

## Bariatric Surgery

**Policy MP-052**

**Origination Date:** 12/18/2019

**Reviewed/Revised Date:** 06/21/2023

**Next Review Date:** 06/21/2024

**Current Effective Date:** 06/21/2023

### Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### Description:

Obesity is an increasingly common conditions in the United States. The Centers for Disease Control and Prevention (CDC) reports that in 2015-2016, the prevalence of obesity was 39.8% in adults in the United States (U.S.), which affects about 93.3 Million people. It can affect the health and wellbeing of an individual and contributes to many other complicating medical conditions such as diabetes mellitus, cardiovascular disease, arthritis, obstructive sleep apnea (OSA) and perhaps even cancer. Doctors measure the Body Mass Index (BMI) and waist circumference to screen and diagnose obesity. BMI is a person's weight in kilograms divided by the square of height in meters. BMI can be used as a screening tool but is not diagnostic of the body fatness or health of an individual.

The National Heart, Lung and Blood Institute (NHLBI) classifies the ranges of BMI in adults as follows:

- < 18.5 - Underweight
- 18.5 to 24.9 kg/m<sup>2</sup> – Normal Weight
- 25-29.9 kg/m<sup>2</sup> – Overweight
- 30.0-34.9 kg/m<sup>2</sup> – Obesity Class I
- 35-39.9 kg/m<sup>2</sup> – Obesity Class II
- > 40 kg/m<sup>2</sup> – Extreme Obesity Class III

As of 2018, the U.S. Preventive Services Task Force (USPSTF) recommends screening all adults for obesity. They have divided the BMI obesity category into 3 classes: Class 1 (BMI of 30.0 to

34.9), Class 2 (BMI of 35.0 to 39.9) and Class 3 (BMI of  $\geq 40$ ). Also, clinicians should offer or refer patients with a BMI of 30 kg or higher to intensive, multicomponent behavioral interventions.

The two main weight-loss surgeries offered for treatment of obesity are restrictive and malabsorptive. Restrictive methods cause weight loss by restricting the amount of food that can be consumed by making the stomach smaller. Malabsorptive methods cause weight loss by limiting the amount of food that is absorbed from the intestines. A procedure can have restrictive features, malabsorptive features, or both. The surgical approach may be open or laparoscopic and the clinical decision on which surgical procedure (or a combination of both) is used will be made based on the medical assessment of the patient's individual situation.

Potential issues related to bariatric procedures may include bowel perforations, adjustable gastric band migration (slippage) that cannot be corrected with manipulation or adjustment, leaks, obstruction, staple-line failure and mechanical adjustable gastric band failure.

## **Policy Statement and Criteria**

### **1. Commercial Plans**

**U of U Health Plans considers the following procedures proven and medically necessary for treating patients with obesity when the criteria below has been met:**

- A. Roux-en-Y gastric bypass
- B. Bilio-pancreatic diversion with duodenal switch (BPD/DS) gastric bypass
- C. Sleeve gastrectomy

**U of U Health Plans does NOT cover gastric banding (e.g. LapBand<sup>®</sup>) bariatric surgery due to lower efficacy and higher complication rates relative to other available options. It is considered not medically necessary.**

**U of U Health Plans covers one bariatric surgery per lifetime, including all related services, when the member is 18 years or older and the following criteria are met (Preauthorization is required):**

- A. A documented history of a BMI  $> 40\text{kg/m}^2$  for the preceding 3 years; or
- B. A documented history of a BMI  $> 35\text{kg/m}^2$  with at least 2 of the following co-existing conditions:
  - i. Medically refractory hypertension: persistent blood pressure readings of  $>140/90$  mmHg (or  $>130/80$  mmHg in diabetic patients) for a minimum of six (6) months despite use of at least two anti-hypertensive medications;
  - ii. Uncontrolled diabetes (defined as a HgbA1c  $>7\%$  of two (2) separate occasions at least six (6) months apart despite taking at least two (2) diabetic medications with separate mechanisms of action during this time;

- iii. Dyslipidemia requiring medical therapy as defined by the American College of Cardiology and American Heart Association guidelines;
  - iv. Proven coronary artery disease OR cerebral artery disease;
  - v. Obstructive sleep apnea (OSA) as diagnosed by a formal sleep study in an American Academy of Sleep Medicine (AASM) certified sleep lab and interpreted by a certified specialist in sleep disorders;
  - vi. Obesity hypoventilation syndrome with a diagnosis supported by a polysomnography with continuous nocturnal carbon monoxide monitoring (performed in an AASM certified sleep lab and interpreted by a certified specialist in sleep disorders), pulmonary function testing, a chest x-ray, and relevant laboratory testing;
  - vii. Debilitating arthritis with disqualification from surgery as a result of obesity.
- C. Active participation for at least 12 months in a structured, medically supervised non-surgical weight reduction program. Documentation from clinical records must indicate that all of the following have been met:
- i. Supervision is provided by an MD, DO, NP, PA; or a registered dietician or certified health coach under the supervision of an MD, DO, NP or PA; and
  - ii. Participation has occurred during at least twelve months within the twenty-four months prior to the request for surgery; and
  - iii. Include at least six visits occurring at intervals of no longer than sixty (60) days apart; and
  - iv. Include a comprehensive medical and surgical history, review of current and past medications/supplements, assessment of health-related behaviors (not limited to substance use, sleep adequacy, nutrition, engagement in physical activity, stress management and coping skills), physical exam, and assessment of overall health as related to weight; and
  - v. Document consideration and medically-appropriate utilization of weight loss medications; and
  - vi. Include assessment and counseling concerning behavior modification, with specific focus on:
    - a) Identification of eating and dietary styles (stress-related eating, nighttime eating, grazing, bingeing, etc.); and
    - b) Recognition of personal lifestyle strengths and challenges as informed by patterns of prior weight losses or gains; and
    - c) Incorporation of physical movement/activity into daily lifestyle habits; and

- d) Identification of weight loss motivations and expectations, and management of stressors and coping skills.
- D. Completion of a psychological evaluation, performed by a practitioner specializing in surgical weight loss, confirming patient suitability for the procedure as evidenced by the lack of significant psychopathology which would impair ability to comply with preoperative and postoperative recommendations.
  - i. Behavioral: untreated mental health or personality disorders, health related risk-taking behaviors
  - ii. Cognitive and Emotional: cognitive functioning, knowledge of obesity and surgical interventions, emotional modulation
  - iii. Developmental History
  - iv. Current Life Situation: stressors and utilization of social support
  - v. Motivations and Expectations
- E. The bariatric surgery must be performed at a **center accredited** by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (**MBSAQIP**).

**U of U Health Plans does NOT cover the reversal of a covered bariatric surgery unless deemed medically necessary to treat other health related issues or medical complications.**

**U of U Health Plans considers revisions of bariatric surgery, using one of the procedures identified above, as proven and medically necessary when due to *a major complications* from the initial bariatric procedure.**

**Non-covered Procedures:**

**U of U Health Plans considers the following procedures NOT medically necessary for treating due to insufficient evidence of efficacy:**

- A. Revision of bariatric surgery for any other indication than those listed above;
- B. Bariatric surgery as the primary treatment for any condition other than obesity;
- C. Bariatric surgical interventions for the treatment of obesity including but not limited to:
  - i. Transoral endoscopic surgery;
  - ii. Mini-gastric bypass (MGB) or laparoscopic mini-gastric bypass (LMGBP);
  - iii. Gastric electrical stimulation with an implantable gastric stimulator (IGS);

- iv. VBLOC® vagal blocking therapy;
- v. Intra-gastric balloon;
- vi. Laparoscopic greater curvature plication, also known as total gastric vertical plication;
- vii. Stomach aspiration therapy (AspireAssist®);
- viii. Bariatric artery embolization (BAE);
- ix. Single-Anastomosis Duodenal Switch (also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery).

**U of U Health Plans considers gastrointestinal liners (EndoBarrier®) investigational and unproven for treating obesity due to lack of U.S. Food and Drug Administration (FDA) approval, and insufficient evidence of efficacy.**

## **2. Medicaid Plans**

**Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: <https://medicaid.utah.gov/utah-medicaid-official-publications/> or the [Utah Medicaid code Look-Up tool](#)**

**CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

## **Clinical Rationale**

These criteria were adapted from the NIH Consensus Conference on Surgical Treatment of Morbid Obesity (1998) which state that obesity surgery should be reserved only for patients who have first attempted medical therapy: “Weight loss surgery should be reserved for patients in whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity.”

**Pre-surgical Preparatory Regimen:** The patient’s ability to lose weight prior to surgery makes surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restriction imposed on patients following surgery.

