Anthem

Clinical UM Guideline

Subject: Bariatric Surgery and Other Treatments for Clinically Severe Obesity
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Description

This document addresses surgical and other treatments for clinically severe obesity. Clinically severe obesity is a result of persistent and uncontrollable weight gain that constitutes a present or potential threat to life. There are a variety of surgical procedures and other treatment modalities intended for the treatment of clinically severe obesity.

Note: For additional information, please see:

- CG-MED-59 Upper Gastrointestinal Endoscopy in Adults
- CG-SURG-92 Paraesophageal Hernia Repair

Clinical Indications

Medically Necessary:

Gastric bypass and gastric restrictive procedures are considered **medically necessary** when **all** of the following criteria are met:

A. Individual is age 18 years or older; **and**
B. The recommended surgery is one of the following procedures:
    1. Biliopancreatic bypass with duodenal switch; **or**
    2. Laparoscopic adjustable gastric banding; **or**
    3. Roux-en-Y procedure up to 150 cm; **or**
    4. Sleeve gastrectomy; **or**
    5. Vertical banded gastroplasty;
    and
C. A body mass index (BMI) of **one** of the following:
    1. 40 or greater, **or**
    2. 35 or greater with an obesity-related co-morbid condition including, but not limited to:
        a. Diabetes mellitus; **or**
        b. Cardiovascular disease; **or**
        c. Hypertension; **or**
        d. Life threatening cardio-pulmonary problems (for example, severe obstructive sleep apnea, Pickwickian syndrome, obesity related cardiomyopathy);
        and
D. Documentation of **all** of the following:
    1. Past participation in a weight loss program; **and**
    2. Inadequate weight loss despite a committed attempt at conservative medical therapy (for example, comprehensive lifestyle interventions, including a combination of diet, exercise, and behavioral modifications); **and**
    3. Pre-operative medical *and* mental health evaluations and clearances; **and**
    4. Pre-operative education which addresses the risks, benefits, realistic expectations and the need for long-term follow-up and adherence to behavioral modifications; **and**
    5. A treatment plan which addresses the pre- and post-operative needs of an individual undergoing bariatric surgery.

Reoperation

Feedback

Surgical repair/correction or reversal following gastric bypass and gastric restrictive procedures is considered **medically necessary** when there is documentation of a surgical complication related to the original surgery, such as a fistula, obstruction, erosion, disruption/leakage of a suture/staple line, band herniation, stricture, documented gastroesophageal reflux disease (GERD) or pouch enlargement/dilation.

Surgical revision/conversion to another surgical procedure* is considered **medically necessary** when *either* criteria A or B are met:

A. For inadequate weight loss or weight gain 1 year or longer after a prior procedure, **all** the following criteria are met:
    1. BMI of 40 or greater; **or**
    2. BMI of 35 **or** greater with an obesity-related co-morbid condition, including but not limited to:
        a. Diabetes mellitus; **or**
        b. Cardiovascular disease; **or**
        c. Hypertension; **or**
        d. Life threatening cardio-pulmonary problems, (for example, severe obstructive sleep apnea, Pickwickian syndrome, obesity related cardiomyopathy);
        and
    3. Pre-operative medical *and* mental health evaluations and clearances; **and**
    4. Pre-operative education which addresses the risks, benefits, realistic expectations and the need for long-term follow-up and adherence to behavioral modifications; **and**
    5. A treatment plan which addresses the pre- and post-operative needs of an individual undergoing bariatric surgery.
B. There is documentation of a complication related to the initial procedure (including but not limited to, obstruction, stricture or documented GERD).

* Revision/ conversion indications apply to the procedures listed under criteria B for the initial procedure.

Not Medically Necessary:

Initial and reoperative bariatric procedures are considered **not medically necessary** when the criteria listed above are not met.

Endoluminal reoperative bariatric procedures including, but not limited to, transoral outlet reduction (TORe) or restorative obesity surgery endoluminal (ROSE) are considered **not medically necessary** for all indications.

Bariatric surgical procedures including, but not limited to, laparoscopic adjustable gastric banding are considered **not medically necessary** for individuals with a BMI below 35 kg/m².

All other gastric bypass/restrictive procedures and other treatment modalities are considered **not medically necessary** including, but not limited to the following:

A. One anastomosis gastric bypass, also known as mini gastric bypass;
B. Malabsorptive procedures including, but not limited to, jejunoileal bypass, biliopancreatic bypass without duodenal switch, single anastomosis duodenal switch or very long limb (greater than 150 cm) gastric bypass (other than the biliopancreatic bypass with duodenal switch);
C. Minimally invasive endoluminal gastric restrictive surgical techniques, such as use of the EndoGastric StomaphyX™ endoluminal fastener and delivery system or endoscopic sleeve gastroplasty;
D. Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding;
E. Balloon systems, (such as the Orbera Intragastic Balloon System or the TransPyloric Shuttle);
F. Vagus (or vagal) nerve blocking devices;
G. Endoscopically placed percutaneous aspiration tube (such as AspireAssist®).

Further Consideration:

A bariatric surgeon with experience in the pediatric population may request further consideration of a case of an individual under 18 years old with severe morbid obesity and unique circumstances by contacting a Medical Director. *For further information, see Rationale section* *Bariatric Surgery in Adolescents and Children.*

Coding

The following codes for treatments and procedures applicable to this guideline are included below 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.

Gastric bypass and gastric restrictive procedures/reoperations:
When services may be Medically Necessary when criteria are met:

CPT

43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; 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	Gastric restrictive procedure, without gastric bypass, for morbid obesity; 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 o less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastr restrictive device (separate procedure)
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

ICD-10 Procedure

0DP60CZ	Removal of extraluminal device from stomach, open approach
0DP64CZ	Removal of extraluminal device from stomach, percutaneous endoscopic approach
0DV60CZ	Restriction of stomach with extraluminal device, open approach
0DV64CZ	Restriction of stomach with extraluminal device, percutaneous endoscopic approach
0DV60ZZ	Restriction of stomach, open approach
0DV64ZZ	Restriction of stomach, percutaneous endoscopic approach
0DW60CZ	Revision of extraluminal device in stomach, open approach
0DW64CZ	Revision of extraluminal device in stomach, percutaneous endoscopic approach

ICD-10 Diagnosis

	All diagnoses

When services may also be Medically Necessary when criteria are met for other bypass and excision procedures:

ICD-10 Procedure

0D160ZA	Bypass stomach to jejunum, open approach
0D160ZB	Bypass stomach to ileum, open approach
0D164ZA	Bypass stomach to jejunum, percutaneous endoscopic approach
0D164ZB	Bypass stomach to ileum, percutaneous endoscopic approach
0D164Z9	Bypass stomach to duodenum, percutaneous endoscopic approach
0D190ZB	Bypass duodenum to ileum, open approach
0DB60Z3	Excision of stomach, open approach, vertical
0DB64Z3	Excision of stomach, percutaneous endoscopic approach, vertical
0DB68Z3	Excision of stomach, via natural or artificial opening endoscopic, vertical
0DB60ZZ	Excision of stomach, open approach
0DB64ZZ	Excision of stomach, percutaneous endoscopic approach

ICD-10 Diagnosis

E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation (Pickwickian syndrome)
E66.3	Overweight
E66.811	Obesity, class 1
E66.812	Obesity, class 2
E66.813	Obesity, class 3
E66.89	Other obesity not elsewhere classified
E66.9	Obesity, unspecified
E88.82	Obesity due to disruption of MC4R pathway
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z68.35-Z68.39	Body mass index [BMI] 35.0-39.9, adult
Z68.41-Z68.45	Body mass index [BMI] 40 or greater, adult
Z68.51-Z68.56	Body mass index [BMI] pediatric [special consideration]
Z98.84	Bariatric surgery status

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, when the following BMI diagnosis codes are indicated, or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis

Z68.20-Z68.29	Body mass index [BMI] 20.0-29.9, adult
Z68.30-Z68.34	Body mass index [BMI] 30.0-34.9, adult

Other procedures:
When services are Not Medically Necessary:

For the following procedure codes or any other procedure code used to describe a procedure identified as not medically necessary

CPT

43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
43632	Gastrectomy, partial distal; with gastrojejunostomy (Billroth II) [when specified as bariatric surgery]
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction [when specified as bariatric surgery]
43659	Unlisted laparoscopy procedure, stomach [when specified as gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding, sleeve gastroplasty, or mini-gastric bypass procedure]
43999	Unlisted procedure, stomach [when specified as endoluminal gastric restrictive surgery, or aspiration therapy]
44238	Unlisted laparoscopy procedure, intestine (except rectum) [when specified as a bariatric procedure identified as not medically necessary such as SADI-S]

64999	Unlisted procedure, nervous system [when specified as implantation, revision, replacement, or removal of vagus nerve blocking neurostimulator electrode array or pulse generator at the esophagogastric junction]
0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon

HCPCS

C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, 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

ICD-10 Procedure

0D160ZA	Bypass stomach to jejunum, open approach [when specified as Billroth II)
0DV60DZ	Restriction of stomach with intraluminal device, open approach
0DV63DZ	Restriction of stomach with intraluminal device, percutaneous approach
0DV64DZ	Restriction of stomach with intraluminal device, percutaneous endoscopic approach
0DV67DZ	Restriction of stomach with intraluminal device, via natural or artificial opening
0DV68DZ	Restriction of stomach with intraluminal device, via natural or artificial opening endoscopic
0DP60DZ	Removal of intraluminal device from stomach, open approach
0DP63DZ	Removal of intraluminal device from stomach, percutaneous approach
0DP64DZ	Removal of intraluminal device from stomach, percutaneous endoscopic approach
0DP67DZ	Removal of intraluminal device from stomach, via natural or artificial opening
0DP68DZ	Removal of intraluminal device from stomach, via natural or artificial opening endoscopic

ICD-10 Diagnosis

E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation (Pickwickian syndrome)
E66.3	Overweight
E66.811-E66.89	Other obesity
E66.9	Obesity, unspecified
E88.82	Obesity due to disruption of MC4R pathway
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z68.20-Z68.29	Body mass index [BMI] 20.0-29.9, adult
Z68.30-Z68.34	Body mass index [BMI] 30.0-34.9, adult
Z68.35-Z68.39	Body mass index [BMI] 35.0-39.9, adult
Z68.41-Z68.45	Body mass index [BMI] 40 or greater, adult
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Discussion/General Information

Background

According to the National Institutes of Health (NIH), an increase of 20 percent or more above an individual's ideal body weight is the point at which excess weight becomes a health risk. By 2030, it is predicted that nearly one in two adults will be obese and nearly one in four adults will be categorized as having severe obesity (Ward, 2019). Clinically severe obesity is associated with a higher risk of one or more obesity-related health conditions that result either in significant physical disability or even death. While medical complications of obesity may occur in moderately obese people, the frequency increases dramatically as weight increases.

