who have first attempted medical therapy. The NIH Consensus Conference noted that the initial goal of medical therapy is a 10% weight reduction with a reasonable duration of six months, stating, "the rationale for this initial goal is that even moderate weight loss can significantly decrease the severity of obesity-associated risk factors." The patient's ability to lose weight prior to bariatric surgery is an indication of the likelihood of compliance with the severe dietary restriction and behavioral changes required for the patient following surgery. Weight loss prior to surgery can also make surgical intervention easier to perform. Based on more recent research and literature, the findings currently demonstrate that pre-surgical weight loss does not impact post-surgical weight loss as much as originally thought. Pre-operative diets delay treatment of obesity and its co-morbidities, do not improve length of stay or complication rates, and do not improve weight loss outcomes.

The Swedish Obese Subjects (SOS) intervention trial has reported on several hundred patients with up to eight years of follow-up. This trial demonstrated that surgery results in large amounts of weight loss, compared to usual care (16% decrease in total body weight at six years versus an increase of 0.8% for usual care). Results of the SOS trial show substantial weight loss in the surgery group of a peak of 44 kg at one year and a gradual weight increase thereafter (mean loss of 30 kg at two years and 20 kg at eight years). The SOS trial also showed that co-morbid conditions and quality of life are improved after surgery, with the most compelling evidence in the co-morbid conditions that exist for diabetics (an 18.5% decrease in diabetes versus 3.6%). The number of patients presenting with hypertension decreased in the short-term, but was not sustained two years following surgery.

With respect to specific bariatric procedures, there is sufficient data published in the medical literature to conclude that surgical management of obesity using open or laparoscopic Roux-en-Y gastric bypass procedures, sleeve gastrectomy, or the duodenal switch procedure improves health outcomes for patients with morbid obesity. Improved health outcomes have been achieved outside the investigational setting.

The FDA has given premarket approval for the LAP-BAND and Realize AGB devices. AGB has been an evolving procedure, with issues of migration and erosion being addressed by varying techniques and surgical modifications. AGB is associated with fewer early complications, but more late complications and re-operations when compared toRoux-en-Y gastric bypass (RGB). Studies report reoperation rates due to adverse events at 5.6%-24%. Weight loss is also significantly less than RGB, in most reported studies of AGB. Evidence for three-year outcomes related to weight loss after AGB was consistent with a 25% or greater excess weight loss reported. The reduction in BMI ranged from 7.9-15, but the typical patient in the studies remained obese (BMI greater than 30) in the majority of the studies. As studies demonstrate, the percentage of estimated weight loss is significantly less with AGB, the procedure that works best for appropriately selected patients. Contraindications to AGB per the product insert of the LAP-BAND are as follows:

1. Patients with inflammatory diseases of the gastrointestinal tract, including severe intractable esophagitis, gastric ulceration, duodenal ulceration, or specific inflammation such as Crohn's disease;
2. Patients with severe cardiopulmonary diseases or other serious organic disease that may make them poor surgical candidates;
3. Patients with potential upper gastro-intestinal bleeding, such as esophageal or gastric varices or congenital-acquired intestinal telangiectases;
4. Patients with portal hypertension;
5. Patients with congenital or acquired anomalies of the gastrointestinal tract, such as atresias or stenoses;

6. Patients who have/experience an intra-operative gastric injury during the implantation procedure, such as a gastric perforation at or near the location of the intended band placement;
7. Patients with cirrhosis;
8. Patients with chronic pancreatitis;
9. Patients who are addicted to alcohol and/or drugs;
10. Non-adult patients (patients under 18 years of age);
11. Patients who have an infection anywhere in their body or for whom the possibility of contamination prior to or during the surgery exists;
12. Patients on chronic, long-term steroid treatment;
13. Patients who are unable or unwilling to comply with dietary restrictions, which are required by this procedure;
14. Patients who are known to have, or suspected to have, an allergic reaction to materials contained in the system or who have exhibited pain intolerance to implanted devices;
15. Patients or family members with a known diagnosis or pre-existing symptoms of autoimmune connective tissue disease, such as systemic lupus erythematosus or scleroderma;
16. Pregnancy: Placement of the LAP-BAND System is contraindicated for patients who currently are or may be pregnant. Patients who become pregnant after band placement may require deflation of their bands.