Given the importance of patient compliance on diet and self-care in improving patient outcomes after surgery, the patient’s refusal to even attempt to comply with a nutrition and exercise regimen prior to surgery portends poor compliance with nutritional and self-care requirements after surgery. Therefore, the appropriateness of obesity surgery in non-compliant patients should be questioned. The patient must be committed to the appropriate work-up for the procedure and for continuing long-term post-operative medical management, and must understand and be adequately prepared for the potential complications of the procedure.

There is rarely a good reason why obese patients (even super obese patients) cannot delay surgery in order to undergo behavioral modification to improve their dietary and exercise habits in order to reduce

surgical risks and improve surgical outcomes. The patient may be able to lose significant weight prior to surgery in order to improve the outcome of surgery.

An individual's understanding of the procedure and ability to comply with life-long follow-up and life-style changes (e.g., as exemplified by compliance with previous medical care) are necessary for the success of the procedure.

Obesity makes many types of surgery more technically difficult to perform and hazardous. Weight loss prior to surgery makes the procedure easier to perform. Weight reduction reduces the size of the liver, making surgical access to the stomach easier. By contrast, the liver enlarges and becomes increasingly infiltrated with fat when weight is gained prior to surgery. A fatty liver is heavy, brittle, and more likely to suffer injury during surgery. Moreover, following surgery, patients have to follow a careful diet of nutritious, high-fiber foods in order to avoid nutritional deficiencies, dumping syndrome, and other complications. The total weight loss from surgery can be enhanced if it is combined with a low-calorie diet. For these reasons, it is therefore best for patients to develop good eating and exercise habits before they undergo surgery.

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

Ideally, the surgical center where surgery is to be performed should be accomplished in bariatric surgery with a demonstrated commitment to provide adequate facilities and equipment, as well as a properly trained and funded appropriate bariatric surgery support staff as individuals undergoing bariatric procedures have unique medical needs and potential for complications not typically experienced with non-obese patients. Minimal standards in these areas are set by the institution and maintained under the direction of a qualified surgeon who is in charge of an experienced and comprehensive bariatric surgery team. This team should include experienced surgeons and physicians, skilled nurses, specialty-educated nutritionists, experienced anesthesiologists, and, as needed, cardiologists, pulmonologists, rehabilitation therapists, and psychiatric staff. The American College of Surgeons (ACS) has stated that the surgeon performing the bariatric surgery be committed to the multidisciplinary management of the patient, both before and after surgery. The ACS recommended: "They develop skills in patient education and selection and are committed to long-term patient management and follow-up. There is active collaboration with multiple patient care disciplines including nutrition, anesthesiology, cardiology, pulmonary medicine, orthopedic surgery, diabetology, psychiatry, and rehabilitation medicine. Appropriate technical skills in the performance of bariatric surgical procedures are acquired."

A number of studies have demonstrated a relationship between surgical volumes and outcomes of obesity surgery. Most recently, an assessment by the Canadian Agency for Drugs and Technologies in Health (CADTH) (Klarenbach et al, 2010) stated that their volume-outcome review found that higher surgical volumes were associated with better clinical outcomes. CADTH was not, however, able to identify specific thresholds for surgical volume that were associated with better clinical outcomes.

The above findings are supported by a Multidisciplinary Care Task Group (MCTG) (Saltzman et al, 2005) in which they conducted a systematic review of the literature to provide evidence-based guidelines for patient selection and to recommend the medical and nutritional aspects of multi-disciplinary care required to minimize peri-operative and post-operative risks in patients with severe obesity who undergo weight loss surgery. The Task Group recommended multi-disciplinary screening of weight loss surgery patients to ensure appropriate selection; pre-operative assessment for cardiovascular,

pulmonary, gastrointestinal, endocrine, and other obesity-related diseases associated with increased risk for complications or mortality; pre-operative weight loss and cessation of smoking; peri-operative prophylaxis for deep vein thrombosis and pulmonary embolism (PE); pre-operative and post-operative education and counseling by a registered dietitian; and a well-defined post-surgical diet progression. The authors explained that obesity-related diseases are often undiagnosed before weight loss surgery, putting patients at increased risk for complications and/or early mortality. Multi-disciplinary assessment and care to minimize short- and long-term risks include: comprehensive medical screening; appropriate pre-, peri-, and post-operative preparation; collaboration with multiple patient care disciplines (e.g., anesthesiology, pulmonary medicine, cardiology, and psychology); and long-term nutrition education/counseling.

The MCTG (Saltzman et al, 2005) also recommends that operative candidates must be committed to the appropriate work-up for the procedure and to continued long-term post-operative medical management. They must also be able to understand, and be adequately prepared for, potential complications. The Multidisciplinary Care Task Group recommended the use of patient selection criteria from the NIH Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, which are consistent with those of other organizations. These include: BMI greater than or equal to 40 kg/m<sup>2</sup> or BMI greater than or equal to 35 kg/m<sup>2</sup> in the presence of significant co-morbidities, a well-informed and motivated patient with a strong desire for substantial weight loss, failure of non-surgical approaches to long-term weight loss, and acceptable operative risks.

The MCTG further recommends that all weight loss surgery patients be encouraged to lose weight before surgery, and to promote 5 to 10% pre-operative weight loss in patients with a BMI greater than 50 kg/m<sup>2</sup> or obesity-related comorbidities (Saltzman et al, 2005). The Task Group recommended to decide on a case-by-case basis whether to proceed with surgery in patients who are unable to lose weight. The Task Group stated that registered dietitians are best qualified to provide nutritional care, including pre-operative assessment and post-operative education, counseling, and follow-up. Weight loss surgery patients need to learn important new skills, including self-monitoring and meal planning. Many forms of weight loss surgery require patients to take lifelong nutritional supplements and to have lifelong medical monitoring. Dedicated dietitians can help patients during their pre-operative education on new dietary requirements and stipulations and their post-surgical adjustment to those requirements. A pre-operative assessment for micronutrient deficiencies is also recommended.

Finally, the MCTG recommends that smokers should be encouraged to stop, preferably at least 6 to 8 weeks before surgery (Saltzman et al, 2005). Bupropion and/or nicotine replacements are recommended to help minimize weight gain associated with smoking cessation. Patients should be encouraged to remain non-smokers after weight loss surgery to reduce the negative long-term health effects of smoking.

Anderin et al (2015) found that weight loss before bariatric surgery is associated with marked reduction of risk of postoperative complications. The investigators reported that the degree of risk reduction seems to be related to amount of weight lost and patients in the higher range of BMI are likely to benefit most from pre-operative weight reduction. The investigators noted that a pre-operative weight-reducing regimen is usually adhered to in most centers performing bariatric surgery for obesity, and that the potential to reduce post-operative complications by such a routine is yet to be defined. The investigators analyzed data from the Scandinavian Obesity Registry on 22,327 patients undergoing primary gastric bypass from January 1, 2008, to June 30, 2012. In all patients, median pre-operative total weight change was -4.8%. Corresponding values in the 25th, 50th, and 75th percentile were 0.5, -4.7, and -9.5%, respectively. Complications were noted in 9.1% of the patients. When comparing patients in the 75th with those in the 25th percentile of pre-operative weight loss, the risk of complications was

reduced by 13%. For specific complications, the corresponding risks were reduced for anastomotic leakage by 24%, for deep infection/abscess by 37%, and for minor wound complications by 54%. Similarly, however, less pronounced risk reductions were found when comparing patients in the 50th with those in the 25th percentile of pre-operative weight loss. For patients in the highest range of body mass index (BMI), the risk reduction associated with pre-operative weight loss was statistically significant for all analyzed complications, whereas corresponding risk reductions were only occasionally encountered and less pronounced in patients with lower BMI.

**Body Mass Index as a Criterion for Candidacy for Obesity Surgery:** Surgery for severe obesity is usually considered an intervention of last resort with patients having attempted other forms of medical management (such as behavior change, increased physical activity and drug therapy) but without achieving permanent weight loss (Colquitt et al, 2014; NIH, 1991). Surgery is indicated for persons with severe obesity (BMI of 40 kg/m<sup>2</sup> or more) or for persons with a BMI of 35 kg/m<sup>2</sup> or more and serious co-morbidities such as diabetes, coronary heart disease, or obstructive sleep apnea. Ideally patients selected for surgery should have no major perioperative risk factors, a stable personality, no eating disorders, and have lost some weight prior to surgery. The patient's ability to lose weight prior to surgery makes surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restriction imposed on patients following surgery.

**Rationale for Six-Month Nutrition and Exercise Program Prior to Surgery:** The NIH Consensus Conference on Surgical Treatment of Morbid Obesity (1998) states that obesity surgery should be reserved only for patients who have first attempted medical therapy: "Weight loss surgery should be reserved for patients in whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity."