The first line treatment of clinically severe obesity is dietary and lifestyle changes, including regular exercise. Weight loss is accomplished when there is a caloric deficit, that is, calories out must be greater than calories in. This can be accomplished by decreasing the calories ingested with some form of dietary restriction and by increasing the calories

expended through increased physical activity. All available therapies (dietary, behavioral, pharmacologic, and surgical) help with weight loss by changing the calories ingested, absorbed, or expended.

Weight loss can result in a reduction of comorbidities, a decrease in mortality and an increase in the quality of life. Wolfe and associates (2016) note:

> The fundamental basis for bariatric surgery for the purpose of accomplishing weight loss is the determination that severe obesity is a disease associated with multiple adverse effects on health which can be reversed or improved by successful weight loss in patients who have been unable to sustain weight loss by non-surgical means.

Surgery for clinically severe obesity (bariatric surgery) falls into two categories: gastric restrictive procedures and malabsorptive procedures. The first category, gastric restrictive procedures, includes procedures in which a small pouch is created in the stomach. Weight loss occurs as the individual feels full sooner, having eaten much less than usual. This category also includes adjustable gastric banding procedures in which a band is placed around the upper portion of the stomach to reduce stomach size. The second category, malabsorptive procedures, includes procedures that rearrange the connections between the stomach and intestines, causing the food to be poorly digested and incompletely absorbed. Weight loss is due to malabsorption without necessarily requiring dietary modification. The two most commonly performed bariatric procedures in the United States (U.S.) are both done laparoscopically- sleeve gastrectomy (LSG) and Roux-en-Y gastric bypass (Kim, 2017). A more recent treatment modality consists of devices which decrease appetite or induce feelings of satiety.

Indications for Treatment

Surgery for the treatment of clinically severe obesity may be appropriate in a select group of individuals. According to the NIH, weight loss surgery candidates include those individuals suffering from the complications of extreme obesity, for whom conservative medical therapy has failed. Possible surgical candidates are those with severe obesity, defined as a body mass index (BMI) of 40 or greater, or 35 or greater with other medical complications. Such complications include, but are not limited, to the following:

- Type 2 diabetes;
- Heart disease;
- Sleep apnea;

BMI is the generally accepted measure of determining the degree of overweight or obesity, being easy to measure, reliable, and correlated with percentage of body fat and body fat mass. However, BMI may overestimate or underestimate the degree of adiposity in certain individuals (for example, muscular persons or in older persons due to loss of muscle mass associated with aging respectively). While some data (American Diabetes Associates, 2022; Mui, 2018) suggests that at-risk BMI for overweight and obesity may be suboptimal for defining diabetes risk in Asian Americans (with a proposal for using a lower BMI cut for diabetes screening), high-quality prospective data is still needed to confirm that lower BMI thresholds are appropriate as a method of identifying candidates for bariatric surgery. The American Society for Metabolic & Bariatric Surgery (ASMBS) recommends the BMI be adjusted for ethnicity, with Asian American adult's BMI cutoff for obesity be lowered. This recommendation is graded D: primary based on expert opinion (Mechanick, 2019). Furthermore, determining the optimal BMI cut point for identifying Asian Americans is complex given that there is tremendous heterogeneity among the Asian American subgroups (Hsu, 2015; Jih, 2014). Hsu (2015) noted:

> Additional research will help to further elucidate current findings on the relationship between BMI and incident diabetes in Asian Americans. … while some data exist for several Asian ethnic subgroups, insufficient disaggregated data are available for many of the Asian ethnic groups that comprise this very heterogeneous population.

Bariatric procedures can be an aid in achieving weight loss, but successful and sustained weight loss requires that individuals are compliant with significant life-long lifestyle changes. Bariatric procedures are invasive therapies, which come with inherent risks associated with all invasive procedures. The risks and potential complications vary between each technique and each individual, some of which are permanent.

The United States Preventive Services Task Force (USPSTF) statement from 2018 recommends that adults with a BMI of 30 or higher be referred to intensive, multicomponent behavioral interventions (Grade B). The USPSTF characterized the intensive behavioral weight loss programs included in their evaluation:

> Most of the intensive behavioral weight loss interventions considered by the USPSTF lasted for 1 to 2 years, and the majority had 12 or more sessions in the first year. One-third of the interventions had a "core" phase (ranging from 3-12 months) followed by a "support" or "maintenance" phase (ranging from 9-12 months). Most behavioral interventions encouraged self-monitoring of weight and provided tools to support weight loss or weight loss maintenance (eg, pedometers, food scales, or exercise videos).
>
> Most behavioral interventions encouraged self-monitoring of weight and provided tools to support weight loss or weight loss maintenance (eg, pedometers, food scales, or exercise videos). Similar behavior change techniques and weight loss messages were used across the trials.

The USPSTF noted that the interventionists collaborating with individuals varied across programs and included primary care physicians, lifestyle coaches, registered dietitians, behavioral therapists, psychologists, and exercise physiologists. The type and number of interactions varied widely across programs. Interventions included group counseling, individual counseling, classroom sessions and phone or web-based messaging. Programs which combined behavioral interventions and pharmacotherapy reported greater success.

The American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) 2016 clinical practice guidelines for medical care in obese individuals recommend lifestyle therapy which includes healthy meals with reduced calories and physical therapy for those suffering with obesity with associated comorbidities or those at risk for developing obesity related comorbidities. AACE and ACE also recommend that lifestyle therapy should include the following:

> Behavioral interventions that enhance adherence to prescriptions for a reduced-calorie meal plan and increased physical activity (behavioral interventions can include: self-monitoring of weight, food intake, and physical activity; clear and reasonable goal-setting; education pertaining to obesity, nutrition, and physical activity; face-to-face and group meetings; stimulus control; systematic approaches for problem solving; stress reduction; cognitive restructuring [i.e., cognitive behavioral therapy], motivational interviewing; behavioral contracting; psychological counseling; and mobilization of social support structures).

The 2019 Clinical practice guideline developed by AACE, ACE, The Obesity Society, ASMBS, Obesity Medicine Association (OMA), and American Society of Anesthesiologists (ASA) addresses the nonsurgical support of those who will be undergoing bariatric procedures (Mechanick, 2019). The societies recommend that the initial history and physical (H&P) include a weight loss history as well an evaluation of commitment. An evaluation of the weight loss history is repeated in the context of the psychosocial evaluation, noting:

> Formal domains for preoperative psychosocial evaluation are weight history, eating-disorder symptoms (e.g., night-eating syndrome, binge eating, compensatory behaviors, anorexia nervosa), psychosocial history, developmental and family history, current and past mental health treatment, cognitive functioning, personality traits and temperament, current stressors, social support, quality of life, health-related behaviors (substance abuse, smoking history, adherence, and physical activity), motivation and knowledge base (including weight loss expectations), and self-harm and suicide.

In 2021, the ASMBS published preoperative recommendations meant to minimize the risk of complications and optimize surgical outcomes by managing modifiable risk factors (Carter, 2021). The society defined preoperative optimization as active risk mitigation, by actively identifying and potentially delaying surgery until a specific goal is met. These recommendations include smoking cessation and achieving adequate glycemic control prior to surgery. The society also recommends a thorough evaluation by an individual's primary care physician as well as assessing behavior patterns such as eating and physical activity patterns.

In 2022, the ASMBS and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) published a guideline on the indications for metabolic and bariatric surgery. The societies note that the standard for selection criteria for bariatric surgery (BMI ≥ 40 kg/m^2 or BMI ≥35 kg/m^2 with co-morbidities) proposed by the NIH in 1991 has evolved. The societies propose less importance on strict BMI categories, arguing that bariatric and metabolic surgery be expanded to include all classes of obesity. The evidence cited by the guideline to support recommending surgery in individuals with BMIs of 30 kg/m^2 to <35 kg/m^2 or expanding recommendations in those with a BMI of ≥ 35 kg/m^2 without comorbidities is limited. The size of the trial arms includes 50 or less participants in most cases, with inclusion criteria being non-specific to the target population. Considerable heterogeneity exists between cited studies, with inconsistent results reported. In a cited joint statement by international diabetes organizations (Brito, 2017), the authors noted that a firm link between the

use of metabolic surgery to control diabetes and to prevent diabetic complications has not yet been established. The authors concluded:

> Bariatric surgery is effective for patients with T2D but is invasive and has risks, and its effects often wane over time.
>
> The consensus guideline recommends considering surgery for patients with T2D, particularly those with severe obesity, and advances the field by providing guidance for preoperative evaluation and postoperative follow-up.

Preoperative weight loss may lead to a less complex surgical procedure and improved postoperative outcomes. This has been theorized to be due to improvements in the vascular or respiratory system or improved technical aspects, such as reduced liver volume (Carter, 2021; Mechanick, 2019; Sun, 2020). However, any delays might be at the expense of further aggravating obesity replated conditions. Pre-procedure weight loss may be recommended in selected cases to improve co-morbidities in some individuals but is not recommended as a standard measure.

Bariatric Surgery to Treat Indications Other than Obesity

The rates of metabolic diseases, such as diabetes and nonalcoholic fatty liver diseases (NAFLD) have increased as the rates of obesity have increased. Approximately 30% to 53% of incident diabetes cases in the U.S can be attributed to obesity (Cameron, 2021). NAFLD affects approximately 20% to 30% of individuals in the general population in western countries. NAFLD also affects up to 90% of morbidly obese individuals and is closely related to both obesity and type 2 diabetes (Laursen, 2019; Lee, 2019).

