Medical Coverage Policy

Effective Date 7/15/2023
Next Review Date 7/15/2024
Coverage Policy Number............ 0051

Bariatric Surgery and Procedures

Table of Contents

Related Coverage Resources

Gastric Pacing/Gastric Electrical Stimulation (GES)
Surgical Treatments for Obstructive Sleep Apnea
Panniculectomy and Abdominoplasty
Sleep Management
Vagus Nerve Stimulation (VNS)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide

guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses bariatric surgery and procedures for the treatment of morbid obesity.

Coverage Policy

Coverage for bariatric surgery or revision of a bariatric surgical procedure varies across plans and may be governed by state mandates. Refer to the customer's benefit plan document for coverage details.

This coverage policy statement is organized as follows:

1) **Criteria that applies to Adults only**
2) **Criteria that applies to Adolescents only**
3) **Criteria that applies to Adults and Adolescents**

Adults

Bariatric surgery for the treatment of morbid obesity in an adult (age ≥ 18 years) using a covered procedure outlined below is considered medically necessary when ALL of the following criteria are met:

- **EITHER** of the following:
  - BMI (Body Mass Index) ≥ 40 kg/m^2 (class 3 obesity) (BMI ≥ 37.5 kg/m^2 in Asians- when ethnicity is confirmed by provider attestation)
  - BMI (Body Mass Index) 35–39.9 kg/m^2 (class 2 obesity) (BMI 32.5–37.4 kg/m^2 in Asians- when ethnicity is confirmed by provider attestation) with at least one clinically significant obesity-related comorbidity, including but not limited to the following:

- mechanical arthropathy in a weight-bearing joint (symptomatic degenerative joint disease in a weight bearing joint)
- diabetes mellitus
- poorly controlled hypertension (systolic blood pressure at least 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite optimal medical management)
- hyperlipidemia
- coronary artery disease
- lower extremity lymphatic or venous obstruction
- obstructive sleep apnea
- pulmonary hypertension
- evidence of fatty liver disease (i.e., nonalcoholic fatty liver disease [NAFLD] or nonalcoholic steatohepatitis [NASH])
- gastroesophageal reflux disease (GERD) refractory to medical therapy

- A thorough multidisciplinary evaluation within the previous 12 months which includes ALL of the following:

  - a description of the proposed procedure(s)
  - documentation of failure of weight loss by medical management
  - unequivocal clearance for bariatric surgery by a mental health provider
  - a nutritional evaluation by a physician, physician assistant, nurse practitioner or registered dietician

Bariatric Surgical Procedures (Adults)

When the specific medical necessity criteria noted above for bariatric surgery for an adult have been met, ANY of the following open or laparoscopic bariatric surgical procedures for the treatment of morbid obesity is considered medically necessary:

Procedure	**Open CPT® Codes**	**Laparoscopic CPT® Codes**
Vertical band gastroplasty	43842	43659
Adjustable silicone gastric banding (e.g., LAP-BAND®, REALIZE™)	43843	43770
Sleeve gastrectomy as a stand-alone or staged procedure	43843	43775
Roux-en-Y gastric bypass (roux limb less than 150 cm)	43846	43644
Roux-en-Y gastric bypass (roux limb greater than 150 cm)	43847	43645
Biliopancreatic Diversion with Duodenal Switch (BPD/DS)	43845	43659 or 44799
Billiopancreatic Diversion (BPD) without DS	43633	43659 or 44799
Single-anastomosis duodenal-ileal bypass with Sleeve gastrectomy (SADI-S) (i.e. Loop duodenal switch)	43999	43659, 44799, 44238, or 43775

Adjustment of a silicone gastric banding is considered medically necessary to control the rate of weight loss and/or treat symptoms secondary to gastric restriction following a medically necessary adjustable silicone gastric banding procedure.

The following bariatric surgical procedures for the treatment of morbid obesity, when performed alone or in conjunction with another bariatric surgical procedure are considered experimental, investigational or unproven:

Procedure	CPT® Code(s)
Band over bypass	43770, 43843, 43999
Band over sleeve	43770, 43843, 43999
Fobi-Pouch (limiting proximal gastric pouch)	43659, 43843, 43999
Gastric electrical stimulation (GES) or gastric pacing	64590 and 43881 **OR** 64590 and 43647
Intestinal bypass (jejunoileal bypass)	44238, 44799
Intragastric balloon (e.g., Orbera™, ReShape™, Obalon)	43999
Laparoscopic greater curvature plication	43659
Mini-gastric bypass/ One Anastomosis Gastric Bypass (OAGB)/Loop gastric bypass	43659, 43843
Endoscopic bariatric surgery procedures, including but not limited to the following: ➢ Natural Orifice Transluminal Endoscopic Surgery (NOTES) ➢ restorative obesity surgery, endoluminal (ROSE) ➢ StomaphyX™, ➢ duodenojejunal bypass liner (e.g., Endobarrier™) ➢ transoral gastroplasty (e.g., TOGA®) ➢ endoscopic closure devices (e.g., Apollo OverStitch™) ➢ Endoscopic sleeve gastroplasty ➢ Transoral Outlet Reduction (TORe)	43289, 43499
Roux-en-Y gastric bypass combined with simultaneous gastric banding	43644 or 43645 and 43770 **OR** 43846 or 43847 and 43843 or 43999
Stomach aspiration therapy (e.g., AspireAssist®)	43659, 43999
Vagus nerve blocking (e.g., Maestro®)	64999
Vagus nerve stimulation	61885 and 64568 **OR** 61885 and 64553

Reoperation and Revisional Bariatric Surgery (Adults)

Replacement of an adjustable silicone gastric band or separate or concurrent band removal and conversion to a second bariatric surgical procedure is considered medically necessary if there is evidence of band slippage or band component malfunction and the faulty component cannot be repaired.

Gastric band removal is considered medically necessary for gastrointestinal symptoms (e.g., persistent nausea and/or vomiting, gastroesophageal reflux) with or without imaging evidence of obstruction.