The NIH Consensus Conference states that the initial goal of medical therapy is a 10% reduction in weight, and that a reasonable duration for medical therapy is 6 months. The Consensus Conference stated: "The initial goal of weight loss therapy is to reduce body weight by approximately 10% from baseline. If this goal is achieved, further weight loss can be attempted, if indicated through further evaluation. A reasonable time line for a 10% reduction in body weight is 6 months of therapy."

The NIH Consensus Conference Statement (1998) explained "The rationale for this initial goal is that even moderate weight loss, i.e., 10% of initial body weight, can significantly decrease the severity of obesity-associated risk factors." The NIH Consensus Conference (1998) states that the combination of a reduced calorie diet and increased physical activity can result in substantial improvements in blood pressure, glucose tolerance, lipid profile, and cardiorespiratory fitness.

The NIH Consensus Conference (1998) has stated that the patient should begin a nutrition and exercise program prior to surgery: "An integrated program must be in place to provide guidance on diet, physical activity, and behavioral and social support both prior to and after the surgery."

The American Dietetic Association (1997), in their position statement obesity surgery, recommends dietetic counseling and behavioral modification commencing prior to, not after, surgery: "Careful dietetics evaluation is needed to determine if the patient will be able to comply with the postoperative diet. A preoperative behavior change program with psychological evaluation should be required."

More recently, evidence-based guidelines from the Scottish Intercollegiate Guidelines Network (2010) have stated that bariatric surgery should be considered on an individual case basis following assessment of risk/benefit in obese patients with "evidence of completion of a structured weight management program involving diet, physical activity, psychological and drug interventions, not resulting in significant and sustained improvement in the comorbidities."



Candidates for obesity surgery should begin a weight reduction diet prior to surgery. The purpose of a pre-operative nutrition program prior to obesity surgery are to test patient motivation, to reduce perioperative morbidity, to accustom patients to the restriction of food intake after surgery, and to increase total weight loss (van de Weijgert et al, 1999; Jung and Cusciheri, 2000; Pekkarinen et al, 1997; Martin et al, 1995). Even super obese patients (BMI greater than 50) may benefit from initiating a nutrition and exercise program prior to surgery. Obesity itself increases the likelihood of pulmonary complications and wound infections (Choban et al, 1995; Abdel-Moneim, 1985; Holley et al, 1990; Myles et al, 2002; Nair et al, 2002; Bumgardner et al, 1995; Perez et al, 2001; Chang et al, 2000; Printen et al, 1975). The higher the patient's BMI, the higher the surgical risk, and the highest risks occur among patients with a BMI over 50 (Gonzalez et al, 2003; Oelschlager and Pellegrini, 2003). Even relatively modest weight loss prior to surgery can result in substantial improvements in pulmonary function, blood glucose control, blood pressure, and other physiological parameters (Anderson et al, 1992; Hakala et al, 1995; Kansanen et al, 1998; Pekkarinen et al, 1998). Factors such as blood glucose control, hypertension, etc., affect surgical risk. Garza (2003) explained that the patient should lose weight prior to surgery to reduce surgical risks. "The overall health of patients should be optimized prior to surgery to reduce the potential for complications. Patients ought to be encouraged to lose as much weight as possible before surgery" (Garza, 2003). Although the long-term effectiveness of weight reduction programs has been questioned, the Institute of Medicine (1995) has reported the substantial short-term effectiveness of certain organized physician-supervised weight reduction programs.

For maximal benefit, dieting should occur proximal to the time of surgery, and not in the remote past to reduce surgical risks and improve outcomes. Even if the patient has not been able to keep weight off long-term with prior dieting, the patient may be able to lose significant weight short term prior to surgery in order to improve the outcome of surgery.

Given the importance of patient compliance in diet and self-care in improving patient outcomes after surgery, the appropriateness of obesity surgery in noncompliant patients should be questioned. The American College of Surgeons has stated: "Not all persons who are obese or who consider themselves overweight are candidates for bariatric surgery. These procedures are not for cosmesis but for prevention of the pathologic consequences of morbid obesity. The patient must be committed to the appropriate work-up for the procedure and for continuing long-term postoperative medical management, and understand and be adequately prepared for the potential complications of the procedure. Screening of the patients to ensure appropriate selection is a critical responsibility of the surgeon and the supporting health care team."

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

**Post-Op Management:** In an updated guideline on the integrated health nutritional guidelines for surgical weight loss, the ASMBS (Parrott et al., 2017) states that optimizing postoperative patient outcomes and nutritional status begins preoperatively. Patients should be educated before and after weight loss surgery (WLS) on the expected nutrient deficiencies associated with alterations in physiology. Although surgery can exacerbate preexisting nutrient deficiencies, preoperative screening for vitamin deficiencies has not been the norm in the majority of WLS practices. Screening is important because it is common for patients who present for WLS to have at least 1 vitamin or mineral deficiency preoperatively.

In a systematic review, Jirapinyo et al. (2017) identified that despite initial successful weight loss, some patients may experience weight regain following RYGB, thus showing the importance of close follow-up, early recognition and intervention. There is a lack of established definition of weight regain in the current literature.

The ASMBS published recommendations for the pre-surgical psychosocial evaluation of bariatric surgery patients (Sogg et al., 2016). They recommend that bariatric behavioral health clinicians with specialized knowledge and experience be involved in the evaluation and care of patients both before and after surgery. Given the importance of long-term follow up after WLS, the preoperative psychosocial assessment provides a valuable opportunity for patients to establish a trusted connection to a behavioral health provider as an additional resource and integral participant in their postoperative care. The need to ensure that postoperative psychosocial care is available has been noted in established practice guidelines and evidence suggests that such care is associated with better outcomes after surgery.

Data continue to suggest that the prevalence of micronutrient deficiencies is increasing, while monitoring of patients at follow-up is decreasing. The ASMBS recommends that their guideline be considered a reasonable approach to patient nutritional care based on the most recent research, scientific evidence, resources, and information available. It is the responsibility of the registered dietitian nutritionist and WLS program to determine individual variations as they relate to patient nutritional care.

#### **Specific Procedure related Evidence**

**Laparoscopic Mini Gastric Bypass (LMGBP)** LMGBP involves the construction of a gastric tube by dividing the stomach vertically, down to the antrum. As in the RYGB, food does not enter the distal stomach. However, unlike gastric bypass surgery, digestive enzymes and bile are not diverted away from the stomach after LMGBP. This can lead to bile reflux gastritis which can cause pain that is difficult to treat.

**Implantable Gastric Stimulator (IGS)** IGS is a small, battery-powered device similar to a cardiac pacemaker, in a small pocket, created beneath the skin of the abdomen using laparoscopy. The IGS is programmed externally using a controller that sends radiofrequency signals to the device. Although the exact mechanism of action is not yet understood, gastric stimulation is thought to target ghrelin, an appetite-related peptide hormone (Gallas and Fetissov, 2011).

**Vagus Nerve Blocking Neurostimulation Therapy (VBLOC)** VBLOC uses an implanted subcutaneous neurostimulator to deliver electrical pulses to the vagus nerve, which may suppress appetite (ECRI, 2016).

VBLOC therapy (such as via the Maestro® System; Enteromedics, Inc.) is designed to target the multiple digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

The ASMBS, in their 2015 position statement on vagal blocking therapy for obesity (Papasavas et al., 2015), conclude that the quantity of the data available at this time (6 published studies; approximately 600 implanted devices) and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies with longer follow-up are required to establish the clinically significant efficacy and patient tolerance of this device.

**Intragastric Balloon (IGB)** IGBs are acid-resistant balloons that are inserted into the stomach via an endoscope and expanded with saline or air. These space-occupying devices promote weight loss by creating a feeling of fullness, which can lead to reduced consumption of food. The devices are intended

as an adjunct to diet, exercise, and behavioral counseling for the treatment of obesity (Hayes, 2019). Available clinical data and manufacturer recommendations indicate 6 months to be the current standard duration of therapy from insertion to removal (ASMBS, 2016).