In 2013, the Agency for Healthcare Research and Quality (AHRQ) conducted an evidence-based practice center systematic review protocol entitled: “Comparative Effectiveness of Bariatric Surgery and Non-Surgical Therapy in Adults with Metabolic Conditions and Body Mass Index of 30 to 34.9 kg/m^2” which examined the evidence regarding the comparative effectiveness of bariatric surgery versus conventional non-surgical therapies for treating adults with a BMI of 30 to 34.9 kg/m^2 and metabolic conditions, including diabetes or impaired glucose tolerance (IGT). The effectiveness of surgery versus nonsurgical interventions in these populations was also compared. This assessment attempted to determine if certain surgical procedures are more effective than others (laparoscopic adjustable gastric banding [LAGB], Roux-en-Y gastric bypass [RYGB], sleeve gastrectomy [SG] or biliopancreatic diversion with duodenal switch [BPD/DS]) and also investigated other individual factors (social support, counseling, pre-operative weight loss, compliance), in terms of how they are related to successful outcomes. This research also reviewed the evidence regarding adverse effects, complication rates and long-term benefits/harms of bariatric surgery for adults with a BMI of 30 to 34.9 kg/m^2 who have metabolic conditions and compared these findings to short-term outcomes (within 2 years from surgery). Twenty-four studies were included in this review which reported bariatric surgery results for the specific target populations. Two trials compared different procedures; three trials compared surgical and nonsurgical interventions, and the remainder were observational studies. Both weight and blood glucose improved significantly for the surgery participants in the trials. In the observational studies, the individuals who underwent surgery showed much greater weight loss at 1 year than what was reported in systematic reviews and randomized controlled trials (RCTs) on diet, exercise, medication, and other behavioral interventions. While both behavioral interventions and medications lowered HbA1c (glycosylated hemoglobin) levels significantly, the decreases reported for the surgical individuals were much greater. Improvements in blood glucose measures were reported as early as 1-month post-surgery. Improvements in hypertension, low-density lipoprotein (LDL) cholesterol, and triglycerides were also reported in some studies. Short-term rates of adverse events associated with bariatric surgery were relatively low. There was one death from sepsis in an individual 20 months post-LAGB. Short-term complications were minor and tended not to require major intervention. The investigators commented:

> Due to the dearth of long-term studies of bariatric surgery in this particular target population, few data exist about long-term adverse effects, and we found no evidence regarding major clinical endpoints, such as all-cause mortality, cardiovascular mortality and morbidity, and peripheral arterial disease.

The AACE, the Obesity Society, and the ASMBS practice guideline for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (Mechanick, 2019) includes lower-level recommendations (Grade B, Best Evidence Level (BEL) 2) for individuals with a BMI of 30-34.9kg/m^2 with diabetes or metabolic syndrome. The authors note that the current evidence does not support that surgery may be appropriate in the absence of obesity.

Bariatric surgery has been investigated as a treatment for type 2 diabetes mellitus (T2DM). To date, studies reporting the results of bariatric surgery on T2DM have primarily focused on individuals with a BMI greater than or equal to 40 or 35-

39.9 kg/m^2 with a clinically significant obesity-related comorbidity. Studies comparing conventional medical therapy and bariatric surgery have reported improved diabetic control in the bariatric surgery groups (Mingrone, 2012; Schauer, 2012). There have been very few studies that investigated the safety and efficacy of bariatric surgery, also referred to as metabolic surgery, in individuals with a BMI less than 35 kg/m^2.

The 2024 American Diabetes Association (ADA) Standards of Medical Care in Diabetes recommend that for metabolic surgery should be considered as a weight and glycemic management approach in adults with type 2 diabetes with a BMI of 30 kg/m^2 (BMI ≥ 27.5 kg/m^2 in Asian Americans) The document notes:

> The evidence demonstrates that bariatric surgery in diabetic individuals with a BMI of 35 or greater can result in greater glycemic control and a reduction of cardiovascular risk factors in obese patients with compared with various lifestyle/medical interventions. However, the current evidence does not support that the benefits of bariatric surgery outweigh the risk in those with a BMI less than 35 or that bariatric surgery provides definable lasting results in this population.

In a 2019 systematic review and meta-analysis, Lee and colleagues reviewed the effects of bariatric surgery on biopsy confirmed NAFLD in obese individuals. While no RCTs were identified, prospective (n=17) and retrospective (n=15) studies were included. Individuals with steatosis (n=1329), inflammation (n=657), ballooning degeneration (n=320) or fibrosis (n=619) prior to bariatric surgery reported complete resolution at 1 year following surgery in 66%, 50%, 76% and 40% of individuals; respectively. While not all of the studies reported on histologic worsening in regard to NAFLD-relevant outcomes, 19 studies reported worsening or new development of NAFLD characteristics following surgery in 12% of individuals. The meta-analysis was limited by a number of factors, including high heterogeneity between the studies, including differences in follow-up time, type of surgery performed, type of biopsy method and degree of obesity. In addition, there was a lack of participant specific data which would allow the authors to better assess outcomes and possible confounders.

Aminian and associates (2021) reviewed the association between bariatric surgery and incident major adverse liver outcomes and cardiovascular events (MACE) in obese individuals with biopsy-proven fibrotic nonalcoholic steatohepatitis (NASH) without cirrhosis. This large-scale retrospective study included individuals who had undergone RYGB or sleeve gastrectomy (n=650) and a nonsurgical control group (n=508). Individuals had a mean BMI of 44.1 (IQR, 39.4-51.4) and were followed for a median follow-up of 7 years (IQR, 4-10 years). The primary endpoints were identified as the incidence major adverse liver outcomes and MACE, which was a composite of coronary artery events, cerebrovascular events, heart failure, or cardiovascular death. At 10 years post-surgery, the reported cumulative incidence of major adverse liver outcomes was 2.3% (95% confidence interval [CI], 0%-4.6%) in the bariatric surgery group and 9.6% (95% CI, 6.1%-12.9%) in the nonsurgical group (adjusted absolute risk difference, 12.4% [95% CI, 5.7%-19.7%]; adjusted HR, 0.12 [95% CI, 0.02-0.63], p=0.01). The bariatric surgery group also reported improved MACE outcomes compared to the nonsurgical group at 10 years: 8.5% (95% CI, 5.5%-11.4%) versus 15.7% (95% CI, 11.3%-19.8%) (adjusted absolute risk difference, 13.9% [95% CI, 5.9%- 21.9%]; adjusted HR, 0.30 [95% CI, 0.12-0.72], p=0.007). The mean body weight in the surgical group was reduced by 22.4% compared to a 4.6% decrease in the nonsurgical group.

While bariatric surgery has been associated with decreased grade of steatosis, hepatic inflammation, and fibrosis in individuals with obesity and NAFLD in a number of cohort studies, available studies are inconsistent and potentially biased. Furthermore, new or worsening features of NAFLD, such as fibrosis, have been noted in some individuals. Randomized trials are needed to evaluate the safety and health outcomes associated with bariatric surgery in individuals with NAFLD, without severe obesity, and/or other obesity-related co-morbid conditions (for example, diabetes mellitus, cardiovascular heart disease, or hypertension).

The ASMBS published a position statement regarding metabolic surgery (MBS) and bariatric surgery on nonalcoholic steatohepatitis (Mazzini, 2021). The guideline addressed the impact of laparoscopic RYGB and LSG on the management of NASH. The society concluded:

> Based on the evidence presented herein, MBS 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.

Gastroparesis is a rare condition affecting the gastric emptying following the ingestion of solid foods. The delayed gastric emptying causes multiple symptoms including nausea, vomiting, early satiety, pain, belching, and bloating. RYGB without gastrectomy has been proposed as a treatment of gastroparesis. Only a few uncontrolled studies with a limited number of

participants have been published (Moszkowicz, 2022; Papasavas 2014). The evidence does not show that bariatric surgery is as effective as the current treatment modalities.

Bariatric Surgery in Adolescents and Children (Return to Clinical Indications)

Greater than 1 in 5 children in the U.S. are classified as obese. These rates continue to increase, with the rise of children with severe obesity experiencing the most significant rise (Skinner, 2018). The classification of obesity in children and adolescents varies from the adult classification system. Obesity categorization is typically based upon relative BMI or BMI percentile (Skinner, 2018). The AAP defines childhood obesity as a BMI of ≥ 95th percentile for age and gender while severe obesity is defined as a BMI of ≥ 120th percentile for age and gender (Hampl, 2023). The use of bariatric surgery in children and adolescents has been limited, but the surgical rates have been increasing since the early 2000s as evidence showing safety, effectiveness and durability has been published (Hampl, 2023; Shoar, 2017).

The 2019, American Academy of Pediatrics (AAP) guidelines noted that severe obesity in the pediatric population (ages 13-18) has been increasingly linked to the development and progression of multiple comorbid states, including increased cardiometabolic risk resulting in end-organ damage in adulthood (Armstrong, 2019). As bariatric surgery has become more common, the outcomes have supported that indications for surgery might mirror adult indications. There are potential complications might be of particular concern in the pediatric population. The long-term effects of micronutrient deficiencies, which are common after RYGB and vertical sleeve gastrectomy, are unknown as most pediatric longitudinal studies of bariatric surgery do not follow participants long-term or through life events such as pregnancy, to assess for related complications. Early data suggests that those individuals with baseline anxiety or depression might be at higher risk for postoperative anxiety and depression. While bariatric surgery has been shown to be an effective tool in treating the pediatric population with severe obesity, the AAP recommends that the pediatrician understand and communicate the efficacy, risks, benefits, and long-term health implications associated with bariatric surgery to the family when making decisions regarding surgical options.