The following procedures are considered medically necessary when the individual develops a major complication from a previous bariatric surgical procedure (e.g., stricture, obstruction, erosion, gastric prolapse, ulceration, fistula formation, esophageal dilatation, gastroesophageal reflux disease refractory to medical therapy):

- surgical repair or reversal (i.e., takedown)
- conversion to a medically necessary bariatric surgical procedure

In the absence of a major complication, revision of a previous bariatric surgical procedure or conversion to another procedure for an adult is considered medically necessary when ALL of the following are met:

- Weight loss failure ≥ two years following a previous bariatric surgical procedure
- Individual must meet the initial medical necessity criteria for surgery
    - The requested procedure includes ANY of the following:

Procedure	Open CPT® Codes	Laparoscopic CPT® Codes
Vertical band gastroplasty	43842	43659
Adjustable silicone gastric banding (e.g., LAP-BAND®, REALIZE™)	43843	43770
Sleeve gastrectomy as a stand-alone or staged procedure	43843	43775
Roux-en-Y gastric bypass (roux limb less than 150 cm)	43846	43644
Roux-en-Y gastric bypass (roux limb greater than 150 cm)	43847	43645
Biliopancreatic Diversion with Duodenal Switch (BPD/DS)	43845	43659 or 44799
Billiopancreatic Diversion (BPD) without DS	43633	43659 or 44799
Revision of gastrojejunal anastomosis (gastrojejunostomy)	43860	43659
Single-anastomosis duodenal-ileal bypass with Sleeve gastrectomy (SADI-S) (i.e. Loop duodenal switch)	43999	43659, 44799, 44238, or 43775

Surgical reversal (i.e., takedown), revision of a previous bariatric surgical procedure or conversion to another bariatric surgical procedure is considered not medically necessary for EITHER of the following:

- **Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations**
- **ANY other indication**

Adolescents

Bariatric surgery for the treatment of morbid obesity in an adolescent (age 11–17 years) is considered medically necessary using a covered procedure outlined below when ALL of the following criteria are met:

- The individual has evidence of EITHER of the following:
- BMI (Body Mass Index) ≥ 40 kg/m^2 or ≥ 140% of the 95th percentile (class 3 obesity) (whichever is lower)
- BMI (Body Mass Index) 35–39.9 kg/m^2 or ≥ 120% of the 95th percentile (class 2 obesity) (whichever is lower) with at least one clinically significant obesity-related comorbidity, including but not limited to the following:

  - coronary artery disease
  - diabetes mellitus
  - idiopathic intracranial hypertension
  - poorly controlled hypertension (systolic blood pressure at least 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite optimal medical management)
  - obstructive sleep apnea
  - gastroesophageal reflux
  - nonalcoholic steatohepatitis [NASH])

- A thorough multidisciplinary evaluation within the previous 12 months which includes ALL of the following:

  - a description of the proposed procedure(s)
  - documentation of failure of weight loss by medical management
  - unequivocal clearance for bariatric surgery by a mental health provider
  - a nutritional evaluation by a physician, physician assistant, nurse practitioner or registered dietician

Bariatric Surgical Procedures (Adolescents)

When the specific medical necessity criteria noted above for bariatric surgery for an adolescent have been met, ANY of the following open or laparoscopic bariatric surgical procedures for the treatment of morbid obesity is considered medically necessary:

Procedure	Open CPT® Codes	Laparoscopic CPT® Codes
Sleeve gastrectomy	43843	43775
Roux-en-Y gastric bypass (roux limb less than 150 CM)	43846	43644
Roux-en-Y gastric bypass (roux limb greater than 150 CM)	43847	43645

All other bariatric surgical procedures for the treatment of morbid obesity in an adolescent are considered experimental, investigational or unproven.

Reoperation and Revisional Bariatric Surgery (Adolescents)

The following procedures are considered medically necessary when the adolescent develops a major complication from a previous bariatric surgical procedure (e.g., stricture, obstruction, erosion, gastric prolapse, ulceration, fistula formation, esophageal dilatation, gastroesophageal reflux disease refractory to medical therapy):

- surgical repair

- conversion to a medically necessary bariatric surgical procedure (i.e., Roux-en-Y or sleeve gastrectomy)

In the absence of a major complication, revision of a previous bariatric surgical procedure or conversion to another procedure for an adult is considered medically necessary when ALL of the following are met:

- Weight loss failure ≥ two years following a previous bariatric surgical procedure
- Individual must meet the initial medical necessity criteria for surgery
    - The requested procedure includes ANY of the following:

Procedure	Open CPT® Codes	Laparoscopic CPT® Codes
Sleeve gastrectomy	43843	43775
Roux-en-Y gastric bypass (roux limb less than 150 CM)	43846	43644
Roux-en-Y gastric bypass (roux limb greater than 150 CM)	43847	43645
Revision of gastrojejunal anastomosis (gastrojejunostomy)	43860	43659

Surgical reversal (i.e., takedown), revision of a previous bariatric surgical procedure or conversion to another bariatric surgical procedure is considered not medically necessary for EITHER of the following:

- **Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations**
- **ANY other indication**

Adults and Adolescents

Bariatric Surgery for the Treatment of Other Conditions

Bariatric surgery is considered experimental, investigational or unproven for the primary treatment of any condition other than morbid obesity.

Cholecystectomy, Liver Biopsy, Herniorrhaphy, Prophylactic Vena Cava Filter Placement, or Upper Endoscopy

Prophylactic vena cava filter placement at the time of bariatric surgery is considered medically necessary for an individual who is considered to be high risk for venous thromboembolism (VTE) due to a history of ANY of the following conditions:

- deep vein thrombosis (DVT)
- hypercoagulable state
- increased right-sided heart pressures
- pulmonary embolus (PE)

The following procedures performed in conjunction with a bariatric surgery are considered not medically necessary:

- cholecystectomy in the absence of signs or symptoms of gallbladder disease

- liver biopsy in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver, abnormal intraoperative findings)
- routine vena cava filter placement for individuals not at high risk for venous thromboembolism (VTE)

When performed concurrently as part of a bariatric surgical procedure EACH of the following is considered integral to the procedure and not separately reimbursable:

- **simple suture repair (i.e., without mesh) of a diaphragmatic defect for a hiatal hernia**
- **upper gastrointestinal endoscopy performed concurrent with a bariatric surgery procedure to confirm a surgical anastomosis or to establish anatomical landmarks**

General Background

Obesity and overweight are defined clinically using the body mass index (BMI). BMI is an objective measurement and is currently considered the most reproducible measurement of total body fat. In adults, excess body weight (EBW) is defined as the amount of weight that is in excess of the ideal body weight (IBW), or a BMI ≥ 25 kg/m^2 The National Heart, Lung and Blood Institute (NHLBI) (1998) clinical guidelines recommended that the BMI should be used to classify overweight and obesity and to estimate relative risk for disease compared to normal weight. The American Heart Association, American College of Cardiology and The Obesity Society (AHA/ACC/TOS) updated the NHLBI guidelines in 2013 (Jensen, et al., 2013). The guidelines defined the following classifications based on BMI:

Classification	**BMI**
Underweight	< 18.5 kg/m^2
Normal weight	18.5–24.9 kg/m^2
Overweight	25.0–29.9 kg/m^2
Obesity (Class 1)	30.0–34.9 kg/m^2
Obesity (Class 2)	35.0–39.9 kg/m^2
Extreme Obesity (Class 3)	≥ 40 kg/m^2