In February 2011, the FDA granted approval for LAGB use in patients with a BMI of 30-35 kg/m^2 in the presence of at least one weight-related comorbidity. The FDA labeling indicates that this procedure should be reserved for patients who are at the highest risk for weight-related complications and who have been unsuccessful in achieving medical weight loss. The evidence is insufficient to determine whether LAGB improves the overall health outcomes for patients with BMIs that are lower than the current thresholds for bariatric surgery. The patients in these studies consist of a heterogenous patient population, and the number and severity of co-morbidities varied considerably. While the short-term evidence in current studies demonstrates weight loss in this patient population, and favorable changes in measures of diabetes, the impact of LAGB on other weight-related co-morbidities is less certain.

J.B. Dixon et al. (2008) performed a randomized, controlled trial designed to determine whether surgically induced weight loss results in better glycemic control and less need for diabetes medication than conventional approaches to weight loss and diabetes control in patients with BMI of greater than 30 and less than 40. (Results were not reported separately for patients with BMI less than or greater than 35.) Sixty patients were enrolled, with 30 randomized to LAGB and 30 to conventional diabetes care. Fifty-five completed the two-year follow-up. Remission of diabetes was achieved by 22 (73%) in the LAGB group and four (13%) in the control group. The surgical group lost 62.5% of excess weight (using BMI of 25 as ideal weight) versus a loss of 4.3% of excess weight in the conventional group. Mean hemoglobin A1c was less than 6.2% at baseline in two surgically and four conventionally treated patients, versus 24 and six patients, respectively, at two years. At baseline, two surgically treated and four conventionally treated patients were using no pharmacotherapy, versus 26 and eight, respectively, at two years. One surgical patient developed a wound infection, two developed gastric pouch enlargement and had laparoscopic revision to remove and replace the band. The remaining evidence at the present time consists of small case series and case reports with short follow-up from non-U.S. centers, employing procedures considered investigational in this policy (e.g., stand-alone sleeve gastrectomy, mini-gastric bypass). Overall, the data are insufficient to allow conclusions regarding the efficacy of bariatric surgical procedures in the treatment or cure of type 2 diabetes.

In 2018, the American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee updated its evidence-based guidelines published in 2012. The committee identified a significant increase in data supporting the use of metabolic and bariatric surgery (MBS) in adolescents since 2012. ASMBS recommended that adolescents with BMI ≥35 kg/m2 or 120% of the 95th percentile with clinically significant co-morbid conditions or BMI ≥40 kg/m2 or 140% of the 95th percentile (whichever is lower) should be considered for MBS. Significant comorbidities include: obstructive sleep apnea (apnea-hypopnia index greater than 5), type 2 diabetes, idiopathic intracranial hypertension, nonalcoholic steatohepatitis (NASH), Blount's disease, slipped capital femoral epiphysis, GERD, or hypertension. The committee stated that a multi-disciplinary team must also consider whether the patient and family have the ability and motivation to adhere to recommended treatments pre-and post-operatively, including consistent use of micronutrient supplements. The committee stated that adjustable gastric band and biliopancreatic diversion procedures in adolescents are less desirable

choices, based on the risk for reoperation. The adjustable gastric band is not currently FDA-approved for use in patients under 18 years of age.

The short- and mid-term outcomes and complication rates of sleeve gastrectomy appear to be similar to those of other restrictive and malabsorptive procedures (Leyba et al. 2011; Himpens et al. 2010; D'Hondt et al. 2011; Chouillard et al. 2011). The procedure was proposed initially as the first step in a staged procedure for high-risk (super-obese) patients, and longest follow-up data is available for these patients.