The AAP published a clinical practice guideline on the evaluation and treatment of children and adolescents with obesity (Hampl, 2023). Procedures most commonly performed in the pediatric age group, laparoscopic RYGB and vertical sleeve gastrectomy have resulted in significant and sustained weight loss. There is evidence to suggest that adolescents following bariatric surgery have a high probability of experiencing a remission of certain cardiometabolic risk factors including, but not limited to hypertension, T2DM and dyslipidemia. While bariatric surgery in this population is associated with a cumulative benefit on obesity related diseases over time, surgery requires long-term follow-up. Approximately 13% to 25% of surgeries performed on the pediatric population require subsequent procedures up to 5 years following the initial surgery. Long-term medical management is required to monitor for and treat any micronutrient deficiencies which might develop. AAP acknowledges that a multicomponent and individualized approach is needed when evaluating and individual for bariatric surgery eligibility noting:

> Age is not the sole determinant of eligibility for metabolic and bariatric surgery. The pediatrician or other pediatric health care providers [PHCP] should take into account the patient's physical and psychosocial needs. Evaluation for metabolic and bariatric surgery should include a holistic view of the patient and family, including individual and social risk factors. Families should be fully informed of the benefits and risks of metabolic and bariatric surgery, and their preferences are paramount.

In 2018, the ASMBS updated the pediatric bariatric surgery guidelines in response to an expanding body of evidence. Severe obesity has been linked to the development of a number of chronic conditions and risk factors associated with premature mortality in adults. These include, but are not limited to, cardiovascular disease, dyslipidemia, hypertension, insulin resistance, type 2 diabetes, obstructive sleep apnea, nonalcoholic fatty liver disease. The ASMBS recommends that surgery be considered for the following:

- BMI ≥ 35 kg/m^2 or 120% of the 95th percentile with a clinically significant co-morbid condition(s); or
- BMI ≥ 40 kg/m^2 or 140% of the 95th percentile (whichever is lower).

While the recommendations are in place for adolescents (defined as between the ages of 10 and 19 years), there may be children who should be considered for surgery prior to adolescence due to the presence of obesity related complications. RYGB and vertical sleeve gastrectomy are considered safe and effective treatments in the pediatric population. Other procedures are considered less desirable; BPD carries a higher risk of reoperation and adjustable lap banding is not FDA approved in those below 18 years of age. In cases in which there is inadequate weight loss, the ASMBS recommends evaluation by a dietician and a psychologist to assess eating patterns. Treatment options can include the addition of weight loss medications or revision surgery.

In a scientific statement on severe obesity in children and adolescents, the American Heart Association reviewed multiple comorbid conditions associated with severe obesity in youths, including metabolic disorders, hypertension, non-alcoholic fatty liver disease, musculoskeletal problems and obstructive sleep apnea syndrome (Kelly, 2013). The AHA concluded that severely obese youths are much more likely to become severely obese adults with commensurate risks and adverse outcomes. Various medical treatment options were also described, along with results of the available studies. Regarding bariatric surgery, it was noted:

> In light of the limited effectiveness of lifestyle modification and medical therapy, shown to date, for severe obesity, surgical procedures that have an evidence base that supports their efficacy and safety should be considered for patients who demonstrate medical necessity and psychosocial readiness… The most recent and authoritative practice recommendations (Pratt, 2009) emphasize the concept that a combination of both severe obesity and the existence of comorbidities should be present to medically justify an operation to treat obesity. There is good evidence that RYGB is reasonably safe and highly effective compared with lifestyle modification for the treatment of severe obesity. Relatively good safety and efficacy data for AGB (adjustable gastric banding) in adolescents have been reported, although a high rate of reoperation and sparse long-term data, along with a lack of FDA approval for the device, hamper recommendations for usage before adulthood. All adolescents undergoing bariatric surgery should be strongly encouraged to participate in prospective longitudinal outcomes studies to improve the evidence base to evaluate the risks and benefits of operations in this age group… Bariatric surgery is the most effective treatment for severe obesity in adolescents; however, surgery is appropriate and available for only some adolescents with severe obesity, and broadening availability will depend on the results of long-term outcome studies, currently in progress… Innovative approaches to fill the gap between lifestyle/medication and surgery are urgently needed.

The Endocrine Society clinical practice guideline on pediatric obesity (2017) reviewed the treatment of pediatric obesity, including bariatric surgery. Bariatric surgery is recommended only under limited circumstances in individuals in the later stages of development (Tanner pubertal development stages 4 or 5 and final or near final adult height) with a BMI of greater than 40 kg/m^2 and mild co-morbidities, or greater than 35 kg/m^2 and major co-morbidities. This recommendation is categorized as a weak recommendation based on low quality evidence. While the results of studies have been promising, there continues to be concerns regarding potential nutritional deficiencies and compliance in this population. Adolescents undergoing bariatric surgery will require life-long follow-up.

Inge and associates (2019) compared the 5-year outcomes of adolescents to adults who underwent RYGB and had previously participated in Longitudinal Assessment of Bariatric Surgery (LABS) and the Teen-LABS studies. Individuals were evaluated at baseline, at 6 months post-operative and then annually for 5 years. The mean age of the adolescent group (n=161) at baseline was 17 years. At 5 years, both groups reported similar weight changes (-26% in adolescents versus -29% in adults). The adolescent group reported higher remission rates of type 2 diabetes and hypertension compared to the adult group. However, the adolescent group also reported a higher rate of abdominal reoperations and nutritional deficiencies compared to the adult group. The authors suggest that there may be greater plasticity for reversal of obesity related complications among adolescent individuals compared to the adults. The authors concluded that in some individuals, the benefits of bariatric surgery as an adolescent may outweigh postponing surgery until adulthood; noting "longer-term follow-up and further research will be important for refinement of the risks and benefits of bariatric surgery in adolescents." Furthermore, the benefits of bariatric surgery need to be balanced with the additional risks in the adolescent age group who may not have a fully developed capacity to make decisions about a life altering procedure (Adams, 2019; O'Brien, 2010; Pratt, 2009; Treadwell, 2008).

The 2024 ADA Standards of Medical Care in Diabetes includes the following recommendations for children and adolescents:

> Metabolic surgery may be considered for the treatment of adolescents with type 2 diabetes who have class 2 obesity or higher (BMI > 35 kg/m^2 or 120% of 95^{th} percentile for age and sex, whichever is lower) and who have elevated A1C and/or serious comorbidities despite lifestyle and pharmacologic intervention. A

> Metabolic surgery should be performed only by an experienced surgeon working as part of a well-organized and engaged multidisciplinary team including a surgeon, endocrinologist, registered dietician nutritionist, behavioral health specialist, and nurse. A

In eligible individuals under the age of 18 years, who are skeletally mature, it is the consensus in the practice community that potential candidates for surgery be evaluated for the following:

- The individual's psychiatric profile and developmental stage is such that the candidate is able to understand, tolerate and comply with all phases of pre- and post-operative care and is committed to long-term post-operative follow-up requirements; and
- An informed consent is conducted including documentation that the individual has received and can fully understand a thorough explanation of the risks, benefits, and uncertainties of the procedure being planned for.

Bariatric Procedures

Gastric bypass and gastric restrictive procedures

Results of a prospective, nonrandomized, comparative trial reported long-term outcomes of 563 vertical banded gastroplasty (VBG) and 554 AGB procedures performed by two surgeons. The mean BMI was 46.9 ± 09.9 kg/m$^{(2)}$ for those undergoing VBG and 46.7 ± 07.8 kg/m$^{(2)}$ for those in the AGB group. VBG was performed by laparotomy and AGB using laparoscopy. The Bariatric Analysis and Reporting Outcome System (BAROS) was used to evaluate postoperative health status and quality of life. The mean duration of follow-up was 92 months (range 60-134), with a minimum of 5 years. The overall follow-up rate was 92%. The 30-day mortality rate was 0.4% for VBG and 0.2% for AGB. The overall re-intervention rate in the long-term was 49.7% for VBG and 8.6% for AGB ($p<0.0001$). The reoperation rate was 39.9% for VBG and 7.5% for AGB ($p<0.0001$). The excess weight loss (EWL) was significantly greater in the VBG group (58%) than in the AGB group (42%) after 12 months ($p<0.05$). At 92-month follow-up, no significant difference in weight loss was found between the two study groups (59% for VBG and 62% for AGB, $p=0.923$). The BAROS score was significantly in favor of the AGB group ($p<0.0001$). The overall resolution rate of co-morbidities was 80% in both groups (Miller, 2007).

A retrospective cohort study of different procedures for morbid obesity was reported for: open VBG (n=125), open Scopinaro biliopancreatic diversion (BPD; n=150), open modified BPD (that is, common limb 75 cm; alimentary limb 225 cm; n=100), and LRYGB (n=115). Mean follow-up was 12 years for VBG, 7 years for BPD, and 4 years for LRYGB. An excellent initial weight loss was observed at the end of the second year of follow-up in all techniques, followed by regain of weight observed in the VBG and LRYGB groups. Participants in the BPD groups maintained their weight loss results. Mortality was: VBG 1.6%, BPD 1.2%, and LRYGB 0%. Early postoperative complications were: VBG 25%, BPD 20.4%, and LRYGB 20%. Late postoperative morbidity was: protein malnutrition of 11% in Scopinaro BPD, 3% in modified BPD group, and no cases reported either in the VBG group or the LRYGB group; iron deficiency was 20% for VBG, 62% for the Scopinaro BPD, 40% for the modified BPD, and 30.5% for the LRYGB group. Conversion to gastric bypass or to BPD was needed for 14.5% of the VBG group, due to 100% weight regain or vomiting. For those in the Scopinaro BPD group, revision surgery was needed to lengthen the common limb to 100 cm in 3.2% of cases, due to severe protein malnutrition. Revision surgery was required in 0.8% of those who underwent LRYGB due to 100% weight regain. It was noted that the more complex bariatric procedures increase effectiveness but also increase morbidity and mortality. The authors concluded:

> LRYGB is safe and effective for the treatment of morbid obesity. Modified BPD (75-225 cm) can be considered for the treatment of super obesity (BMI greater than 50 kg/m^2), and restrictive procedures, such as VBG, should only be performed in well-selected patients, due to high rates of failure in long-term follow-up (Gracia, 2009).