BMI is a direct calculation based on height and weight, regardless of gender:

$$\textbf{BMI} = \frac{weight\ (kg)}{height\ (m^2)}\ \textbf{OR}\ \left[\frac{weight\ (lb)}{height\ (in)^2}\right] x\ 703$$

Clinically severe or morbid obesity is defined as a BMI ≥ 40 kg/m^2 or a BMI of 35–39.9 kg/m^2 with comorbid conditions. Another group of individuals who have been identified are the super-obese. Super-obesity has been defined in the literature as a BMI > 50 kg/m^2. Comorbidities of morbid obesity that may be considered include any of the following:

- mechanical arthropathy (weight-related degenerative joint disease)
- type 2 diabetes
- clinically unmanageable hypertension (systolic blood pressure at least 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, or if individual is taking antihypertensive agents)
- hyperlipidemia

- coronary artery disease
- lower extremity lymphatic or venous obstruction
- severe obstructive sleep apnea
- obesity-related pulmonary hypertension

Other severe obesity-related co-morbidities including obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of obstructive sleep apnea [OSA] and OHS), nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), pseudotumor cerebri, gastroesophageal reflux disease (GERD), asthma, venous stasis disease, severe urinary incontinence, or considerably impaired quality of life, may also be considered for bariatric surgical intervention (Mechanick, et al., 2013, updated 2020).

Epidemiologic data has shown that lower BMI values are correlated with risk of type 2 diabetes, cardiometabolic risk factors and increased risk of mortality in South Asian, Southeast Asian, and East Asian populations when compared to other ethnic groups (Ntuk, et al., 2014; Razak et al., 2007; Zhou, 2002). In 2000, the World Health Organization proposed the following weight classification in adult Asians: BMI < 18.5 kg/m^2 indicates underweight, 18.5 to 22.9 kg/m^2 healthy weight, 23 to 24.9 kg/m^2 overweight, 25 to 29.9 kg/m^2 obese class I, and ≥ 30 kg/m^2 obese class II. The U.S. Census Bureau collects race data according to U.S. Office of Management and Budget guidelines and this data is based on self-identification. According to the U.S. Census Bureau, an Asian is a person with origins from the Far East (China, Japan, Korea, and Mongolia), Southeast Asia (Cambodia, Malaysia, the Philippine Islands, Thailand, Vietnam, Indonesia, Singapore, Laos, etc.), or the Indian subcontinent (India, Pakistan, Bangladesh, Bhutan, Sri Lanka, and Nepal) (2010). The National Center for Health Statistics, a division of the Centers for Disease Control (CDC), also collects data on race and states that race is based on a respondent's description of their own racial background, regardless of Hispanic or Latino origin (2019).

The U.S. Department of Health and Human Services set 10-year, measurable public health objectives for the nation, most recently with Healthy People 2030. Healthy People 2030 retained the Healthy People 2020 goal to reduce the proportion of adults with obesity. According to Healthy People 2030, 41.8% of American adults are obese. Healthy People 2020 states, "Obesity is a problem throughout the population. However, among adults, the prevalence is highest for middle-aged people and for non-Hispanic black and Mexican American women (Flegal, et al., 2010). Among children and adolescents, the prevalence of obesity is highest among older and Mexican American children and non-Hispanic black girls (Ogden, et al., 2010). The association of income with obesity varies by age, gender, and race/ethnicity (Ogden, et al., 2007)." According to the National Health and Nutrition Examination Survey 2013-2016 data, more women (40.8%) than men (36.5%) were obese, with non-Hispanic black women having the highest prevalence (55.9%) (Hales , et al., 2018).

Health disparities have been identified in outcomes of bariatric surgery among ethnic groups. Sheka et al. (2019) reported on an analysis of 108,198 patients from the 2015 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program national database to identify differences in mortality, length of stay, readmission, and reintervention by race in patients undergoing laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy (SG). Black patients had a higher body mass index (BMI) preoperatively (laparoscopic Roux-en-Y gastric bypass: 48.0 kg/m^2 vs. 45.7 kg/m^2; SG 46.8 kg/m^2 vs. 44.9 kg/m^2). In both the laparoscopic Roux-en-Y gastric bypass and SG groups, black patients had significantly longer length of stay and higher rates of readmission. Black patients had significantly higher 30-day mortality (0.2% versus 0.1%, $p<.001$) and higher rates of reoperation or reinterventions in the SG group. Amirian et al. (2020) compared the 30-day postoperative outcomes of 106,932 patients from the 2016 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database who underwent primary laparoscopic Roux-en-Y gastric bypass (LRYGB) or laparoscopic sleeve gastrectomy (LSG). The majority of the patients were white (79.5%), followed by 19.3% African American (AA), 0.5% Asian, 0.4% American Indian or Alaska Native, 0.3% Native Hawaiian or other Pacific Islander. After controlling for other covariates in multivariate logistic regression and selecting whites as reference, AA was the only race associated with a higher risk of postoperative complications and readmissions. Additionally, AA and American Indian or Alaska Natives were associated with a higher reintervention rate. For postoperative complications, AA had higher rates of pulmonary embolism and longer length of stay; Asian patients had higher wound disruption, urinary tract infections, and myocardial infarction.

Mocanu et al. (2020) conducted a retrospective review of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program data registry (MBSAQIP) patients who underwent primary laparoscopic sleeve gastrectomy (LSG) or Roux-en-Y gastric bypass (RYGB) from 2015 to 2017 to identify rates of postoperative complications based on specific patient populations. A total of 430,936 patients were identified with 79.3% female, 73.1% white, 17.6% African-American and 9.3% other. When compared to females, males were more likely to develop complications (3.7% versus 3.45%; p=0.002), had increased reoperation rates (1.33% vs. 1.18%; p<0.001) and a 2-fold greater mortality (0.18% vs. 0.07; p<0.001). At 30 days, female patients had increased intervention rates (1.34% vs. 1.18%; p<0.001) and readmission rates (3.89% vs. 3.53%; p<0.001). Black patients had higher rates of serious complications (4.14% vs. 3.41%; p<0.001), mortality (0.13% vs. 0.09%; p<0.001), intervention (1.74% vs. 1.24%; p<0.001), and readmission (5.03% vs. 3.56%; p<0.001) at 30 days when compared with white patients. Independent predictors of major complications were female sex (p<0.001) and black race (p<0.001). Black race was one of the greatest independent predictors of mortality (p<0.001). As identified in these studies, there are significant differences in outcomes following bariatric surgery. The factors that underlie these disparities are unclear and requires further study to optimize bariatric surgery outcomes.