The ReShape Integrated Dual Balloon System (REShape Medical, Inc.) received FDA approval in July 2015. The device is also intended to facilitate weight loss in obese adult patients with a BMI of 30-40 who have been unsuccessful in losing weight through diet and exercise. Patients must have one or more obesity-related conditions, such as diabetes, high blood pressure, or high cholesterol. Both approved devices are considered temporary and should be removed after six months. The ORBERA Intragastric Balloon (Apollo Endosurgery, Inc.) received FDA approval in August 2015 for patients with a BMI of 30-40, to assist those patients in losing and maintaining weight. Obalon Therapeutics received FDA approval for the Obalon Balloon System in September 2016. The Obalon Balloon System is a swallowable intragastric balloon system indicated for temporary use, to facilitate weight loss in adults with obesity (BMI of 30 – 40 kg/m2) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed. Peer-reviewed literature is currently insufficient to determine the efficacy and safety of an intragastric balloon as a weight loss technique. A systematic review (Fernandes et al., 2007) to assess the efficacy of the intragastric balloon (IGB) found that studies had very short follow-up, and, when compared to conventional management, IGB outcome data did not provide convincing evidence of a greater weight loss. More recent studies (e.g., REDUCE trial by Ponce et al., 2015) found promising short-term (up to 48 weeks) results of weight loss with balloon insertion, compared to diet and exercise alone. In the Obalon clinical trial, 387 patients in the United States across fifteen clinical trial sites were randomized in a double-blind, sham-controlled study. The patients in the clinical trial received either three Obalon balloons or three sham placebo-like devices that looked similar to the balloons but were filled with sugar. The patients in both groups were given minimal diet counseling of 25 minutes every three weeks. Both co-primary weight loss endpoints were met, with approximately 65% of patients who received the Obalon Balloon System experiencing clinically meaningful weight loss of at least 5% of their total body weight, which is twice as many people than in the sham-control group. Further studies are needed to demonstrate the long-term effects of utilizing intragastric balloon as a weight loss strategy.

Literature reporting on transoral gastroplasty for the treatment of obesity is limited; data are insufficient to provide conclusions on its safety and efficacy. The results of two studies (n=21, BMI range 35-53) were presented at the 2007 SAGES Annual Scientific Session. Follow-up for six patients at six months demonstrated an average weight loss of 31 pounds and an EWL of 24.9%. Sham-controlled trials are needed, to further evaluate the utility of the EndoCinch device in obesity. Well-designed studies with long-term follow-up are needed, to measure the durability of the observed weight loss. In particular, the stability of the gastric sutures procedure remains unproven, given the lack of long-term data.

There is insufficient data published in the medical literature to draw conclusions about the safety and effectiveness of the mini-gastric bypass (also called loop gastric by-pass) procedure.

While preliminary data show that gastric plication has acceptable complication rates and weigh loss outcomes in the short-term (e.g., Fried et al., 2012; Skrekas et al., 2011; Kourkoulos et al., 2012; Talebpour et al., 2012), additional, well-designed comparative studies with established bariatric procedures are needed, to determine its overall safety, efficacy, and impact on health outcomes.

No controlled trials of single-anastomosis duodeno-ileal bypass with sleeve gastrectomy have been identified. Some case series have reported on weight loss and other clinical outcomes up to five years post-surgery. One larger series was published in 2015 (Sanchez-Pernaute et al.) and reported on 97 patients with obesity and T2D. The authors reported that control of diabetes, defined as an HbA1c less than 6.0%, was achieved by between 70% and 84% of patients at different time points. Remission rates were higher for patients on oral therapy than for those on insulin, and were higher in patients with a shorter duration of diabetes. Currently, data is insufficient to provide conclusions on SADI-S safety and efficacy.

The AspireAssist obesity device (Aspire Bariatrics) received FDA approval in June 2016. Per the manufacturer, the AspireAssist device should not be used in patients with eating disorders, and it is not intended to be used for short durations

in those who are moderately overweight. It is intended to assist in weight loss in patients aged 22 and older who are obese, with a body mass index of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy. And tThe FDA reviewed results from a clinical trial of 111 patients treated with AspireAssist and appropriate lifestyle therapy, and 60 control patients who received only the lifestyle therapy. After one year, patients using AspireAssist lost an average of 12.1 percent of their total body weight, compared to 3.6 percent for the control patients. There is insufficient literature to determine its overall benefit and safety as a bariatric procedure.

Transoral outlet reduction is being evaluated as an endoscopic revisional surgery in patients with weight regain following their primary bariatric procedure (e.g., gastric bypass). Preliminary results are promising, with feasibility, safety, and short-term efficacy being demonstrated in case series (Jirapino et al., 2013; Thompson et al., 2013; Kumar et al., 2014). However, the long-term durability of the procedure still needs to be proven in larger studies.