There is sufficient evidence to support the use of the biliopancreatic bypass with duodenal switch (BPD/DS) for individuals who have clinically severe obesity. BPD/DS mortality is similar to RYGB mortality, and the evidence suggests that up to 70% EWL can be maintained over long-term follow-up (up to 6 years post-surgery). The evidence supporting this conclusion includes multiple large case series.

VBG is an early form of a primarily restrictive procedure which had been used to treat morbid obesity. This surgery has been largely replaced by other procedures and is rarely performed anymore due to a general lack of sustained weight loss and a high rate of complications which require revision surgery (Ece, 2016; Griggs, 2018).

Sleeve gastrectomy

Sleeve gastrectomy is the most common bariatric procedure performed. In 2020, sleeve gastrectomy accounted for over 60% of all procedures performed (ASMBS, 2022). Sleeve gastrectomy is commonly performed laparoscopically. Sleeve gastrectomy can be associated with gastroesophageal reflux (GERD), esophagitis, and Barrett esophagus (BE). The long-term results of studies evaluating sleeve gastrectomy has supported the overall safety and efficacy of this established

procedure. Sleeve gastrectomy is associated with significant and sustained weight loss (Himpens, 2010; Peterli, 2018; Salminen, 2022; Shoar, 2017).

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)

The SADI-S, also known as loop duodenal switch, stomach intestinal pylorus-sparing surgery or the single-anastomosis duodenal switch, is a variant of the duodenal switch (DS) which was developed to address the inherent limitations of the current standard bariatric surgeries including inadequate weight loss, weight regain, variable improvement of weight-related co-morbidities, hypoabsorptive complications, internal hernias, and technical difficulty (Kallies, 2020). The procedure involves first creating a sleeve gastrectomy then replacing the RYGB reconstruction with a single anastomosis duodenoileostomy with a 250 cm or longer absorptive channel. The 1-loop Billroth II-like connection avoids the need for forming a distal ileo-ileal anastomosis and alimentary limb. These changes reduce operative time and decrease postoperative complications, including nutritional deficiencies, obstruction, anastomotic leak, and hernias (Nakanishi, 2022).

In 2020, the ASMBS issued an updated statement on SADI-S, revising their previous recommendation that the procedure be done only under a study protocol to recommending SADI-S as a primary treatment of obesity or metabolic disease. The recommendation is partially based on the fact that the SADI-S is a variant of the established DS rather than a novel surgical procedure; therefore less published, peer-reviewed evidence is required. While the ASMBS has endorsed the SADI-S procedure, the society also notes the following:

> Publication of long-term safety and efficacy outcomes is still needed and is strongly encouraged, particularly with published details on SG size and common channel length.
>
> There remain concerns about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure. As such, ASMBS recommends a cautious approach to the adoption of this procedure, with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients, in particular for DS patients.

The studies cited by the ASMBS include retrospective studies, a case series, and a systematic review. The systematic review was limited by the heterogeneity within the studies. The systematic review included primary and revisional SADI-S, a variety of absorptive limb lengths, bougie sizes, and anastomotic techniques. Some studies were missing data, such as the absorptive limb length and data regarding the number of individuals with 5-year follow-up.

Since the publication of the 2020 ASMBS statement, additional literature has been published. Finno and colleagues (2020) reported on the outcomes of individuals were treated with either duodenal switch or SADI-S up to 2 years following surgery at a single institution. At 2 years, both groups reported similar BMI changes, % EWL and rate of participants who reached a BMI < 35. The duodenal switch group had a significantly higher number of long-term complications, primarily mesenteric internal hernias. The SADI-S group reported a higher incidence of GERD. These findings were limited by the retrospective nature of this study and the disparity in length of postoperative follow-up between the groups (27.2 ± 18.9 months for SADI-S and 56.1 ± 37.2 months for duodenal switch. These studies consist of retrospective reviews and are associated with a number of limitations including, but not limited to, lack of direct comparisons to the current standard bariatric surgeries and limited scope of studies such as size of study or lack of participating providers (Bashah, 2020; Surve, 2021a; Surve, 2021b).

Malabsorptive procedures (other than the biliopancreatic bypass with duodenal switch)

Malabsorptive procedures represent earliest forms of surgical treatment for severe obesity. Procedures such as jejunoileal bypass were associated with severe short- and long-term complications and are no longer recommended as a treatment of severe obesity (Morris, 2017). The available evidence does not support that the safety, efficacy, and durability is comparable to the standard DS procedure.

Mini gastric bypass

The mini gastric bypass is also known as one AGB (OAGB or omega-loop gastric bypass (Solouki, 2018). The procedure is a modified gastric bypass which consists of one gastrojejunal anastomosis between a long gastric pouch and a jejunal omega loop, with the standard biliopancreatic limb length being 200 cm (Robert, 2019). Complications can include biliary reflux and anastomotic ulcers (Robert, 2019; Ruiz-Taylor, 2019). The use of the mini gastric bypass, specifically the OAGB has been growing and it is the third more frequently performed procedure performed worldwide, following SG and RYGB (Ruiz-Tovar, 2019).

Ruiz-Taylor and colleagues (2019) reported on the outcomes of a Spanish prospective study in which individuals with a BMI > 40 or > 35 with the presence of comorbidities were randomized to receive either SG, RYGB or OAGB. Individuals were followed up to 5 years postoperatively. The biliopancreatic limb length in the OAGB group ranged from 200 to 350 cm long. The authors noted, “A weight loss of at least 10% of the patient’s weight was considered an indispensable condition to undergo the selected bariatric technique”. At 1 year, the BMI for the SG, RYGB, and OAGB groups were 28.9 ± 2.1 Kg/m^2, RYGB 28.7 ± 2 Kg/m^2, and 25 ± 1.6 Kg/m^2 respectively. At 5 years, the BMI for the SG, RYGB, and OAGB groups were 30.8 ± 2.2 Kg/m^2, 29.9 ± 2.3 Kg/m^2, and 25.1 ± 1.8 Kg/m^2 respectively. The BMI was significantly lower in the OAGB group compared to the RYGB or SG groups. In addition to BMI, the authors reported on the remission rates of type 2 diabetes, hypertension and dyslipidemia for each group. At 5 years, the OAGB group reported significantly greater remission rates for all three conditions when compared to both SG and RYGB. During the 5-year follow-up period, 2 individuals presented with uncontrollable biliary reflux and were converted to RYGB, and 3 individuals presented with anastomotic ulcers and were medically treated. A total of 3 individuals each in the SG and RYGB group presented with weight regain. Over the follow-up period, the OAGB group had higher iron and folic acid needs, which the authors noted would be expected as this procedure is a mostly malabsorptive procedure.

In the Omega Loop Versus Roux-en-Y Gastric Bypass (YOMEGA) trial, a French multicentre, randomised, open-label, non-inferiority trial, Robert and associates (2019) compared the outcomes between laparoscopic OAGB (n=129) and RYGB (n=124). Individuals with a BMI ≥ 40 or ≥ 35 with at least one comorbidity, were randomized to the OAGB or RYGB group. The biliopancreatic limb length in the OAGB group was 200 cm long. Individuals were subject to follow-up to 2 years. The primary endpoint was set as the percentage excess BMI at 2 years while secondary endpoints included early and late complications as well as disease remission status. Data was available for 117 participants in each group. At 2 years, the mean percentage excess BMI loss in the RYGB group versus the OAGB group was -85.8% (SD 23.1) and -87.9% (SD 23.6) respectively. There was no significant difference between the groups in the proportions of diabetic individuals who were in diabetes remission at 2 years. There were significantly more overall and surgery-related serious adverse events in the OAGB group compared to the RYGB group at 2 years follow-up. The authors noted that in terms of weight loss and metabolic improvement, OAGB does not appear to be inferior to RYGB. However, the OAGB group did report higher incidences of diarrhea, steatorrhoea, and nutritional adverse events. A total of 4 of the individuals who initially underwent OAGB surgery later converted to RYGB due to anastomotic leak (1), Wernicke encephalopathy (1), and intractable severe biliary reflux (2). Endoscopy performed at 2 years showed the presence of bile in the gastric pouch in 9 individuals in the OAGB group and 1 individual having intestinal metaplasia compared to none of the individuals in the RYGB group having these issues. The authors note the small trial size and short follow-up as limitations to the study, stating that “other complications such as those associated with malabsorption, which can take years to develop, could not be assessed in our trial.” The authors conclude:

> OAGB is not inferior to RYGB in terms of weight loss and metabolic improvement at 2 years … Higher incidences of diarrhea, steatorrhea, and nutritional adverse events were observed in the OAGB group than in the RYGB group, suggesting a malabsorptive effect of this bariatric procedure.

While OAGB is used in other countries, it is not considered to be a clinically appropriate for the treatment of obesity in the United States at this time. The American Society for Metabolic and Bariatric Surgery (ASMBS) does not recommend OAGB as a primary weight loss procedure.

Laparoscopic gastric plication

On October 6, 2011, the ASMBS issued a policy statement on laparoscopic gastric plication, also known as laparoscopic greater curvature plication (LGCP). Gastric plication involves mobilizing the greater curvature of the stomach similar to the dissection for a SG and infolding (or imbricating) the stomach to achieve gastric restriction utilizing specialized surgical tools and sutures manufactured by Ethicon Endo-Surgery, Inc. (Cincinnati, OH). According to the ASMBS statement:

> The rationale for this procedure addresses issues that may limit the acceptance of other bariatric procedures, specifically, gastric plication does not involve gastric resection, intestinal bypass or placement of a foreign body, and could potentially provide a lower risk alternative for individuals and referring physicians.

The current available literature regarding gastric plication procedures does not support that this procedure provides improved health outcomes, both long and short term over the standard techniques, such as laparoscopic sleeve gastrectomy (Grubnik, 2016; Tang, 2015; Ye, 2017).

Endoscopic Surgery

Currently there are two FDA approved endoscopic procedures, primary obesity surgery endoluminal (POSE) and endoscopic sleeve gastrectomy (ESG).