Strategies for Weight Loss

Treatment of obesity is generally described as a two-part process: 1) assessment, including BMI measurement and risk factor identification; and 2) treatment/management. Obesity management includes primary weight loss, prevention of weight regain and the management of associated risk. During the assessment phase, the individual needs to be prepared for the comprehensive nature of the program, including realistic timelines and goals. General recommendations for an overall weight-loss strategy include the following (Gorroll and Mulley, 2009):

- For overweight or obese patients not ready to lose weight, the best approach is to educate them about health risks, address other cardiovascular risk factors, and encourage the maintenance of their current weight.
- For motivated persons who are overweight (BMI 25 to 29.9 kg/m^2) and have two or more obesity-related medical conditions or are frankly obese (BMI >30 kg/m^2), a six-month goal of a 10% weight loss can be set (1 to 2 lb/week) and a program of diet, exercise, and behavioral therapy prescribed. If, after six months, the target weight is not achieved, one can consider adding pharmacologic therapy for those at greatest risk (BMI > 27 kg/m^2 plus two or more cardiovascular risk factors, or BMI > 30 kg/m^2).
- For markedly obese persons at greatest risk (BMI > 35 kg/m^2 with two or more obesity-related medical conditions or BMI > 40 kg/m^2), consider a surgical approach if serious and repeated attempts using the foregoing measures have been unsuccessful.

The NHLBI guidelines (1998) include the following recommendations regarding nonsurgical strategies for achieving weight loss and weight maintenance:

- Dietary Therapy:

- Low-calorie diets are recommended for weight loss in overweight and obese persons. Reducing fat as part of a low-calorie diet is a practical way to reduce calories.
- Optimally, dietary therapy should last at least six months, as many studies suggest that the rate of weight loss decreases after about six months. Shorter periods of dietary therapy typically result in lesser weight reductions.
- The literature suggests that weight-loss and weight-maintenance therapies that provide a greater frequency of contacts between the individual and the practitioner and are provided over the long term should be put in place. This can lead to more successful weight loss and weight maintenance.

- Increased Physical Activity/Exercise is recommended as part of a comprehensive, weight-loss therapy and weight-maintenance program because it:

    - modestly contributes to weight loss in overweight and obese adults
    - may decrease abdominal fat
    - increases cardiorespiratory fitness
    - may help with maintenance of weight loss

- Combined Therapy: The combination of a reduced-calorie diet and increased physical activity is recommended, since it produces weight loss, decreases abdominal fat and increases cardiorespiratory fitness.

- Behavior Therapy: Is a useful adjunct when incorporated into treatment for weight loss and weight maintenance.

In addition, the NHLBI recommended that weight-loss drugs approved by the U.S. Food and Drug Administration (FDA) only be used as part of a comprehensive weight-loss program, including diet and physical activity for individuals with a BMI ≥ 30 with no concomitant obesity-related risk factors or diseases, or for individuals with a BMI ≥ 27 with concomitant obesity-related risk factors or diseases.

Clinical supervision is an essential component of dietary management. According to the NHLBI (1998), "frequent clinical encounters during the initial six months of weight reduction appear to facilitate reaching the goals of therapy". Nutritional counseling by a registered dietitian (RD) in the course of treatment for patients with eating disorders, including overweight and obesity is optimal, as the RD is uniquely qualified to provide medical nutrition therapy for the normalization of eating patterns and nutritional status (American Dietetic Association, 2006). Lifestyle modification should include a referral to a registered dietitian or credible weight loss program/service for counseling in energy intake reduction and nutritional strategies with a weight reduction goal of 5—10% of total body weight. During the period of active weight loss, regular visits of at least once per month and preferably more often with a health professional for the purposes of reinforcement, encouragement, and monitoring will facilitate weight reduction (NHLBI, 1998). Physicians can also provide clinical oversight and monitoring of what are often complex comorbid conditions and can select the optimal and most medically appropriate weight management, nutritional and exercise strategies. Some commercially available diet programs do not consistently provide counselors who are trained and certified as registered dieticians or with other equivalent clinical training. However, diet programs/plans, such as Weight Watchers®, Jenny Craig® or similar plans are acceptable methods of dietary management if there is concurrent documentation of at least monthly clinical encounters with a physician.

Surgical Intervention

The NHLBI recommended weight-loss surgery as an option for carefully-selected adult patients with clinically severe obesity (BMI of 40 or greater; or BMI of 35 or greater with serious comorbid conditions) when less-invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. Surgical therapy for morbid obesity is not only effective in producing weight loss but is also effective in improving several significant complications of obesity, including diabetes, hypertension, dyslipidemia, and sleep apnea. The degree of benefit and the rates of morbidity and mortality of the various surgical procedures vary according to the procedure (Bouldin, et al., 2006).

Access to a multidisciplinary team approach, involving a physician with a special interest in obesity; a surgeon with extensive experience in bariatric procedures, a dietitian or nutritionist; and a psychologist, psychiatrist or licensed mental health care provider interested in behavior modification and eating disorders, is optimal. A mental health evaluation should specifically address any mental health or substance abuse diagnoses, the emotional readiness and ability of the patient to make and sustain lifestyle changes, and the adequacy of their support system. Realistic expectations about the degree of weight loss, the compromises required by the patient and the positive effect on associated weight-related comorbidities and quality of life should be discussed and contrasted with the potential morbidity and operative mortality of bariatric surgery.

With bariatric surgery procedures, patients lose an average of 50–60% of excess body weight and have a decrease in BMI of about 10kg/m^2 during the first 12–24 postoperative months. Long-term studies show a tendency for a modest weight gain (5–7 kg) after the initial postoperative years; long-term maintenance of an overall mean weight loss of about 50% of excess body weight can be expected.

BMI Requirement

Selection criteria for studies have uniformly included BMI ranges for clinically severe or morbid obesity, as outlined by the NHLBI. The use of bariatric procedures in patients with lower BMI measurements, with or without comorbidities, has been evaluated primarily in case series with small patient populations and short-term follow-ups. Cohen et al. (2006) reported an excess weight loss (EWL) rate of 81% for patients (n=37) with uncontrolled co-morbidities who underwent laparoscopic Roux-en-Y gastric bypass. The mean preoperative BMI for these patients was 32.5 kg/m^2. The follow-up range was 6—48 months. A case series (n=93) by Parikh et al. (Sept-Oct 2006) examined the effectiveness of laparoscopic adjustable gastric banding with the LAP-BAND in patients with a BMI of 30-35 kg/m^2. Of the 93 patients, 42 (45%) had co-morbidities, including asthma, diabetes, hypertension, and sleep apnea. At three years of follow-up, the BMI was 18-24 kg/m^2 in 34%, 25-29 kg/m^2 in 51%, and 30-35 kg/m^2 in 10%.