An announcement from the FDA on August 10, 2017 reported 5 unanticipated deaths that occurred from 2016 to the present in patients who received a liquid-filled intra-gastric balloon system to treat obesity; 4 reports involve the Orbera Intra-gastric Balloon System (Apollo Endosurgery) and 1 report involves the ReShape Integrated Dual Balloon System (ReShape Medical). All 5 patients died within 1 month or less of balloon placement; 3 patients died 1 to 3 days after the balloon was placed. The FDA stated that "At this time, we do not know the root cause or incidence rate of patient death, nor have we been able to definitively attribute the deaths to the devices or the insertion procedures for these devices (e.g., gastric and esophageal perforation, or intestinal obstruction)". The FDA has also received 2 additional reports of deaths from 2016 to the present related to potential complications associated with balloon treatment: 1 gastric perforation with the Orbera Intra-gastric Balloon System and 1 esophageal perforation with the ReShape Integrated Dual Balloon System. As part of the ongoing, FDA-mandated post-approval studies for these devices, the FDA will obtain more information to help evaluate the continued safety and effectiveness of these approved medical devices (Brooks, 2017).

A 2017 systematic review and meta-Analysis (Popov, et. al.) analyzed the effect of intra-gastric balloons (IGBs) on metabolic outcomes associated with obesity. Medline, Embase, and Cochrane Database were searched through July 2016. Dual extraction and quality assessment of studies using Cochrane risk of bias tool were performed independently by 2 authors. Primary outcomes included the change from baseline in metabolic parameters. Secondary outcomes included resolution and/or improvement in metabolic co-morbidities and association with baseline parameters. A total of 10 randomized controlled trial (RCTs) and 30 observational studies including 5,668 subjects were analyzed. There was moderate-quality evidence for improvement in most metabolic parameters in subjects assigned to IGB therapy as compared to conventional non-surgical therapy in RCTs: mean difference (MD) in fasting glucose change: -12.7 mg/dL (95% confidence interval [CI]: -21.5 to -4); MD in triglycerides: -19 mg/dL (95% CI: -42 to 3.5); MD in waist circumference: -4.1 cm (95% CI: -6.9 to -1.4); MD in diastolic blood pressure: -2.9 mm Hg (95% CI: -4.1 to -1.8). The odds ratio for diabetes resolution after IGB therapy was 1.4 (95% CI: 1.3 to 1.6). The rate of serious adverse events was 1.3%. In conclusion, the authors found that IGBs were more effective than diet in improving obesity-related metabolic risk factors with a low rate of adverse events, however the strength of the evidence was limited given the small number of participants and lack of long-term follow-up.

***Laparoscopic Greater Curvature Plication (LGCP) [also known as Total Gastric Vertical Plication (TGVP)]*** LGCP is a restrictive procedure that involves folding and suturing the stomach onto itself to decrease the size of the stomach and requires no resection, bypass, or implantable device. This procedure is a modification of the gastric sleeve which requires surgical resection of stomach.

***Stomach Aspiration Therapy*** Stomach aspiration therapy, such as with the AspireAssist®, is a relatively new type of treatment for obesity which uses a surgically-placed tube to drain a portion of the stomach contents after every meal. The AspireAssist is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring. Patients must be monitored regularly for weight loss progress, stoma site health, and metabolic and electrolyte balance.

Nyström et al. (2018) assessed the long-term safety and efficacy of aspiration therapy in 5 European clinics using the AspireAssist® in a post-market study. A total of 201 participants (mean BMI  $43.6 \pm 7.2$  kg/m<sup>2</sup>) participated. Mean percent total weight loss at 1, 2, 3, and 4 years, respectively, was  $18.2\% \pm 9.4\%$  (n/N = 155/173),  $19.8\% \pm 11.3\%$  (n/N = 82/114),  $21.3\% \pm 9.6\%$  (n/N = 24/43), and  $19.2\% \pm 13.1\%$

(n/N = 12/30), where n is the number of measured participants and N is the number of participants in the absence of withdrawals or lost to follow-up. Clinically significant reductions in HbA1C, triglycerides, and blood pressure were observed. For participants with diabetes, HbA1C decreased by 1% ( $P < 0.0001$ ) from 7.8% at baseline to 6.8% at 1 year. The only serious complications were buried bumpers, experienced by seven participants and resolved by removal/replacement of the A-Tube, and a single case of peritonitis, resolved with a 2-day course of intravenous antibiotics. The authors concluded that aspiration therapy is a safe, effective, and shows durable weight loss therapy in people with classes II and III obesity. However, to validate these findings, further RCTs comparing aspiration therapy to other bariatric procedures are needed.

A 2017 randomized controlled trial (Thompson et al.) describes the Pivotal Aspiration Therapy with Adjusted Lifestyle (PATHWAY) study. This 52-week clinical trial had a total of 207 patients, with a BMI of 35.0 to 55.0 kg/m<sup>2</sup>, within 10 leading institutions across the United States. Patients were randomly assigned in a 2:1 ratio for treatment with AspireAssist plus Lifestyle Counseling ( $n = 137$ ; mean BMI was  $42.2 \pm 5.1$  kg/m<sup>2</sup>) or Lifestyle Counseling alone ( $n = 70$ ; mean BMI was  $40.9 \pm 3.9$  kg/m<sup>2</sup>). The co-primary end points were mean percent excess weight loss and the proportion of participants who achieved at least a 25% excess weight loss. At 52 weeks, participants in the AspireAssist group, on a modified intent-to-treat basis, had lost a mean ( $\pm$  s.d.) of  $31.5 \pm 26.7\%$  of their excess body weight ( $12.1 \pm 9.6\%$  total body weight), whereas those in the Lifestyle Counseling group had lost a mean of  $9.8 \pm 15.5\%$  of their excess body weight ( $3.5 \pm 6.0\%$  total body weight) ( $P < 0.001$ ). A total of 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight ( $P < 0.001$ ). The most frequently reported AEs were abdominal pain and discomfort in the perioperative period and peristomal granulation tissue and peristomal irritation in the post-operative period. The authors suggest that the weight loss efficacy and safety profile of this treatment approach may bridge the therapeutic gap between more conservative lifestyle modifications and bariatric surgical procedures. Also, the post-approval study may provide more solid evidence regarding efficacy of the AspireAssist.

**Bariatric Artery Embolization (BAE)** BAE is a minimally invasive procedure which is the percutaneous, catheter-directed, trans-arterial embolization of the left gastric artery (LGA). The procedure is performed by an interventional radiologist and targets the fundus that produces the majority of the hunger-controlling hormone ghrelin. Beads placed inside the vessels purportedly help decrease blood flow and limit the secretion of ghrelin to minimize feelings of hunger to initiate weight loss.

The BEAT Obesity Trial, a U.S. Food and Drug Administration (FDA)-approved prospective investigational device exemption study, is being conducted to evaluate the feasibility, safety, and short-term efficacy of bariatric artery embolization (BAE) (Weiss et al., 2017). In the initial phase of the study, 5 severely obese patients (four women, one man) who were 31-49 years of age and who had a mean body mass index of  $43.8 \text{ kg/m}^2 \pm 2.9$  with no clinically significant comorbidities were enrolled in this study and received BAE. There were no major adverse events (AEs), 2 minor AEs healed prior to the time of the 3-month endoscopy. Mean change in serum ghrelin was  $8.7\% \pm 34.7$  and  $-17.5\% \pm 29$  at 1 month and 3 months, respectively. Mean changes in serum glucagon-like peptide 1 and peptide YY were  $106.6\% \pm 208.5$  and  $17.8\% \pm 54.8$  at 1 month. There was a trend toward improvement in QOL parameters. Hunger/appetite scores decreased in the first 2 weeks after the procedure and then rose without reaching pre-procedure levels. The authors concluded that in this initial phase of the study, BAE is feasible and appears to be well tolerated in severely obese patients. In this small patient cohort, it appears to induce appetite suppression and may induce weight loss. Further expansion of this study will provide more insight into the long-term safety and efficacy of bariatric embolization.

A 2018 small case series (Bai et al.) evaluated the safety and 9-month effectiveness of transcatheter left gastric artery (LGA) embolization for treating patients with obesity (mean BMI  $38.1 \text{ kg/m}^2 \pm 3.8$  [range,  $32.9\text{-}42.4 \text{ kg/m}^2$ ]). Average body weight loss at 3, 6, and 9 months was  $8.28 \pm 7.3 \text{ kg}$  ( $p = 0.074$ ),  $10.42 \pm 8.21 \text{ kg}$  ( $p = 0.047$ ), and  $12.9 \pm 14.66 \text{ kg}$  ( $p = 0.121$ ), respectively. The level of serum ghrelin decreased by 40.83% ( $p = 0.009$ ), 31.94% ( $p = 0.107$ ), and 24.82% ( $p = 0.151$ ) at 3, 6, and 9 months after LGAE, respectively. The authors concluded that this study indicates that bariatric embolization of the LGA is safe and may be a promising strategy to suppress the production of ghrelin and results in weight loss and abdominal fat reduction. However, larger RTCs with longer-term outcomes to further evaluate BAE in the treatment of obesity are needed.