Dayyeh and colleagues (2022) compared the safety and efficacy of lifestyle modifications and lifestyle modifications combined with ESG in a prospective, multicenter, randomized trial (MERIT). Individuals with a BMI between 30kg/m^2 and less than 40kg/m^2 were randomized to the control group (n=124) or the trial group (n=85). The primary efficacy endpoint was the comparison between percentage of EWL at 52 weeks. At the end of 52 weeks, participants were eligible to crossover to the trial group. They were then followed for an additional 52 weeks. The ESG group had a significant percentage of EWL at 52 weeks (49.2%) compared to the control group (3.2%). The ESG group also experienced greater total body weight loss (13.6%) versus the control group (0.8%). Improvements in metabolic comorbidities were observed in 80% of the ESG group compared to 45% of the control group. Moreover, 93% of ESG participants showed improvement in diabetes indices, versus 15% in the control group with similar trends observed for hypertension and metabolic syndrome. At 104 weeks, 83% of the achieved weight loss was maintained. The short-term results show that ESG can improve clinical outcomes in the short term. However, long-term data is needed to evaluate whether ESG results in a durable improvement in health.

Brunaldi and associate (2017) provided commentary on the MERIT study, noting:

> Although these results are impressive, because obesity is chronic, relapsing, and progressive, 5-year and 10-year data are essential (allowing for periodical retightening). Characteristics such as long-term reduction in comorbidities and overall all-cause mortality, and improvement in quality of life, are crucial, being the most important justifications for adoption of bariatric surgery as the gold standard in the treatment of obesity….. Additionally, there is a need for well-designed randomised controlled trials comparing ESG with surgical bariatric techniques such as sleeve gastrectomy to better define the spectrum of indications and patient selection criteria for endoscopic suturing procedures.

Bariatric Medical Devices

The FDA (2019) currently includes four categories of regulated devices which are intended for weight loss. These devices include:

- Gastric Band - bands are placed around the top portion of the stomach leaving only a small portion available for food.
- Electrical Stimulation Systems - electrical stimulator is placed in the abdomen to block nerve activity between the brain and stomach (currently there are no marketed devices).
- Gastric Balloon Systems - inflatable balloons are placed in the stomach to take up space and delay gastric emptying.
- Gastric Emptying Systems - a tube is inserted between the stomach and outside of abdomen to drain food after eating.

AGB

AGB is a restrictive procedure which involves surgically placing a gastric band around the exterior of the stomach; the stomach is not entered. The procedure can be reversed by removing the band. Complications may include slippage of the external band or band erosion through the stomach wall (2-5% of surgeries). Furthermore, incorrect positioning of the band may result in vomiting, as well as ineffective weight loss. In June 2001, the FDA cleared the Lap-Band® System (Allergan, Inc., Irvine, CA and sold to Apollo Endosurgery, Inc., Austin, TX, in 2013). In 2007, the FDA approved a second gastric band device, (REALIZE™ Adjustable Gastric Band, Ethicon Endo-Surgery®, Inc., Cincinnati, OH) to be used for weight reduction for morbidly obese individuals and is indicated for individuals with a BMI of at least 40 kg/m2, or a BMI of at least 35 kg/m2 with one or more co-morbid conditions. However, in 2016 Ethicon announced plans to discontinue marketing the REALIZE adjustable gastric band in the United States due to declining gastric band trends. The LAP-BAND system is the only FDA approved system for adjustable gastric banding in the United States. The popularity of adjustable lap bands has decreased significantly since 2011. In 2020, there was an estimated 2393 lap bands placed compared to an estimated 55,932 in 2011. This decrease can be attributed to a high rate of complications which required revision or removal of the band and less than optimal weight loss for many individuals.

A number of studies supported the clinical efficacy of adjustable gastric banding, although weight loss tended to be less robust when compared to other surgical procedures, such as Roux-en-Y (Angrisani, 2007; Arterburn, 2014; Biertho, 2003; Bowne, 2006; Dolan, 2004; Jan, 2005; Morino, 2003). Initially, LAGB was a popular choice as the procedure is minimally invasive and reversible. While the short-term results were promising, the long-term failure and complications rates are

substantial. Approximately 70% of individuals reported complications at 15 years follow-up with 61.7% requiring additional surgery to address the complication (Gangemi, 2018),

On February 16, 2011, the FDA approved an expanded indication for the Lap-Band device to include individuals with a BMI at least 30 kg/m^2 with one or more obesity related comorbid conditions. This expansion was based on the results of a prospective, single-arm, nonrandomized, 5-year study sponsored by the manufacturer, Allergan, Inc. At the time of the FDA approval, the 1-year results showed device clinical efficacy with at least 80.5% of the participating individuals achieving at least a 30% EWL at 1 year (FDA, 2011). At 2 years, the 1-year results were maintained (Michaelson, 2013). There are several limitations associated with this study. The study included individuals with a BMI of up to 40 kg/m^2, only 41% had a BMI of 30-35 kg/m^2. Based upon the design of the study, there appears to be a significant potential for bias. Arterburn (2013) noted that as the prevalence of severe comorbidities in this population is less, the evidence currently does not support that the benefit of preventing comorbidities in this population outweighs the risk.

Intragastric Balloon Devices (IGBs)

IGBs are endoscopically implanted intragastric devices which are filled with liquid or gas after insertion and intended to reduce gastric capacity, delay gastric empyting and stimulate the feeling of satiety. IGBs are intended for temporary use, approximately 6 to 12 months, as the risk of complications, such as balloon deflation and migration significantly increase after this time (Tate, 2018). There are currently four FDA approved devices: Orbera™ Intragastric Balloon System (Apollo Endosurgery, Inc., Austin, TX); TransPyloric Shuttle Delivery Device (BAROnova, Inc., San Carlos, CA) and the Obalon Balloon System (Obalon® Therapeutics, Inc., San Diego, CA). The FDA approved device, Spatz3 (Spatz FGIA, Inc., Fort Lauderdale, FL) is the only adjustable gastric balloon system. Tate and Geliebter (2017) reviewed eight recent RCTs which compared percentage total body weight loss (%TBWL) between IGBs to control groups or bariatric surgery and pharmacotherapy. The authors noted that while IGBs did appear to provide statistically significant weight loss, IGB is not as efficacious as bariatric surgery. The current evidence does not show that long-term health outcomes associated with the use of this temporary device are equivalent to the accepted standard treatments (Brunaldi, 2019; Dang, 2018; Moore, 2020). A previous liquid-filled device, ReShape Balloon, is no longer available in the U.S market. The Allurion balloon device is not FDA approved in the United States, but a clinical study is underway (AllUrion Device in Adults With Clinical ObesITY [AUDACITY]; NCT05368259).

On April 27, 2020, the FDA communicated the risks of liquid-filled intragastric balloons, namely the Orbera and ReShape, to health care providers. The letter addressed the potential risks of these devices, including hyperinflation, acute pancreatitis and death. The recommendations including:

- Instruct patients about the symptoms of potentially life-threatening complications such as balloon deflation, gastrointestinal obstruction, ulceration, and gastric and esophageal perforation and advise them when to seek medical attention.
- Monitor patients closely during the entire duration of treatment with liquid-filled intragastric balloon systems for potential complications, including acute pancreatitis, spontaneous hyperinflation, and other potentially life-threatening complications.
- Report any adverse events related to intragastric balloon systems through MedWatch, the FDA Safety Information and Adverse Event Reporting program.

IGBs have been associated with a number of complications including gastrointestinal symptoms (for example, nausea, vomiting, abdominal pain, constipation, acid reflux, dyspepsia) gastric ulcers, small bowel obstruction, pancreatitis or gastric erosion. Severe adverse events including esophageal tears or perforation, pulmonary embolism, pneumonia and gastric perforation were reported. Up to 9% of IGBs require early removal due to intolerance (Dang, 2018). In a propensity-matched analysis evaluating safety, the safety profile of IGBs and laparoscopic bariatric surgery were compared (Dang, 2018). IGB had twice the adverse outcome rate of laparoscopic bariatric surgery, largely due to a nonoperative reintervention rate that was more than quadruple in the IGB arm. The authors noted that while the nonoperative reintervention rate will be inherently higher in the IGB group due to the need for balloon removal at 6 months, the study looked at only unplanned removal before 30 days. Complications can be the related to the placement of the IGB, the location of the device or IGB removal. Procedure related complications occur primarily during balloon removal. The use of IGB therapy is not generally associated with meaningful and sustained weight loss and frequently individuals undergo repeated usage of IGB therapy (Crossan, 2022).

Aspiration Therapy

The first and currently only FDA approved device, AspireAssist® (Aspire Bariatrics, Inc., King of Prussia, PA) was approved on June 14, 2016. A tube placed inside the stomach is connected to an outer port, and 20 to 30 minutes following a meal, the stomach contents are drained via gravity through the outer port. As the food has not been fully broken down and absorbed, approximately 30% of the calories consumed are removed. The device is intended for long-term use. Common adverse events include complications at the tunneling site, pain, nausea/vomiting, abdominal discomfort, and change in bowel habits.

Thompson and associates (2019) reported on the 4-year outcomes of individuals who participated in the pivotal, multicenter RCT in which participants received either aspiration therapy and lifestyle therapy or lifestyle therapy only. While the authors reported that 69% (40/58) of the participants achieved at least 10% total weight loss at 4 years post procedure, there was a significant drop-out rate throughout the course of the study. A total of 111 individuals originally received the AspireAssist device, with 29 individuals electing to have the tube removed within the first year. Between years 2, 3, and 4, the number of individuals with the AspireAssist device remaining in place dropped each year (43, 22, and 15, respectively). Individuals remaining in the study at 4 years reported an average number of connections as 1.5, raising questions regarding the long-term effectiveness of treatment.