A randomized controlled trial conducted by O'Brien et al. (May 2006) assigned 80 patients with mild to moderate obesity (i.e., BMI 30 kg/m^2 to 35 kg/m^2) to a program of very-low-calorie diets, pharmacotherapy, and lifestyle change for 24 months (nonsurgical group) or to a laparoscopic adjustable gastric band placement. The surgical group was found to have significantly greater weight loss (87.2% EWL) compared to the nonsurgical group (21.8% EWL) ($p<0.001$) at two-year follow-up. Limitations of this RCT include small sample size, short-term follow-up, and the fact that the study was not powered for comparison of adverse events.

Some study results suggest that bariatric surgery may be effective for weight loss in obese patients (i.e., BMI 30—35), with or without comorbidities. However, larger well-designed studies with long-term follow-ups are needed to further define the role of bariatric procedures for this subset of individuals.

The American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE), the Obesity Society (TOS), American Society for Metabolic & Bariatric Surgery

(ASMBS), Obesity Medicine Association (OMA), and American Society of Anesthesiologists (ASA) 2019 updated guidelines have a new guideline regarding adjusting body mass index criterion for bariatric procedures based on ethnicity (e.g., 18.5 to 22.9 kg/m2 is normal range, 23 to 24.9 kg/m2 overweight, and ≥25 kg/m2 obesity for Asians) (Mechanick et al., 2020). This is based on epidemiologic studies that indicate the prevalence of diabetes and cardiovascular disease occur at lower BMI levels in the Asian population than in the white population (Mechanick, et al., 2020; Ntuk et al., 2014; WHO, 2000).

Preoperative Weight Loss

Some propose that participation in a pre-operative weight loss program may provide better postoperative outcomes and reduce or prevent perioperative surgical complications. Weight loss programs may also help to identify those individuals who will be committed to and compliant with the short-term, long-term and lifelong medical management, behavioral changes, lifestyle changes, and diet and physical exercise regimens required to ensure the long-term success of bariatric surgery. However, there is a lack of consensus by professional societies and a lack of evidence in the published peer-reviewed literature to support the clinical effectiveness of preoperative weight loss prior to bariatric surgery. The outcomes of the available evidence are limited and conflicting (Cassie, et al., 2011; National Heart, Lung and Blood Institute [NHLBI], 1998). Despite limited evidence-based support, it is optimal for patients to demonstrate good eating and exercise habits prior to undergoing bariatric surgery in preparation for the post-surgical regimen.

According to the NHLBI Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults (1998), the initial goal of weight-loss therapy should be to reduce body weight by approximately 10% from baseline. With success, further weight loss can be attempted, if indicated, through additional assessment. The NHLBI guidelines further stated that:

- Bariatric surgery is not considered a first-line treatment.
- Even the most severely obese individuals (i.e., super-obese with BMI over 50) can be helped by a preoperative weight loss through a program of reduced-calorie diet and exercise therapy.
- Optimally, dietary therapy should last at least six months.
- Moderate weight loss (i.e., 10% of initial body weight) can significantly decrease the severity of obesity-associated risk factors. It can also set the stage for further weight loss, if indicated.

Bariatric surgeons and centers have advocated for preoperative weight loss, as it is believed that patients who are able to achieve this weight loss are most likely to have successful outcomes after surgery. The benefits of a preoperative weight-loss program include all of the following:

- reduction of the severity of obesity-associated risk factors, such as blood pressure, glucose intolerance, cardiorespiratory function and pulmonary function
- reduction of operative morbidity and surgical risk
- improvement in surgical access with weight loss
- identification of those individuals who will be committed to and compliant with the short-term, long-term and lifelong medical management follow-up, behavioral changes, lifestyle changes, and diet and physical exercise regimen required to ensure the long-term success of this surgery

Literature Review

Studies in the published peer-reviewed medical literature evaluating the impact of preoperative weight loss on the outcomes of bariatric surgery have yielded mixed results. There is a lack of evidence to support the clinical effectiveness of participation in a structured preoperative weight loss program.

Benotti et al. (2009) reported on 881 patients undergoing open or laparoscopic gastric bypass. All preoperative patients completed a six-month multidisciplinary program that encouraged a 10% preoperative weight loss. Study analysis demonstrated that increasing preoperative weight loss was associated with reduced complication frequencies in the entire group for total complications ($p=0.004$) and most likely for major complications ($p=0.06$).

Solomon and colleagues (2009) conducted a prospective randomized controlled trial of patients who underwent laparoscopic Roux-en-Y gastric bypass (LRYGB) after being randomized to either the non-weight-loss group (n=35) or the weight-loss group (n=26). Patients in the weight-loss group were requested to lose 10% or more of their excess body weight prior to surgery. One-year follow-up data were available for 26 patients in the weight-loss group and 18 in the non-weight-loss group. The patients in the weight-loss group had a better weight loss profile in all categories. However there were no statistically significant differences between the two groups in patient weight, BMI, amount of excess weight-loss, change in BMI, and resolution of comorbidities.

Alami et al. (2007) performed a prospective randomized trial (n=61) of patients undergoing laparoscopic gastric bypass surgery. Patients were assigned preoperatively to either a weight loss group (n=26) with a 10% weight loss requirement or a group that had no weight loss requirements (n=35). The two groups were identical in terms of initial weight, BMI, and incidence of comorbidities. Perioperative complications, operative time, postoperative weight loss, and resolution of co-morbidities were analyzed. Of the 61 patients, data was available for 12 at one-year follow-up. Preoperative weight loss before LRYGB was found to be associated with a decrease in the operating room time ($p=0.0084$) and an improved percentage of excess weight loss in the short term ($p=0.0267$). Complication rates were similar in both groups. Preoperative weight loss was also not shown to have a statistically significant impact on the resolution of comorbidities. Study limitations include the small sample size and the number of patients lost to follow-up.

A study by Jamal et al. (2006) compared outcomes of gastric bypass patients undergoing a mandatory 13 weeks of preoperative dietary counseling (PDC) (n=72) to a group of patients without this requirement (n=252). The PDC group had a higher incidence of obstructive sleep apnea compared to the no-preoperative dietary counseling group ($p<0.04$). The two groups had similar incidences of obesity-related comorbidities. The dropout rate prior to surgery was reported to be 50% higher in the PDC group than in the no-preoperative dietary counseling group ($p<0.05$). The no-preoperative dietary counseling patients had a statistically greater percentage of excess weight loss ($p<0.0001$), lower BMI ($p<0.015$), and lower body weight ($p<0.01$) at one-year follow-up. Resolution of major comorbidities, complication rates, 30-day postoperative mortality, and postoperative compliance with follow-up were similar in the two groups (Jamal, et al., 2006). Limitations to the study include its lack of randomization and the relatively short-term follow-up of one year which may not have been long enough to demonstrate differences in outcomes.

Professional Societies/Organizations

American Society for Metabolic and Bariatric Surgery (ASMBS): A 2016 position statement issued by ASMBS cited the lack of data from RCTs supporting mandated preoperative weight loss. The ASMBS stated that patients seeking surgical treatment for clinically severe obesity should be evaluated based on their initial BMI and co-morbid conditions (Kim, et al., 2016).