**Gastrointestinal Liners** The endoscopic placement of a duodenal-jejunal bypass sleeve (e.g., gastrointestinal liners), such as the EndoBarrier™ system, lines the first section of the small intestine which causes food to be absorbed further down. The device is suggested to promote weight loss in patients, who are too heavy to safely undergo bariatric surgery, by influencing gastrointestinal hormones and satiety. After the appropriate weight loss has been achieved, the sleeve is removed. However, the EndoBarrier system is not approved for use by the FDA.

An UpToDate review on "Bariatric surgical operations for the management of severe obesity: Descriptions" (Lim, 2022) lists "Endoscopic gastrointestinal bypass devices" as investigational. It states that "Endoscopic gastrointestinal bypass device (EGIBD) -- A barrier device is deployed to prevent luminal contents from being absorbed in the proximal small intestine. The EndoBarrier is 60-cm long and it extends from the proximal duodenum to the mid-jejunum and thus mimics a duodenojejunal bypass. It is a safe procedure but is hallmarked by an up to 20% rate of early removal due to patient intolerance. The ValenTx is a 120-cm barrier device that extends from the gastroesophageal junction to the jejunum. This too has a high rate of early removal, but excess weight loss at 3 months was reported to be 40%, and significant improvement was seen in 7 out of 7 diabetic patients within those 3 months. Data are still lacking about the longevity of these endobarriers and their outcomes once the barrier is removed".

A 2012 study (Escalona et al.) assessed the safety, weight loss, and cardio-metabolic changes in obese subjects implanted with the DJBL for 1 year. Morbidly obese subjects were enrolled in a single-arm, open-label, prospective trial and implanted with the DJBL. Primary endpoints included safety and weight change from baseline to week 52. Secondary endpoints included changes in waist circumference, blood pressure, lipids, glycemic control, and metabolic syndrome. The DJBL was implanted endoscopically in 39 of 42 subjects (mean age of  $36 \pm 10$  years; 80% female; mean weight of  $109 \pm 18 \text{ kg}$ ; mean BMI of  $43.7 \pm 5.9 \text{ kg/m}^2$ ); 24 completed 52 weeks of follow-up. Three subjects could not be implanted due to short duodenal bulb. Implantation time was  $24 \pm 2$  mins. There were no procedure-related complications and there were 15 early endoscopic removals. In the 52-week completer population, total body weight change from baseline was  $-22.1 \pm 2.1 \text{ kg}$  ( $p < 0.0001$ ) corresponding to  $19.9 \pm 1.8\%$  of total body weight and  $47.0 \pm 4.4\%$  excess of weight loss. There were also significant improvements in waist circumference, blood pressure, total and low-density lipoprotein cholesterol, triglycerides, and fasting glucose. In conclusion, the DJBL is safe when implanted for 1 year, and results in significant weight loss and improvements in cardio-metabolic risk factors. Also, these results suggested that this device may be suitable for the treatment of morbid obesity and its related comorbidities.

Another 2012 study (Mathus-Vliegen) described the EndoBarrier as a unique concept that starts to ameliorate the symptoms of diabetes mellitus type 2, soon after positioning. Weight-loss results are moderate, with 8% of patients showing a more than 10% excess weight loss in the 12 weeks pre-operatively. Sufficient implant training is required, but problems can still occur (e.g., due to a short duodenal bulb length). The stability of the anchors and the tolerability of the device still leave much to be desired. In 25% of patients the EndoBarrier is explanted early, because of migration, physical

symptoms, gastrointestinal hemorrhage, rotation and obstruction. Only 7 studies on the EndoBarrier are available and these are mostly small in size, short-term and with limited follow-up. In conclusion, a large, long-term, randomized, placebo-controlled, double-blind trial is needed as there are still questions about the safety and effectiveness of this product and others like it.

***Roux-en-y Bypass (RYGB)/Gastric Bypass*** RYGB procedure involves creating a stomach pouch out of a small portion of the stomach and attaching it directly to the small intestine, bypassing a large part of the stomach and duodenum.

A 2018 multi-center randomized clinical trial (Ikramuddin et al.) organized an observational follow-up of 120 participants who had a hemoglobin A1c (HbA1c) level of 8.0% or higher and a BMI between 30.0 and 39.9. Lifestyle-intensive medical management intervention was based on the Diabetes Prevention Program and Look AHEAD trials for 2 years, with and without (60 participants each) RYGB followed by observation to year 5. Ninety-eight (82%) patients completed 5 years of follow-up. At 5 years, 13 participants (23%) in the gastric bypass group and 2 (4%) in the lifestyle-intensive medical management group had achieved the composite triple end point (difference, 19%; 95% CI, 4%-34%;  $P = .01$ ). In the 5th year, 31 patients (55%) in the gastric bypass group vs 8 (14%) in the lifestyle-medical management group achieved an HbA1c level of less than 7.0% (difference, 41%; 95% CI, 19%-63%;  $P = .002$ ). Gastric bypass had more serious adverse events than did the lifestyle-medical management intervention, 66 events versus 38 events, most frequently gastrointestinal events and surgical complications such as strictures, small bowel obstructions, and leaks. In conclusion, for this patient population there remained a significantly better composite triple end point in the surgical group at 5 years. Nonetheless, further follow-up is needed to understand the durability of the improvement since the effect size diminished over 5 years.

In a 2017 matched observational cohort study, (Liakopoulos et al.) assessed 6132 patients with a baseline BMI of 42 kg/m<sup>2</sup> and type 2 diabetes who underwent RYGB. Over a 6 year follow-up period, beneficial changes in body mass index (BMI), hemoglobin A1C, blood lipids and blood pressure were seen compared with control persons. In conclusion, improvements in risk factors might contribute to the reduction of mortality risk after RYGB in obese individuals with type 2 diabetes, but the main effect seems to be mediated through a decrease in BMI, which could serve as a proxy for several mechanisms.

***Laparoscopic Adjustable Gastric Banding (LAGB)*** The laparoscopic adjustable gastric banding procedure involves placing an inflatable silicone band around the upper portion of the stomach. The silicone band contains a saline reservoir that can be filled or emptied under fluoroscopic guidance to change the caliber of the gastric opening.

***Sleeve Gastrectomy*** Sleeve gastrectomy can be performed as part of a two-staged approach to surgical weight loss or as a stand-alone procedure. It involves the removal of 60-75% of the stomach, leaving a narrow gastric “tube” or “sleeve.” This small remaining “tube” cannot hold as much food and produces less of the appetite-regulating hormone ghrelin, lessening a patient’s desire to eat. Sleeve gastrectomy is not a purely malabsorptive procedure, so there is no requirement for lifetime nutritional supplementation (California Technology Assessment Forum, 2015).

A technology assessment by the California Technology Assessment Forum (CTAF) determined that sleeve gastrectomy does not meet CTAF technology assessment criteria for improvement in health outcomes for the treatment of obesity (Walsh, 2010). The CTAF assessment reported that the results of multiple case series and retrospective studies have suggested that sleeve gastrectomy as a primary procedure is associated with a significant reduction in excess weight loss. The CTAF assessment reported that the complication rate from sleeve gastrectomy ranged from 0% to 4.1% and complications included leaks, bleeding, strictures and mortality. The CTAF assessment found few comparative studies of sleeve

gastrectomy. CTAF identified only 2 randomized controlled trials that have compared sleeve gastrectomy to another surgical procedure. These trials included a total of 112 participants who were followed from 1 to 3 years. Among the 80 subjects followed for 3 years, there were a similar number of complications in the sleeve gastrectomy and the RYGB groups, although the complications in the sleeve gastrectomy group were more severe. The CTAF assessment stated that, "[t]o date, long term outcomes from registry studies are relatively limited, but longer term follow-up will provide additional important information."

**Vertical Banded Gastroplasty (VBG)** VBG restricts the size of the stomach using a stapling technique; there is no rearrangement of the intestinal anatomy. VBG has been abandoned by many due to a high failure rate, a high incidence of long-term complications, and the newer adjustable gastric band (AGB) and sleeve gastrectomy (van Wezenbeek et al., 2015). David et al. (2015) estimated the failure rate to be approximately 50% based on results from long-term studies.

A 2015 retrospective study, (van Wezenbeek et al.,) assessed a total of 392 patients (80% female) with a mean body mass index of  $44 \pm 5$  kg/m<sup>2</sup> who underwent primary VBG. Mean follow-up after VBG was  $66 \pm 50$  months and showed a mean excess weight loss (EWL) of  $53 \pm 27\%$  and comorbidity reduction of 54%. One hundred fifty-two patients (39%) out of 227 patients (58%) with long-term complaints underwent revisional surgery. Main reasons for revision were weight regain and vomiting/food intolerance. Analysis before revision showed an outlet dilatation (17%), pouch dilatation (16%), and outlet stenosis (10%). After revision, an additional EWL of 23% and 33% further reduction in comorbidities was seen. The authors concluded that primary VBG has an acceptable EWL of 53% and 55% of comorbidities were improved however, this procedure is limited due to high complication rates, and often needed revisions.