Electrical Stimulation System

In 2015, the FDA approved the MAESTRO® Rechargeable System (EnteroMedics, Inc., St. Paul, MN) for use in individuals with a BMI of 40 to 45 or with a BMI of 35 to 39.9 and one or more comorbidity. MAESTRO provides vagal blocking (VBLOC®) therapy by delivering intermittent, controllable, electrical blocking signals to the abdominal anterior and posterior nerve trunks of the vagus nerve. The FDA clearance was based on results of two randomized controlled trials, the first of which included 233 participants with a BMI of 35 or greater. The weight loss and adverse events of 157 individuals who received the active Maestro device were compared to 76 participants in the control group who received a Maestro electrical pulse generator that was not activated. The 12-month outcomes data found that the trial participants in the group with the activated device lost 8.5% more excess weight than the control group (with the inactivated device). The investigators noted that approximately half (52.5%) of the participants in the activated device group lost at least 20% of their excess weight, while 38.3% of participants with the activated device lost at least 25% of their excess weight. However, the study did not meet its original endpoint, which was for the group with the activated device to lose at least 10% more excess weight than the control group (Sarr, 2012). In the second study, the ReCharge trial, all participants had devices implanted but no leads were placed in the sham group. Primary efficacy outcomes were not met in either of these trials (Ikramuddin, 2014). The MAESTRO device is no longer being marketed in the United States. There remains no evidence that VBLOC therapy is an appropriate and accepted treatment of obesity.

Complications

Revision/Reoperation

According to the ASMBS, in 2016 a total of 216,000 bariatric surgeries were performed with 13.9% of these surgeries being classified as revisions. This is an increase from 2011 when the revision rate was reported as 6%. Some procedures, such as the adjustable gastric band, reported significant rates of revision at 30-60% (Kirshtein, 2016). In a retrospective review of 214 individuals who had subsequent revisional bariatric procedures following adjustable lap band removal, Kirshtein and associates (2016) noted that individuals who underwent band removal without conversion or rebanding gained weight, while those who underwent further bariatric surgery succeeded in further weight loss.

In a 2014 systematic review, Brethauer and colleagues reviewed the current evidence regarding reoperative bariatric surgery. A total of 175 articles covering multiple procedures, such as Roux-en-Y, adjustable gastric banding, sleeve gastrectomy, vertical banded gastroplasty and biliopancreatic diversion with or without duodenal switch, were included. The authors concluded:

> The reported outcomes after reoperative bariatric surgery are generally favorable and demonstrate that additional weight loss and co-morbidity reduction is achieved with additional therapy. The risks of reoperative bariatric surgery are higher than with primary bariatric surgery and the evidence highlights the need for careful patient selection and surgeon expertise.

In addition to surgical complications following bariatric procedures (for example, stricture, erosion, leakage, band slippage), it has been noted that some individuals do not achieve or maintain adequate weight loss post-operatively, despite documented compliance with postoperative nutritional and exercise regimens. In general, it may take up to 2 years to reach maximum weight loss following bariatric surgery. Conversion bariatric surgery may be proposed when adequate weight loss has not occurred after 1 to 2 years following the initial surgery or weight loss has not been maintained. There is

overall agreement that adequate weight loss has been achieved when at least 50% of EWL has been achieved, or when the body weight has reached within 30% of ideal weight ranges (by age, gender, height, etc.). Inadequate weight loss due to noncompliance with the recommended postoperative regimens is not considered to be a failure of the original surgery.

GERD

Increased BMI, waist circumference and weight gain are associated with the presence of GERD (Katz, 2013; Flores, 2019). New-onset GERD, or the exacerbation of GERD is common following bariatric surgery, affecting up to 33% of individuals (Brethauer, 2014). The typical symptoms of GERD include dyspepsia, epigastric pain, early satiety, belching, and bloating (Katz, 2013). As noted by Brethauer (2014) “treatment of GERD is initially medical with acid suppression but if symptoms are refractory to medical therapy or if there is an associated anatomic etiology for the GERD, surgical revision may be required”. The American College of Gastroenterology’s (ACG) 2013 guideline on GERD notes that a presumptive diagnosis of GERD can be made based on a clinical history of heartburn and regurgitation and can be empirically treated with empiric proton pump inhibitors (PPIs). The ACG guideline also notes “The diagnosis of GERD is made using some combination of symptom presentation, objective testing with endoscopy, ambulatory reflux monitoring, and response to antisecretory therapy”. The ACG includes several recommendations regarding objective testing to confirm the diagnosis of GERD:

> Patients with non-cardiac chest pain suspected due to GERD should have diagnostic evaluation before institution of therapy. (Conditional recommendation, moderate level of evidence) A cardiac cause should be excluded in patients with chest pain before the commencement of a gastrointestinal evaluation (Strong recommendation, low level of evidence).
>
> Barium radiographs should not be performed to diagnose GERD (Strong recommendation, high level of evidence).
>
> Upper endoscopy is not required in the presence of typical GERD symptoms. Endoscopy is recommended in the presence of alarm symptoms and for screening of patients at high risk for complications. Repeat endoscopy is not indicated in patients without Barrett’s esophagus in the absence of new symptoms. (Strong recommendation, moderate level of evidence).
>
> Ambulatory esophageal reflux monitoring is indicated before consideration of endoscopic or surgical therapy in patients with non-erosive disease (NERD), as part of the evaluation of patients refractory to PPI therapy, and in situations when the diagnosis of GERD is in question. (Strong recommendation, low level evidence). Ambulatory reflux monitoring is the only test that can assess reflux symptom association (Strong recommendation, low level of evidence).

The incidence of GERD related to bariatric surgery varies with the procedure performed. Approximately 33.3% of LAGB postoperative individuals report exacerbated or new onset GERD at 7 years post-operative. Sleeve gastrectomy (SG) has a similar incidence rate of long-term GERD at 20-30%. GERD is initially treated with conservative measures such as acid suppression or band deflation/adjustment in LAGB. If symptoms are not controlled by medical therapy, there are several surgical options available including band repositioning, hiatal hernia repair or conversion to RYGB (Brethauer, 2014). In individuals initially treated with VBG who are undergoing corrective surgery, approximately 5.6-16.0% of these cases are related to GERD. While revision surgery is an option, revisions do not eliminate the potential mechanical complications; as a result many VBG procedures are converted to an RYGB. Individuals complaining of GERD following biliopancreatic diversion with duodenal switch are initially treated with conservative measures such as behavioral or medical therapies, while a resleeve or fundectomy surgery is an option for those individuals with GERD refractory to conservative therapy.

Surgical treatment of GERD involves augmenting lower esophageal sphincter (LES) pressure, decreasing LES compliance, and, restoring functional anatomy when needed. The gold standard surgical treatment of GERD is laparoscopic antireflux surgery (Flores, 2019). There is no literature regarding the use of bariatric surgery therapy as primary therapy in treatment resistant GERD.

Obstruction or stricture

The incidence of strictures following bariatric procedures vary based on the initial surgical procedure but is generally reported to be between 1-2% and 16-23.0%. Treatment options include endoscopic balloon dilation, endoscopic dilatation with or without stenting and resection of the stricture to conversion to another procedure, generally RYGB (Brethauer, 2014).

Obstructions commonly occur early in the post-operative period but can occur at any time interval following surgery. The treatment of obstructions varies depending upon the cause of the obstruction and the type of bariatric procedure performed. Obstructions following RYGB or biliopancreatic diversion with duodenal switch occur for a variety of reasons and typically require surgical repair to identify and correct the source of the obstruction. Treatment options of post-operative obstruction following LAGB include conservative measures such as observation, band adjustments (fluid removal) or more invasive measures such as the endoscopic removal of impacted food, replacement of the band with a larger band or band removal. Treatment of obstructions following SG include supportive therapy and endoscopic dilation/stenting. Cases of persistent obstruction are treated with conversion to RYGB.

Endoluminal procedures to treat weight regain or insufficient weight loss

Dilatation of the gastrojejunal anastomosis or the gastric pouch following the initial bariatric surgery causes insufficient weight loss or weight recidivism. Weight regain following RYGB is not unusual, with individuals regaining approximately 20% to 30% of the weight they lost at 10 years postoperative (Jirapinyo, 2020). Several endoluminal procedures have been developed as a way to correct the dilatation without re-exposure to surgical risks. Endoluminal procedures include the use of suturing procedures or devices to decrease gastric pouch size (Goh, 2020). The current data fails to show sustained adequate weight loss compared to surgical revision (Goh, 2020).

Transoral outlet reduction (TORe) or Endoscopic gastrojejunal revision

TORe is a minimally invasive endoscopic procedure which reduces the size of the gastrojejunal anastomosis and is proposed as a revisional surgical option for RYGB. TORe can be accomplished a number of ways including with plication devices superficial suturing devices and over-the-scope clip devices. TORe procedures can be further defined by the suture pattern used: purse string or interrupted.

A meta-analysis by Dhindsa and colleagues (2020) evaluated the efficacy and safety of a particular TORe device (Overstitch™; Apollo Endosurgery, Texas, United States) to treat weight regain following RYGB. The primary outcomes chosen included technical success of the procedure, the absolute weight loss and the percent of total weight loss at 3, 6, and 12 months after the procedure. A total of 13 prospective and retrospective studies with 850 individuals were included in the analysis. The pooled rate of technical success was 99.89%. While the pooled percent absolute weight loss and percent total weight loss at 3 and 6 months showed persistent weight loss, there was some weight recidivism at 12 months. The adverse event rate was 11.4% (± 10.11); there was no mortality. The meta-analysis was limited by the short-term follow-up and lack of any control or comparison groups.

Brunaldi and associations (2018) evaluated several endoscopic therapies which were used to address weight regain following RYGB. A total of 32 observational studies were evaluated, including full-thickness endoscopic suturing (n=26), superficial-thickness endoscopic suturing (n=3,), argon plasma coagulation (n=2) and over-the-scope clip (n=1). Full-thickness suturing device studies reported 20% excess weight loss at 1 year. While full endoscopic suturing appeared to be effective at treating weight regain, the follow-up on the included studies was largely limited to 12 months or less. Adverse event rates were not reported. The applicability of the findings were limited by the lack control or comparison arms, low quality of the studies, heterogeneity within the individuals and short-term follow-up.