American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS): According to the guidelines for bariatric surgery from AACE/TOS/ASMBS all patients seeking bariatric surgery should have a comprehensive preoperative evaluation. A brief summary of personal weight loss attempts, commercial plans, and physician-supervised programs should be reviewed and documented, along with the greatest duration of weight loss and maintenance. This information is useful in substantiating that the patient has made reasonable attempts to control weight before considering obesity surgery. The guidelines stated that preoperative weight loss should be considered for patients in whom reduced liver volume can improve the technical aspects of surgery (Mechanick, et al., 2008, updated 2013, 2020).

American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): In a 2022 joint statement the indications for metabolic and bariatric surgery, the ASMBS and IFSO state the lack of data to support the practice of mandated preoperative weight loss. A multidisciplinary team should be utilized to assess and manage the patient's modifiable risk factors with a goal of reducing risk of perioperative complications and improving outcomes (Eisenberg, et al., 2022).

Medical Clearance Recommendations

The American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines on support for the bariatric surgery patient stated that all patients should undergo preoperative evaluation for obesity, related co-morbidities and causes of obesity, with special attention directed to those factors that could affect a recommendation for bariatric surgery. The preoperative evaluation must include a comprehensive medical history, psychosocial history, physical examination and appropriate laboratory testing to assess surgical risk. A GI evaluation may be indicated preoperatively in symptomatic patients (e.g. H. pylori screening in areas of high prevalence; gallbladder evaluation and upper endoscopy). Patients should be followed by their primary care physician and have age and risk appropriate cancer screening before surgery. Recommended elements of medical clearance for bariatric surgery include the following (Mechanick, et al., 2013, updated 2020):

1. In patients considered for bariatric surgery, chest radiograph and standardized screening for obstructive sleep apnea (with confirmatory polysomnography if screening tests are positive) should be considered.
2. Tobacco use should be avoided at all times by all patients. In particular, patients who smoke cigarettes should stop, preferably at least six weeks before bariatric surgery.
3. Noninvasive cardiac testing beyond an electrocardiogram is determined on the basis of the individual risk factors and findings on history and physical examination
4. All patients should undergo evaluation of their ability to incorporate nutritional and behavioral changes before and after bariatric surgery.
5. All patients should undergo an appropriate nutritional evaluation, including micronutrient measurements, before any bariatric surgical procedure. In comparison with purely restrictive procedures, more extensive perioperative nutritional evaluations are required for malabsorptive procedures.
6. A psychosocial-behavioral evaluation, which assesses environmental, familial, and behavioral factors, should be required for all patients before bariatric surgery. Any patient considered for bariatric surgery with a known or suspected psychiatric illness, or substance abuse, or dependence, should undergo a formal mental health evaluation before performance of the surgical procedure.

Bariatric Surgical Procedures

Bariatric surgery for morbid obesity involves reducing the size of the gastric reservoir, contributing to the establishment of an energy deficit by restricting caloric intake. The goal of bariatric surgery is to induce and maintain permanent loss of at least half of the preoperative, excess body weight.

This amount of weight loss should bring the patient to a weight at which many or most weight-related comorbidities are reverted or markedly ameliorated. The NHLBI report (1998) has recognized two types of operations that have proven to be effective: restrictive procedures that limit gastric volume and malabsorptive procedures which in addition to limiting food intake also alter digestion.

Gastric Bypass

Gastric bypass procedures combine the creation of a small stomach pouch to restrict food intake and construction of a bypass of the duodenum and other segments of the small intestine to produce malabsorption. The Roux-en-Y gastric bypass (RYGB) is the most commonly performed gastric bypass procedure. RYGB has also been less frequently performed for other indications such as gastroparesis. During RYGB, a small stomach pouch is created by stapling or by vertical banding to restrict food intake. Next, a Y-shaped section of the small intestine consisting of two limbs and a common channel is attached to the pouch to allow food to bypass the duodenum and jejunum. This procedure results in reduced calorie and nutrient absorption. The degree of intended malabsorption is determined by the length of the Roux limb or common channel and varies as follows: standard (short-limb), 40 cm; long-limb, 75 cm; and very long-limb, 150 cm. Complications of the RYGB include anastomotic leaking and strictures, nutritional deficiencies, and the dumping syndrome. The dumping syndrome occurs when a large amount of undigested food passes rapidly from the stomach into the small intestine and is characterized by abdominal pain, nausea, vomiting and weakness.

RYGB can be performed via open and laparoscopic approaches. A systematic review of the scientific literature on open and laparoscopic surgery for morbid obesity (Gentileschi, et al., 2002) concluded that laparoscopic Roux-en-Y is as safe as open RYGB. The overall body of evidence indicates that, in general, laparoscopic RYGB has been shown to achieve significant sustained weight loss with resolution of obesity-related comorbidities (Jan, et al., 2005; DeMaria, et al., 2002; Schauer, et al., 2000; Wittgrove and Clark, 2000). Evidence suggests that weight-loss outcomes are comparable to open gastric bypass at one year. In comparative trials, RYGB has been reported to be associated with substantially greater weight loss and reduction of comorbidities following surgery. It continues to be the surgical treatment of choice for morbid obesity (Weber, et al., 2004; Lee, et al., 2004).

Gastric Banding

In this restrictive procedure**,** a band made of special material (e.g., silicone, polypropylene mesh, Dacron vascular graft) is placed around the stomach near its upper end, creating a small pouch and a narrow passage into the larger remainder of the stomach. Adjustable gastric banding refers to bands in which the pressure can be changed without an invasive procedure. The open approach to gastric banding is considered obsolete in practice and has largely been replaced by laparoscopic techniques.

Laparoscopic Adjustable Silicone Gastric Banding (LASGB)

LASGB is a minimally invasive gastric restrictive procedure that involves the wrapping of a saline-filled band around an area of the stomach with the goal of limiting food consumption. The adjustable band can be inflated or deflated percutaneously via an access port (reservoir) attached to the band, based on weight changes. The access port is placed in or on the rectus muscle, allowing for noninvasive band adjustment. This adjustment process helps determine the rate of weight loss and is an essential part of LASGB therapy. Appropriate adjustments, made up to six times annually, are critical for successful outcomes (Buchwald, 2005). Adjustable gastric banding devices approved for marketing in the U.S. include the Bioenterics® LAP-BAND® Adjustable Gastric Banding (LAGB®) System (ReShape Lifesciences, Inc, San Clemente, CA), and the REALIZE™ Adjustable Gastric Band (Ethicon Endo-Surgery, Inc., Cincinnati, OH).