Also in 2015, David and colleagues compared their experience in laparoscopic conversion of failed VBG to RYGB or Biliopancreatic Diversion (BPD) (n=39), noting that the reoperation rate for VBG in long-term studies is approximately 50%. Most (89%) of the conversions were completed laparoscopically. The mean operative time was 195 and 200 min for RYGB and BPD, respectively. There was no mortality. Complications occurred in 11 patients (28%), 5 in RYGB (19%) and 6 in BPD (42%). At the 3-year follow-up, the mean body mass index decreased from  $47 \pm 8$  kg/m<sup>2</sup> to  $26 \pm 4$  kg/m<sup>2</sup> for BPD, and from 43 kg/m<sup>2</sup> to 34 kg/m<sup>2</sup> (P = .05) for RYGB. Weight (kg) decreased from 110 to 84 and to 92, and from 123 to 81 and 68, at 1 and 3 years for RYGB and BPD, respectively. The weight loss for RYGB and BPD was equal at 1 year but tended to be better for BPD at 3 years postoperatively. Laparoscopic conversion of failed VBG to RYGB or BPD was feasible, but it was followed by prohibitively high complication rates in BPD patients. In conclusion, these procedures in this series are questionable due to the risk/benefit ratios.

***Biliopancreatic Diversion with Duodenal Switch (BPD/DS) (also known as the Scopinaro Procedure)***

BPD is primarily malabsorptive but has a temporary restrictive component. As in RYGB, three "limbs" of intestine are created: one through which food passes, one that permits emptying of fluids (e.g., bile) from digestive organs, and a common limb through which both food and digestive fluids pass. This procedure involves removal of the greater curvature of the stomach instead of the distal portion. The two limbs meet in a common channel measuring only 50 to 100 cm, thereby permitting relatively little absorption.

***Transoral Endoscopic Surgery*** Transoral endoscopic surgery is an option being explored for bariatric surgery. Natural orifice transluminal endoscopic surgery (NOTES) is performed via a natural orifice (e.g., mouth, vagina, etc.), and in some cases eliminates the need for abdominal incisions. This form of surgery is being investigated as an alternative to conventional surgery.

Transoral restorative obesity surgery (ROSE) is another endoscopic procedure. The endoscope with four channels is inserted into the esophagus and then the stomach. Specialized instruments are placed through the channels to create multiple folds around the existing stoma to reduce the diameter.

The Transpyloric Shuttle (TPS) device is a non-balloon, space occupying device with a 12-month treatment duration that is proposed as a new endoscopic bariatric therapy. The TPS device is comprised of a spherical silicone bulb connected to a smaller cylindrical silicone bulb by a flexible tether; it is delivered to and removed from the stomach using transluminal endoscopic procedures in the outpatient setting (Marinos, 2014; Hayes, 2019). The device was granted FDA premarket approval on April 16, 2019 and was approved for up to 12 months weight loss therapy in patients with a BMI of 35.0 kg/m<sup>2</sup> to 40.0 kg/m<sup>2</sup> or a BMI of 30.0 kg/m<sup>2</sup> to 34.9 kg/m<sup>2</sup> with 1 or more obesity-related comorbid condition. The device is intended to be used in conjunction with a diet and behavior modification program (ECRI, 2019).

***Single-Anastomosis Duodenal Switch (SADS)*** SADS is also called single-anastomosis loop duodenal switch, single-anastomosis duodeno ileal bypass with sleeve gastrectomy, or stomach intestinal pylorus-sparing surgery—is a modification of biliopancreatic diversion with duodenal switch (BPD-DS). SADS consists of a sleeve gastrectomy to remove most of the stomach and an intestinal bypass to shorten the length of the small intestine and to allow bile and pancreatic digestive juices to mix with the food. SADS is typically performed laparoscopically as an inpatient procedure (Hayes, 2018).

In 2017, Surve et al. examined biliopancreatic diversion with duodenal switch with single anastomosis duodenal switch (SIPS-stomach intestinal pylorus sparing surgery) at a single institution with two year follow-up. One-hundred eighty two patients received either a BPD-DS (n=62) or SIPS (n=120) procedure. BPD-DS and SIPS had statistically similar weight loss at 3 months but percent excess weight loss (%EWL) was more with BPD-DS than SIPS at 6, 9, 12, 18, and 24 months. Patient lost a mean body mass index (BMI) of 23.3 (follow-up: 69%) and 20.3 kg/m<sup>2</sup> (follow-up: 71%) at 2 years from the BPD-DS and SIPS surgery, respectively. However, patients who had undergone SIPS procedure had significantly shorter operative time, shorter length of stay, fewer perioperative and postoperative complications than BPD-DS (P<.001). There was no statistical difference between 2 groups for postoperative nutritional data such as vitamins D, B1, B12, serum calcium, fasting blood glucose, glycosylated hemoglobin (HbA1C), insulin, serum albumin, serum total protein, and lipid panel. The authors concluded that as the BPD-DS procedures were done prior to SIPS, learning curve and experience may account for the post-operative complications. However, further RCTs are needed to evaluate the SIPS procedure with larger patient populations and longer follow-up periods.

### **Pediatrics**

The ASMBS Pediatric Committee released best practice guidelines for treatment of obese adolescents in 2012. While the guidelines outlined acceptable criteria, the ASMBS stated that the available evidence-based literature was insufficient to identify recommendations for specific bariatric procedures. It was also noted that there is a lack of long-term follow-up on the risks of micronutrient and vitamin deficiencies.

## **Applicable Coding**

### **CPT Codes**

**0312T** Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming



<b>0313T</b>	; laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
<b>0314T</b>	; laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
<b>0315T</b>	; removal of pulse generator
<b>0316T</b>	; replacement of pulse generator
<b>0317T</b>	; neurostimulator pulse generator electronic analysis, includes reprogramming when performed
<b>43633</b>	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
<b>43644</b>	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
<b>43645</b>	; with gastric bypass and small intestine reconstruction to limit absorption
<b>43647</b>	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
<b>43648</b>	; revision or removal of gastric neurostimulator electrodes, antrum
<b>43659</b>	Unlisted laparoscopy procedure, stomach
<b>43770</b>	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
<b>43771</b>	; revision of adjustable gastric restrictive device component only
<b>43772</b>	; removal of adjustable gastric restrictive device component only
<b>43773</b>	; removal and replacement of adjustable gastric restrictive device component only
<b>43774</b>	; removal of adjustable gastric restrictive device and subcutaneous port components
<b>43775</b>	; longitudinal gastrectomy (i.e., sleeve gastrectomy)
<b>43842</b>	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
<b>43843</b>	; other than vertical-banded gastroplasty
<b>43845</b>	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)
<b>43846</b>	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
- 43850** Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy
- 43855** Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy
- 43860** Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
- 43865** ; with vagotomy
- 43881** Implantation or replacement of gastric neurostimulator electrodes, antrum, open
- 43882** Revision or removal of gastric neurostimulator electrodes, antrum, open
- 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
- 64590** Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
- 64595** Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

### **HCPSC Codes**

- C9784** Gastric restrictive procedure, endoscopic sleeve gastropasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
- C9785** Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

### **References:**

1. Abdel-Moneim RI. The hazards of surgery in the obese. *Int Surg*. 1985;70(2):101-103.
2. Ali, M. R., et al. (2016). "American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons." *Surg Obes Relat Dis* **12**(3): 462-467.
3. American Academy of Sleep Medicine (AASM). AASM Manual for the Scoring of Sleep and Associated Events: Rules, terminology and technical specifications. V2.5. April 2018.
4. American Bariatric Society in 2004. Critical assessment of the current guidelines for the management and treatment of morbidly obese patients. Burguera B, et. Al. *J Endocrinol Invest*. 2007 Nov;30(10):844-52.
5. American Dietetic Association. Position of the American Dietetic Association: Weight management. *J Am Diet Assoc*. 1997;97(1):71-74.
6. American Society for Bariatric Surgery (ASBS). Rationale for the surgical treatment of morbid obesity. November 23, 2005.
7. American Society for Metabolic and Bariatric Surgery (ASMBS). Approved procedures and devices. October 2016. Accessed December 24, 2019.