TORe has been evaluated in several retrospective studies. While there is limited evidence that reports outcomes showing efficacy and safety for up to 5 years, this study as well as the other published trials are limited by multiple factors, including a lack of a control arm, limited sample size, limited long-term data, significant loss to follow-up and heterogeneity among the devices used (Dolan, 2021; Franken, 2023; Jirapinyo, 2018; Jirapinyo, 2020; Trans, 2016; Vargas, 2018). The ASMBS does not address TORe in any clinical guidelines. The use of TORe, a revisional procedure, is not considered in accordance with generally accepted standards of medical practice.

Restorative Obesity Surgery Endoluminal (ROSE)

ROSE utilizes a device which creates plications in the stoma and stomach to decrease the size and fuse the tissue into place using anchors to restore the stomach structure to its original size following surgery. Like all endoluminal procedures, the benefit is there are no incisions and a shorter post-operative recovery period. While the intended reduction in pouch and stoma diameter size is generally achieved, over the first-year post-procedure, the size generally increases. The procedure has been shown to achieve only modest reductions in weight loss in the short-term and fail to maintain weight loss over time (Gallo, 2016).

Operator Dependence in the Safety and Efficacy of Bariatric Procedures

Evidence from a number of reports and case series exists for “operator dependence” in determining the risks and benefits of any bariatric procedure. It is important that the surgeon be extensively trained in the respective procedure and that the initial surgeries are supervised by an experienced bariatric surgeon during the early “learning curve.” It is also important that these surgeries be performed in facilities that are appropriately qualified to support peri-operative and post-op services by an appropriately trained, multi-disciplinary team to ensure maximal success.

Definitions

Adjustable Gastric Banding (AGB): A gastric restrictive procedure in which a gastric band which holds fluid is placed around the exterior of the stomach. Common complications may include slippage of the external band, band erosion, vomiting and ineffective weight loss.

Biliopancreatic Bypass Procedure (also known as the Scopinaro procedure) BPB: A malabsorptive procedure, which consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the small intestine long Roux-en-Y procedure. Potential complications in iron deficiency anemia, protein malnutrition, hypocalcemia, and bone demineralization.

Biliopancreatic Bypass with Duodenal Switch (BPD/DS): A variant of the biliopancreatic bypass in which a sleeve gastrectomy is performed instead of a distal gastrectomy.

Body mass index (BMI): The key index for relating body weight to height. The BMI is a person's weight in kilograms (kg) divided by their height in meters (m) squared. To convert pounds to kilograms; multiply pounds by 0.45; to convert inches to meters, multiply inches by 0.0254. (See the definition below for obesity for further information).

Classifications of Obesity: Adults; children (respectively)

1. BMI of 30 to < 35; BMI ≥ 95th percentile
2. BMI of 35 to < 40; BMI ≥ 120% percentile
3. BMI of 40 or higher; BMI ≥ 140% percentile

Excess body weight: This term refers to the difference between an individual’s actual (measured) and ideal body weight. Ideal body weight ranges are established based on height, body frame, gender and age; an example is available from the National Heart Lung and Blood Institute [NHLBI] at: http://www.nhlbi.nih.gov/guidelines/obesity/bmi_tbl.htm. Accessed on April 11, 2025.

Gastric balloon (Gastric bubble): This device is inserted into the stomach to reduce the stomach’s capacity and produce early satiety. It was generally considered obsolete and was originally intended for temporary use as an adjunct to diet and behavior modification to assist with weight loss.

Gastric banding: This surgical procedure is intended to help a person lose weight. A band is placed around the upper part of the stomach, creating a small pouch that can hold only a small amount of food. The narrowed opening between the stomach pouch and the rest of the stomach controls how quickly food passes from the pouch to the lower part of the stomach. This system helps the person to eat less by limiting the amount of food that can be eaten at one time and increasing the time it takes for food to be digested.

Gastroesophageal Reflux Disease (GERD): Reflux of gastric contents into the upper structures (such as the esophagus, oral cavity, larynx or lung) which causes symptoms or complications. GERD in which there are symptoms without erosions present is further classified as nonerosive disease or NERD. GERD with damage or erosions present on endoscopic exam is classified as erosions present or ERD. The diagnosis of GERD is made using some combination of symptom presentation, objective testing with endoscopy, ambulatory reflux monitoring, and response to antisecretory therapy. Objective documentation of GERD is by confirmed by the presence of erosive reflux disease on endoscopy and or abnormal pH monitoring.

Gastroplasty: A surgical procedure that decreases the size of the stomach.

Laparoscopic gastric plication (laparoscopic greater curvature plication [LGCP]): A gastric restrictive bariatric procedure, which is performed alone or in combination with adjustable gastric banding, where the stomach’s volume is reduced by dissecting the greater omentum and short gastric vessels, and the greater curvature is invaginated using multiple rows of non-absorbable sutures performed over a bougie or endoscope to ensure a patent lumen.

Long Limb Gastric Bypass (i.e., greater than 150 cm): A malabsorptive procedure in which the stomach is bypassed, either by resection or stapling along the horizontal or vertical axis, and the jejunum functions as the alimentary limb. Potential complications are similar to other malabsorptive procedures.

Obesity: The state of being well above one's normal weight, which is measured and determined by the Body Mass Index (BMI). Severe obesity is defined by the NIH as a BMI of 40 kg/m^2 or greater, or a BMI of 35 kg/m^2 or greater along with other medical complications. The NIH defines obesity as a BMI of greater than or equal to 30 kg/m^2 and considers a person overweight with a BMI of 25 to 29.9 kg/m^2.

Roux-en-Y Gastric bypass (RYGB): A restrictive and malabsorptive procedure reduces the stomach capacity and diverts partially digested food from the duodenum to the jejunum (section of the small intestine extending from the duodenum). Often associated with the dumping syndrome in which a large portion of partially digested food is delivered directly to part of the small intestine from the stomach and can cause nausea, weakness, sweating, faintness, abdominal pain and vomiting. This procedure requires that individuals take vitamin and mineral supplements due to decreased ability to absorb nutrients. Complications can include leakage and stomal stricture.

Sleep apnea: The temporary stoppage of breathing during sleep, often resulting in daytime sleepiness.

Sleeve Gastrectomy (SG): Surgical alternative to gastrectomy which involves resection of the greater curvature of the stomach resulting in a sleeve or tube-shaped stomach remnant. Can be performed alone with followed by a malabsorptive procedure.

Surgical conversion or revision: Surgery to switch from the initial procedure to a different procedure.

Surgical correction or repair: Surgery to correct problems, which are the result of the initial procedure, such as complications or incomplete treatment effect.

Surgical reversal: Surgery that restores the original anatomy of an individual.

Vertical Banded Gastroplasty (VBG): A gastric restrictive procedure in which the stomach is divided vertically, and a band is stapled around the top portion of the stomach to decrease its size. Common complications of this procedure include esophageal reflux, as well as either widening or blockage of the narrow portion of the stomach, which may require reoperation.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/08/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Clinical Indications section to reformat MN criteria for initial surgery and remove bariatric arterial embolization from the NMN statement. Revised Discussion and References sections. Revised Coding section, removed 37242, 04L23DZ, 04L23ZZ no longer addressed.
Revised	11/14/2024	MPTAC review. Added endoluminal reoperative bariatric procedure NMN statement. Revised Discussion and References sections.
	10/01/2024	Updated Coding section with 10/01/2024 ICD-10-CM changes; added E88.82, E66.811-E66.89 replacing E66.8, and Z68.56 to end of range.
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion and References sections. Updated Coding section with 01/01/2024 CPT changes to add 0813T; also added CPT NOC code 44238.

Revised	08/10/2023	MPTAC review. Added criteria regarding BMI parameters, pre-operative evaluations and education and treatment plans and removed criteria regarding % weight loss amounts and compliance evaluation for revision/conversion indications. Removed NMN statement regarding stomach stretching and overeating. Updated References section.
	06/28/2023	Updated Coding section with 07/01/2023 HCPCS changes; added C9784, C9785.
Reviewed	02/16/2023	MPTAC review. Updated Discussion and References sections.
Revised	11/10/2022	MPTAC review. Revised reference to children and adolescent section to reflect name of section. Updated Discussion and References sections. Updated Coding section with 01/01/2023 CPT changes; added 43290, 43291 and added 64999 NOC replacing 0312T-0317T deleted 12/31/2022; also removed CPT 00797 associated anesthesia.
Reviewed	08/11/2022	MPTAC review. Updated Discussion and References sections.
	11/17/2021	Updated Discussion and References sections, adding a section NAFLD as an independent risk factor in individuals.
Reviewed	08/12/2021	MPTAC review. Updated Discussion and References sections.
	11/30/2020	Updated the Background/Discussion section to clarify that there is sufficient evidence to support the use of BPD/DS in clinically severe obesity.
Revised	08/13/2020	MPTAC review. Revised criteria requiring participation of at least 6 months in a weight reduction program. Revised not medically necessary indications to remove examples of devices which are no longer available. Updated Discussion and References sections. Reformatted Coding section.
Revised	08/22/2019	MPTAC review. Revised “gastric bypass, using a Billroth II type of anastomosis (also known as a “mini gastric bypass”)” to “One anastomosis gastric bypass, also known as mini gastric bypass”. Added TransPyloric Shuttle and bariatric arterial embolization as not medically necessary indications. Updated Description, Clinical Indications, References, Websites and Index sections. Updated Coding section; added CPT 37242; added ICD-10-PCS 04L23DZ, 04L23ZZ.
	02/27/2019	Added related guideline CG-SURG-92 to the description section.
Revised	01/24/2019	MPTAC review. Revised Medically Necessary indications to simplify criteria regarding preoperative and postoperative documentation and reformatted criteria without a change in intent. Revised criteria regarding reoperations/repeat surgery to clarify th types of surgery. Included additional examples of potential complications. Added N Medically Necessary statement when medically necessary indications are not met. Reformatted Not Medically Necessary section without change in intent.
New	07/26/2018	MPTAC review. Initial document development. Moved contents of SURG.00024 Bariatric Surgery and Other Treatments for Clinically Severe Obesity to clinical utilization management guideline document with the same title.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.