US Food and Drug Administration (FDA)
The LAP-BAND (ReShape Lifesciences, Inc., San Clemente, CA) received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) in June 2001. The FDA- approval letter stated that the LAP-BAND is indicated for use in weight reduction for severely obese patients with a BMI of at least 40; with a BMI of at least 35 with one or more severe comorbid conditions; or who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables. The letter further states that the device is indicated for use only in severely obese patients who have failed more conservative weight reduction alternatives, such as supervised diet, exercise and behavior modification programs (FDA, 2001).

On February 16, 2011, the FDA expanded the indication for use of the LAP-BAND to include obese individuals with a BMI of 30–35 who also have an existing condition related to their obesity. The expanded approval was based on the results of a prospective, non-randomized, multi-center five-year study (n=149) conducted under an FDA-approved Investigational Device Exemption, that examined the use of the LAP-BAND in patients with BMI measurements between 30 and 40. Of the 149 subjects, 63 had a BMI between 30 and 35. Results showed that 80% of patients demonstrated a 30% loss of excess weight which was maintained at one year. Some patients in the study lost no weight, while others lost more than 80% of their excess weight. Approximately 70% of patients experienced an adverse event, most often vomiting and difficulty swallowing. These events ranged from mild to severe; most were mild and resolved quickly. Of the 149 patients, seven required additional procedures after LAP-BAND implantation. The FDA has required that post-approval studies be performed by the manufacturer (FDA, 2011).

According to patient information provided by the manufacturer of the LAP-BAND, when the band is initially placed, it is usually left empty or only slightly inflated to allow time for adjustment to the device and healing. The first band adjustment is typically done approximately four to six weeks after the initial placement. There is no set schedule for adjustments. The surgeon decides when it is appropriate to adjust the band based on weight loss, amount of food the individual can eat, exercise and amount of fluid currently in the band. Adjustments can be made in the hospital or in a doctor's office. Fluoroscopy may be used to assist in locating the access port, or to guide the needle into the port. It is also used after the band has been adjusted to evaluate the pouch size and stoma size. During each adjustment, a very small amount of saline will be added to or removed from the band. The exact amount of fluid required to make the stoma the right size is unique for each person. More than one adjustment may be needed to achieve an ideal fill that will result in gradual weight loss. If a band is too loose, this may cause a patient to feel hungry or dissatisfied with small meals. A band that is too tight may result in dysphagia, regurgitation or maladaptive eating.

The REALIZE Adjustable Gastric Band received FDA PMA approval September 2007. Similar to the LAP-BAND, the REALIZE is indicated for weight reduction in morbidly obese patients with a BMI of at least 40 or a BMI of at least 35 combined with one or more comorbid conditions. The Band is also indicated for use only in morbidly obese adult patients who have failed more conservative weight-reduction alternatives such as supervised diet, exercise and behavior modification programs. The Band comes in one size and the fit is customized by increasing or decreasing the amount of saline in the balloon. The balloon is designed to hold up to nine milliliters of saline. Contraindications for the Band are also similar to those of the LAP-BAND and include inflammatory diseases of the gastrointestinal tract, severe cardiopulmonary disease, portal hypertension, and cirrhosis of the liver.

Literature Review
Evidence in the published, peer-reviewed scientific literature suggests that laparoscopic adjustable gastric banding (LAGB) is a safe and effective surgical treatment option for patients with morbid obesity. Although a large number of studies have reported on the effectiveness of this technique,

available evidence supporting the use of adjustable gastric banding is primarily in the form of retrospective reviews and prospective case series. Numerous case series have been published, with several studies including over 500 patients each. A limited number of randomized trials have been published, with few studies comparing adjustable gastric banding with established surgical approaches, such as gastric bypass. Well-designed comparative clinical trials comparing adjustable banding with established bariatric surgical procedures are limited. BMI inclusion criteria for studies have generally been within the guidelines set forth by the NHLBI (i.e., BMI ≥ 40 or 35–39.9 with an obesity related co-morbid condition). While a number of these studies and case series report a substantial weight loss following laparoscopic banding, the percentage of excessive weight loss (EWL) after one year appears to be less than the percentage of EWL associated with gastric bypass procedures (O'Brien, et al., 2003). Reported success rates and results have been variable across studies.

Angrisani et al. (2007) performed a prospective, randomized comparison (n= 51) of LAGB with the LAP-BAND system and LRYGB. At five-year follow-up, the LRYGB patients had significantly lower weight and BMI and a greater percentage of excess weight loss than those in the LAGB group ($p<0.001$). Weight loss failure was observed in nine of 26 LAGB patients and in one of 24 LRYGB patients ($p<0.001$). These study results suggested that LRYGB resulted in a higher percentage of weight loss compared to LAGB.

Jan et al. (2005) studied a consecutive series of patients who underwent either LRYGB (n=219) or LAGB (n=154) over a three-year period by a single surgeon. The authors reported that the LAGB group had shorter operative times, less blood loss and shorter hospital stays as compared to the LRYGB group. The incidence of minor and major complications was reported to be similar in the two groups, with the morbidity potentially greater after LRYGB and the reoperation rate greater after LAGB group. Early weight loss was greater in the bypass group; however, it was noted that the difference appeared to diminish over time.

Several early studies reported high failure and complication rates associated with the banding procedure. Reported complications include both operative complications (splenic or esophageal injury) and late complications (band slippage, gastric erosion of the band, dilatation, reservoir deflation/leak, persistent vomiting, long-term failure to lose weight and gastric reflux) (Gustavsson, et al., 2002; Victorzon and Tolonen, 2001; Holeczy, et al., 2001).

More recent studies have reported varying rates of complications, with a focus on the more commonly occurring complications of band slippage and erosion. Rates of slippage have reportedly decreased with band improvements over time and changes in surgical technique. Himpens et al. (2011) presented long-term data from a case series of 82 patients who underwent LAGB. At 12-year follow-up, 54.3% of patients were available. Band erosion occurred in 28% of patients, with 17% of patients converting to laparoscopic Roux-en-Y gastric bypass. Overall, the mean excessive weight loss (EWL) was 42.8% (range, 24%-143%) at 12 years of follow-up. A mean EWL of 48% was found for patients who still had a band in place (51.4%).

Singhal et al. (2010) performed a meta-analysis (n=19 studies) of LAGB patients to examine the correlation between the occurrence rates for band erosion and slippage. The mean rates of erosion and slippage at two years or more of follow-up were found to be 1.03% and 4.93% respectively. The results demonstrated a statistically significant correlation between erosion and slippage rates ($p=0.48$; $p=0.032$).

Currently there is insufficient evidence to support the use of LAGB in patients with a BMI less than 35.