8. American Society for Metabolic and Bariatric Surgery (ASMBS). Position statement on intragastric balloon therapy endorsed by SAGES. Available at: <https://asmbs.org/resources/position-statement-on-intragastric-balloon-therapy-endorsed-by-sages>.
9. American Society for Metabolic and Bariatric Surgery: [www.asmbs.org](http://www.asmbs.org)
10. Anderin C, Gustafsson UO, Heijbel N, Thorell A. Weight loss before bariatric surgery and postoperative complications: Data from the Scandinavian Obesity Registry (SOREg). *Ann Surg*. 2015;261(5):909-913.
11. Anderson JW, Brinkman VL, Hamilton CC. Weight loss and 2-y follow-up for 80 morbidly obese patients treated with intensive very-low-calorie diet and an education program. *Am J Clin Nutr*. 1992;56(1 Suppl):244S-246S.
12. Arterburn DE, Olsen MK, Smith VA, et al. Association between bariatric surgery and long-term survival. *JAMA*. 2015; 313(1):62-70.
13. Arterburn, D. E., Telem, D. A., Kushner, R. F., & Courcoulas, A. P. (2020). Benefits and risks of bariatric surgery in adults: a review. *Jama*, 324(9), 879-887.
14. Bays HE, Jones PH, Jacobson TA, et al. Lipids and bariatric procedures part 1 of 2: scientific statement from the National Lipid Association, American Society for Metabolic and Bariatric Surgery, and Obesity Medicine Association: full report. *J Clin Lipidol*. 2016a Jan-Feb;10(1):33-57.
15. Bays HE, Kothari SN, Azagury DE, et al. ASMBS guidelines/statements. Lipids and bariatric procedures part 2 of 2: scientific statement from the American Society for Metabolic and Bariatric Surgery (ASMBS), the National Lipid Association (NLA), and Obesity Medicine Association (OMA). *Surg Obes Relat Dis*. 2016b Mar-Apr;12(3):468-495.
16. Bindal V, Bhatia P, Dudeja U, et al. Review of contemporary role of robotics in bariatric surgery. *J Minim Access Surg*. 2015 Jan-Mar; 11(1):16-21.
17. Brethauer SA, Kothari S, Sudan R, et al. Systematic review on reoperative bariatric surgery: American Society for Metabolic and Bariatric Surgery Revision Task Force. *Surg Obes Relat Dis*. 2014. Sep-Oct;10(5):952-72.
18. Brooks M. Five deaths tied to intragastric balloons, FDA says. *Medscape Pharmacists*. August 10, 2017. Available at: [http://www.medscape.com/viewarticle/884089?nlid=117258\\_3901&src=wnl\\_newsalert\\_170810\\_MSCPEDIT&uac=15916AK&impID=1408009&faf=1](http://www.medscape.com/viewarticle/884089?nlid=117258_3901&src=wnl_newsalert_170810_MSCPEDIT&uac=15916AK&impID=1408009&faf=1) . Accessed December 23, 2019.
19. Bumgardner GL, Henry ML, Elkhammas E, et al. Obesity as a risk factor after combined pancreas/kidney transplantation. *Transplantation*. 1995;60(12):1426-1430.
20. California Technology Assessment Forum. Institute for Clinical and Economic Review 2015. Controversies in obesity management. A technology assessment. June 2015.
21. Centers for Disease Control and Prevention (CDC). National Center for Health Statistics. Prevalence of obesity among adults and youth: United States, 2015–2016. October 2017. Accessed: June 8, 2023. Available at: <https://www.cdc.gov/nchs/products/databriefs/db288.htm>.
22. Chang DW, Wang B, Robb GL, et al. Effect of obesity on flap and donor-site complications in free transverse rectus abdominis myocutaneous flap breast reconstruction. *Plast Reconstr Surg*. 2000;105(5):1640-1648.
23. Choban PS, Heckler R, Burge JC, Flancbaum L. Increased incidence of nosocomial infections in obese surgical patients. *Am Surg*. 1995;61(11):1001-1005.
24. Collazo-Clavell ML. Safe and effective management of the obese patient. *Mayo Clin Proc*. 1999;74(12):1255-1260.
25. Colquitt JL, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. *Cochrane Database Syst Rev*. 2014;8:CD003641.
26. David MB, Abu-Gazala S, Sadot E, et al. Laparoscopic conversion of failed vertical banded gastroplasty to Roux-en-Y gastric bypass or biliopancreatic diversion. *Surg Obes Relat Dis*. 2015 Sep-Oct;11(5):1085-91.
27. Economopoulos KP, Theocharidis V, McKenzie TJ, et al. Robotic vs. laparoscopic Roux-En-Y gastric bypass: a systematic review and meta-analysis. *Obes Surg*. 2015 Nov;25(11):2180-9.
28. ECRI Institute. Custom Product Brief. TransPyloric Shuttle implant (BAROnova, Inc.) for Treating Obesity. May 2019.
29. ECRI Institute. Rechargeable vagal blocking system (Maestro) for treating obesity. July 2016. Updated May 2017.
30. Ellsmere JC. Late complications of bariatric surgical operations. *UpToDate* [online serial]. Waltham, MA: UpToDate; Reviewed July 2019.
31. Escalona A, Pimentel F, Sharp A, et al. Weight loss and metabolic improvement in morbidly obese subjects implanted for 1 year with an endoscopic duodenal-jejunal bypass liner. *Ann Surg*. 2012;255(6):1080-1085.
32. Fisher DP, Johnson E, Haneuse S, et al. Association between bariatric surgery and macrovascular disease outcomes in patients with type 2 diabetes and severe obesity. *JAMA*. 2018;320(15):1570-1582.
33. Gallas S, Fetissova S. Ghrelin, appetite and gastric electrical stimulation. *Peptides*. Volume 32, Issue 11, November 2011, Pages 2283–2289.
34. Garza SF. Bariatric weight loss surgery. Patient education, preparation, and follow-up. *Crit Care Nurs Q*. 2003;26(2):101-104.
35. Gonzalez R, Bowers S, Venkatesh K, et al. Preoperative factors predictive of complicated post-operative management after gastric bypass for morbid obesity. Program and abstracts of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Annual Scientific Session and Postgraduate Course; March 12-15, 2003; Los Angeles, California. Cited in: Oelschlager BK, Pellegrini CA. Advances in the surgical treatment of obesity. Conference Report. *Medscape Gastroenterol*. 2003;5(1).