The literature is insufficient to determine the long-term outcomes of stomach intestine pylorus sparing surgery (SIPS) in the treatment of morbid obesity.

Twelve months of abstinence is usually required for patients with a history of drug/alcohol abuse, as liver toxins need to be avoided due to the higher rate of liver disease post-bariatric surgery.

Medical literature does not support routine liver biopsy as a standard practice during bariatric surgery. Its impact on patient health outcomes has not been well-established, and there is insufficient clinical evidence to support routine liver biopsy in patients undergoing bariatric surgery. The British Society of Gastroenterology guidelines on the use of liver biopsy in clinical practice do not identify routine biopsy of the liver during bariatric surgery or, indeed, any other abdominal surgery. Recent American guidelines also do not endorse routine liver biopsies with abdominal surgeries.

Mazzini, et. al., concludes in the American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on the impact of metabolic and bariatric surgery on nonalcoholic steatohepatitis published March 2022 that metabolic and bariatric surgery has a positive impact on NAFLD and NASH, either with or without fibrosis, and should be considered as a therapeutic tool among those patients with severe obesity. Randomized controlled trials are needed to determine whether MBS should be considered as a frontline therapy for NAFLD and NASH. This position statement also notes that the American Association for the Study of Liver Diseases (AASLD) does not currently recommend screening high-risk patient populations including those with obesity and diabetes due to lack of available interventions with long-term benefits. Currently however AASLD recommends biopsy for only those patients with NAFLD who are at increased risk of steatohepatitis and/or advanced fibrosis and for patients in whom competing liver diseases, not NAFLD, are being considered or cannot be ruled out. In practice, in patients with NAFLD, liver biopsy is reserved for suspicion of advanced fibrosis where noninvasive testing shows discordant results.

In a Choosing Wisely statement (2015), the American Society for Metabolic and Bariatric Surgery stated that the incidence of bile duct injury rates has increased since the introduction of laparoscopic cholecystectomy. The removal of normal and asymptomatic gallbladders at the time of bariatric surgery has not been shown to be necessary. In a 2016 retrospective cohort study, Sucandy et al. found a 22.7% incidence of subsequent biliary complications in patients who underwent biliopancreatic diversion and duodenal switch (BPD/DS).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
0813T **(E/I)**	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon *(Effective 01/01/24)*
43290 **(E/I)**	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon *(Effective 01/01/23)*
43291 **(E/I)**	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s) *(Effective 01/01/23)*
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	revision of adjustable gastric restrictive device component only
43772	removal of adjustable gastric restrictive device component only
43773	removal and replacement of adjustable gastric restrictive device component only
43774	removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	other than vertical-banded gastroplasty
43845	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)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	removal of subcutaneous port component only
43888	removal and replacement of subcutaneous port component only

HCPCS Codes

Code	Description
C9784 (**E/I)**	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components (*Effective 07/01/2023*)

Code	Description
C9785 (**E/I**)	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components (*Effective 07/01/2023*)
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD10 Codes

Code	Description
E66.01	Morbid (severe) obesity due to excess calories
E66.2	Morbid (severe) obesity with alveolar hypoventilation
K91.0-K91.32	Postprocedural complications and disorders of digestive system, code range
K95.01-K95.09	Complications of gastric band procedure (code range)
K95.81-K95.89	Complications of other bariatric procedure (code range)
Z68.35-Z68.45	Body mass index (BMI), 35.0-70 or greater, adult (code range)

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*Key Article

KEY WORDS

Adjustable gastric band, Aspiration therapy, Bariatric, Endobarrier, Gastric bypass, Gastric plication, Imbrication, intragastric balloon, Lap Band, ROSE, Roux-en-Y, SIPS, Sleeve gastrectomy, Transoral outlet reduction.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for bariatric surgery. Please refer to the following NCD website for Medicare Members: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&ncdver=5&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&]

There is also a local coverage article from the National Government Services contractor related to sleeve gastrectomy. Please refer to the following web site: [https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52447&ver=29&keyword=sleeve%20gastrectomy&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1]