36. Hakala K, Mustajoki P, Aittomaki J, Sovijarvi AR. Effect of weight loss and body position on pulmonary function and gas exchange abnormalities in morbid obesity. *Int J Obes Relat Metab Disord*. 1995;19(5):343-346.
37. Hayes, Inc. Hayes Emerging Technology Report. Transpyloric Shuttle Device. Lansdale, PA: Hayes Inc.; April 2019.
38. Hayes, Inc. Hayes Medical Technology Directory. Intra-gastric balloons for treatment of obesity. Lansdale, PA: Hayes, Inc.; March 2018. Updated April 2019.
39. Hayes, Inc. Health Technology Brief. Maestro Rechargeable System (EnteroMedics Inc.) for vagal blocking for obesity control. Lansdale PA: Hayes, Inc.; February 2016. Archived February 2019.
40. Hayes, Inc. Medical Technology Directory. Comparative Effectiveness Review of Bariatric Surgeries for Treatment of Obesity in Adolescents. Lansdale, PA: Hayes Inc.; January 2022.
41. Hayes, Inc. Search and Summary. Roux-en-Y Gastric Bypass (RYGB) for treatment of obesity in adolescent patients. Landsale PA: Hayes, Inc., November 2017. Archived December 2018.
42. Hayes, Inc. Search and Summary. Sleeve gastrectomy for treatment of obesity in adolescent patients. Landsale PA: Hayes, Inc., December 2017. Archived January 2019.
43. Hayes, Inc., Health Technology Assessment. Revisional Surgery for Treatment of Complications after Bariatric Surgery. Lansdale, PA: Hayes, Inc.; July 2014. Updated July 2018. Archived: August 23, 2019.
44. Holley JL, Shapiro R, Lopatin WB, et al. Obesity as a risk factor following cadaveric renal transplantation. *Transplantation*. 1990;49(2):387-389.
45. Jambhekar A, Maselli A, Robinson S, et al. Demographics and socioeconomic status as predictors of weight loss after laparoscopic sleeve gastrectomy: A prospective cohort study. *Int J Surg*. 2018 Jun;54(Pt A):163-169.
46. Jirapinyo P, Abu Dayyeh BK, Thompson CC. Weight regain after Roux-en-Y gastric bypass has a large negative impact on the bariatric quality of life index. *BMJ Open Gastro* 2017;4:e000153.
47. Jirapinyo P, Thompson CC. A Comparison of Distal POSE Techniques for the Treatment of Obesity. *Gastrointest Endosc*. 2022 May 11:S0016-5107(22)01665-0. doi: 10.1016/j.gie.2022.04.1346. Epub ahead of print. PMID: 35568242.
48. Jung RT, Cuschieri A. Obese patients. In: *Essential Surgical Practice*. Vol. 1. A Cuschieri, RJC Steele, AR Moosa, eds. 4<sup>th</sup> ed. London, UK: Butterworth Heinemann; 2000.
49. Kansanen M, Vanninen E, Tuunainen A, et al. The effect of a very low-calorie diet-induced weight loss on the severity of obstructive sleep apnoea and autonomic nervous function in obese patients with obstructive sleep apnoea syndrome. *Clin Physiol*. 1998;18(4):377-385.
50. Liakopoulos V, Franzén S, Svensson AM, et al. Changes in risk factors and their contribution to reduction of mortality risk following gastric bypass surgery among obese individuals with type 2 diabetes: a nationwide, matched, observational cohort study. *BMJ Open Diabetes Res Care*. 2017 Jun 14;5(1):e000386.
51. Lim RB. (2022). UpToDate “Bariatric operations for management of obesity: Indications and preoperative preparation”. Literature review current through: April 2022. Last updated: April 27, 2022. Accessed May 18, 2022. Available at: <https://www.uptodate.com/contents/bariatric-surgery-for-management-of-obesity-indications-and-preoperative-preparation>
52. Magallares A. Mental and physical health-related quality of life in obese patients before and after bariatric surgery: a meta-analysis. *Psychology, Health & Medicine*. 2015; 20(2):165-176.
53. Martin LF, Tan TL, Holmes PA, et al. Can morbidly obese patients safely lose weight preoperatively? *Am J Surg*. 1995;169(2):245-253.
54. Mathus-Vliegen EM. Endobarrier: A unique but still premature concept. *Ned Tijdschr Geneesk*. 2012;156(13):A4590.
55. Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). Available at: <https://www.facs.org/quality-programs/mbsaqip..>
56. Myles TD, Gooch J, Santolaya J. Obesity as an independent risk factor for infectious morbidity in patients who undergo cesarean delivery. *Obstet Gynecol*. 2002;100(5 Pt 1):959-964.
57. Nair S, Verma S, Thuluvath PJ. Obesity and its effect on survival in patients undergoing orthotopic liver transplantation in the United States. *Hepatology*. 2002;35(1):105-109.
58. National Academy of Science, Institute of Medicine, Committee to Develop Criteria for Evaluating the Outcomes of Approaches to Prevent and Treat Obesity. *Weighing the Options: Criteria for Evaluating Weight-Management Programs*. PR Thomas, ed. Washington, DC: National Academy Press; 1995.
59. National Heart, Lung, and Blood Institute (NHLBI). “Assessing Your Weight and Health Risk-Body Mass Index (BMI)”. Accessed: June 8, 2023. Available at: [https://www.nhlbi.nih.gov/health/educational/lose\\_wt/risk.htm](https://www.nhlbi.nih.gov/health/educational/lose_wt/risk.htm)
60. National Institutes of Health (NIH) Consensus Development Panel in 1991 NIH conference. Gastrointestinal surgery for severe obesity. Consensus Development Conference Panel. *Ann Intern Med*. 1991;115(12):956.
61. National Institutes of Health (NIH), National Heart, Lung and Blood Institute, Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. *Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. Executive Summary*. Bethesda, MD: National Institutes of Health; September 1998.
62. Nystrom M, Machytka E, Noren E, et al. Aspiration therapy as a tool to treat obesity: 1- to 4-year results in a 201-patient multi-center post-market European registry study. *Obes Surg*. 2018;28(7):1860-1868.

63. Oelschlager BK, Pellegrini CA. Advances in the surgical treatment of obesity. Conference Report. Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Annual Scientific Session and Postgraduate Course; March 12-15, 2003; Los Angeles, California. *Medscape Gastroenterol.* 2003;5(1). Available at: [http://www.medscape.com/viewarticle/451082\\_1](http://www.medscape.com/viewarticle/451082_1).
64. Papasavas P, El Chaar M, Kothari SN. American Society for Metabolic and Bariatric Surgery Clinical Issues Committee vagal blocking therapy for obesity. December 2015.
65. Parrott J, Frank L, Rabena R, et al. American Society for Metabolic and Bariatric Surgery integrated health nutritional guidelines for the surgical weight loss patient 2016 update: micronutrients. *Surg Obes Relat Dis.* 2017 May;13(5):727-741.
66. Pekkarinen T, Mustajoki P. Use of very low-calorie diet in preoperative weight loss: Efficacy and safety. *Obes Res.* 1997;5(6):595-602.
67. Pekkarinen T, Takala I, Mustajoki P. Weight loss with very-low-calorie diet and cardiovascular risk factors in moderately obese women: One-year follow-up study including ambulatory blood pressure monitoring. *Int J Obes Relat Metab Disord.* 1998;22(7):661-666.
68. Perez AR, Moncure AC, Rattner DW. Obesity adversely affects the outcome of antireflux operations. *Surg Endosc.* 2001;15(9):986-989.
69. Popov VB, Ou A, Schulman AR, Thompson CC. The impact of intragastric balloons on obesity-related co-morbidities: A systematic review and meta-analysis. *Am J Gastroenterol.* 2017;112(3):429-439.
70. Printen KJ, Paulk SC, Mason EE. Acute postoperative wound complications after gastric surgery for morbid obesity. *Am Surg.* 1975;41(8):483-485.
71. Raj PP, Bhattacharya S, Misra S, et al. Gastroesophageal reflux-related physiologic changes after sleeve gastrectomy and Roux-en-Y gastric bypass: A prospective comparative study. *Surg Obes Relat Dis.* 2019 May 20 [Epub ahead of print].
72. Saltzman E, Anderson W, Apovian CM, et al. Criteria for patient selection and multidisciplinary evaluation and treatment of the weight loss surgery patient. *Obes Res.* 2005;13(2):234-243.
73. Scottish Intercollegiate Guidelines Network (SIGN). Management of obesity. A National Clinical Guideline. No. 115. Edinburgh, Scotland: NHS Quality Improvement Scotland (NHS QIS); February 2010.
74. Sewefy AM, Atyia AM, Mohammed MM, Kayed TH, Hamza HM. Single anastomosis sleeve jejunal (SAS-J) bypass as a treatment for morbid obesity, technique and review of 1986 cases and 6 Years follow-up. Retrospective cohort. *Int J Surg.* 2022 May 11:106662. doi: 10.1016/j.ijssu.2022.106662. Epub ahead of print. PMID: 35568310.
75. Sogg S, Lauretti J, L West-Smith. Recommendations for the presurgical psychosocial evaluation of bariatric surgery patients *Surg Obes Relat Dis* 2016;12:731–749.
76. Surve A, Zaveri H, Cottam D, et al. A retrospective comparison of biliopancreatic diversion with duodenal switch with single anastomosis duodenal switch (SIPS-stomach intestinal pylorus sparing surgery) at a single institution with two year follow-up. *Surg Obes Relat Dis.* 2017 Mar;13(3):415-422.
77. Thompson CC, Abu Dayyeh BK, Kushner R, et al. Percutaneous Gastrostomy Device for the Treatment of Class II and Class III Obesity: Results of a Randomized Controlled Trial. *Am J Gastroenterol.* 2017;112(3):447-457.
78. United States Preventive Services Task Force (USPSTF) (2018). Recommendation Statement: “Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions”. Accessed June 8, 2023. Available at: <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/obesity-in-adults-interventions1>
79. van de Weijert EJHM, Ruseler CH, Elte JWF. Long-term follow up after gastric surgery for morbid obesity: Pre-operative weight loss improves the long-term control of morbid obesity after vertical banded gastroplasty. *Obes Surg.* 1999;9:426-432.
80. van Wezenbeek MR, Smulders JF, de Zoete JP, et al. Long-term results of primary vertical banded gastroplasty. *Obes Surg.* 2015 Aug;25(8):1425-30.
81. Walsh J. Sleeve gastrectomy as a stand-alone procedure for obesity. A Technology Assessment. San Francisco, CA: CTAF; October 13, 2010.

#### **Disclaimer:**

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member’s individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from U of U Health Plans.

"University of Utah Health Plans" and its accompanying logo, and its accompanying marks are protected and registered trademarks of the provider of this Service and or University of Utah Health. Also, the content of this Service is proprietary and is protected by copyright. You may access the copyrighted content of this Service only for purposes set forth in these Conditions of Use.

© CPT Only – American Medical Association