Biliopancreatic Diversion with and without Duodenal Switch

As described originally by Scopinaro, the biliopancreatic diversion (BPD) is principally a malabsorptive procedure in which the distal two-thirds of the stomach are removed. The small pouch that remains is connected directly to the final segment of the small intestine, diverting bile and pancreatic juice into the distal ileum. Increased malabsorption and greater excess weight loss (EWL) occur, but at the expense of a higher incidence of both surgical and metabolic complications. These complications include: anastomotic ulceration, diarrhea, protein caloric malnutrition, metabolic bone disease and deficiencies in the fat-soluble vitamins, vitamin B_{12}, iron and calcium.

Hess adapted the procedure to include the duodenal switch (DS). The biliopancreatic diversion with duodenal switch (BPD/DS) incorporates both malabsorptive and restrictive mechanisms to minimize complications while still producing significant therapeutic weight loss. The procedure involves vertical subtotal gastrectomy with preservation of the pylorus. The first part of the duodenum is divided and attached to the terminal ileum. Sparing the pylorus significantly reduces the incidence of dumping syndrome, obstruction and stricture. Preservation of the early part of the duodenum results in a reduction in the incidence of vitamin and iron deficiencies. The majority of surgeons who perform BPD now incorporate DS (Neligan and Williams, 2005). In some centers, BPD/DS has been proposed as the procedure of choice for a subset of patients with a BMI > 50 or the super morbidly obese. The procedure is considered technically demanding with an operative mortality of 2% and major perioperative morbidity of 10%. Postoperative EWL is reported to range between 70% and 80%.

Literature Review
Biliopancreatic Diversion (BPD) without Duodenal Switch (DS): There is limited available evidence in the published literature evaluating the safety and effectiveness of BPD without duodenal switch (DS). Evidence supporting BPD without DS is primarily in the form of case series with up to five years follow-up (Guedea, et al. 2004), nonrandomized studies comparing outcomes based on the length of the common and alimentary limbs in the procedures (Gracia, et al., 2007) and retrospective reviews (Sethi, et al., 2016). Some studies reported favorable weight loss and remission of comorbidities following surgery. This established procedure has been largely replaced by BPD with duodenal switch (BPD/DS).

Biliopancreatic Diversion (BPD) with Duodenal Switch (DS): Randomized controlled trials, comparative studies and case series support BPD with DS for the treatment of obesity when medical management has failed. The results of the studies included statistically significant improvements in BMI and co-morbid conditions (e.g., total cholesterol, low-density lipoprotein cholesterol concentration, anthropometric measures) (Sovik et al. 2011; Sovik, et al. 2010; Topart, et al., 2011; O'Rourke, et al., 2006, Prachand, et al., 2006; Hess, et al., 2005; Parikh, et al., 2005; Rabkin, et al., 2003; Anthone, et al., 2003).

Professional Societies/Organizations
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES): The SAGES (2008) guideline for laparoscopic bariatric surgery stated that In BPD, the common channel should be 60–100 cm, and the alimentary limb 200–360 cm. DS diminishes the most severe complications of BPD, including dumping syndrome and peptic ulceration of the anastomosis. BPD is effective in all BMI > 35 kg/m^2 subgroups, with durable weight loss and control of comorbidities beyond five years. Laparoscopic BPD provides equivalent weight loss, shorter hospital stay, and fewer complications than the open approach. BPD may result in greater weight loss and resolution of comorbidities than other bariatric surgeries, but with the highest mortality rate.

Single Anastomosis Duodenal-ileal Bypass with Sleeve Gastrectomy (i.e. Loop duodenal switch)

The biliopancreatic diversion with duodenal switch (BPD/DS), while proven to be efficacious for excessive weight loss (EWL) is technically difficult to perform and comes with possibility of long-term nutritional problems. Various modifications of the DS procedure have been introduced in an attempt to simplify the procedure and decrease the associated adverse effects. The single-anastomosis duodenal switch, also called stomach intestinal pylorus sparing surgery (SIPS), or the single loop DS, is similar to the standard DS procedure, with the exception of the small intestine being transected at one point instead of two. With this operation, the majority of the fundus is removed as in a sleeve gastrectomy, but basic stomach function remains. In addition, approximately one half of the upper small intestine is bypassed, resulting in a moderate decrease in calorie absorption. Weight loss is achieved both through restriction of food consumption and malabsorption. Another modification is the single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) which is based on the BPD in which a sleeve gastrectomy is followed by an end-to-side duodeno-ileal diversion. The preservation of the pylorus allows for reconstruction in one loop, which reduces operating time and needs no mesentery opening. In theory, single-anastomosis duodenoileal bypass with sleeve gastrectomy is a simplification of the DS that may mimic the standard BPD, but is faster and easier to perform. The single anastomosis duodenal-ileal bypass with sleeve gastrectomy and one anastomosis duodenal switch (SADI-S/OADS) is another proposed modification of duodenal switch anastomosing the duodenum directly to an omega loop of ileum 200 cm proximal to the ileo-cecal valve, eliminating the need for the Roux-en-Y jejunal-ileal anastomosis. Theoretical benefits over duodenal switch (DS) include reduction of the operative risk by eliminating one anastomosis with potentially similar outcomes in weight loss and health benefits. Other similar one anastomosis duodenal switch procedures reported in the literature include: SIPS (stomach intestinal pyloric sparing surgery), single anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG), loop duodeno-jejunal bypass with sleeve gastrectomy (LDJBSG), single anastomosis duodenal switch, distal loop duodeno-ileostomy (DIOS) and proximal duodenojejunotomy (DJOS) (Brown, et al., 2018).

Literature Review

The SADI-S technique is a simplification of the biliopancreatic diversion with duodenal switch (BPD-DS) and provides similar outcomes to those reported after the classic DS (Kallies, et al., 2020). The evidence evaluating single anastomosis duodeno-ileal bypass, SADI-S or other modifications of this procedure for morbid obesity consists primarily of case series and retrospective reviews (Spinos, et al., 2021; Yashkov, et al., 2021; Zaveri, et al., 2019; Moon, et al., 2019; Neichoy, et al., 2018; Surve, et al., 2018; Surve, et al., 2017; Cottam, et al., 2016; Mitzman, et al., 2016; Sánchez-Pernaute, et al., 2015; Lee, et al., 2014; Sánchez-Pernaute, et al., 2012).

Spinos, et al. (2021) conducted a systematic review to evaluate the effectiveness, complications and long-term overall nutritional status of patients who have undergone single-anastomosis duodenoileal bypass with sleeve gastrectomy/one anastomosis duodenal switch (SADI-S/OADS). A total of 14 studies reporting on the weight loss and metabolic/nutrient impact of SADI-S (five retrospective cohort and nine case series) met inclusion criteria. Narrative reviews, systematic reviews and meta-analyses, case reports, basic science papers, letters to the editor, commentaries, and published abstracts were excluded. All papers reporting on any modifications of the standard SADI-S procedure were also excluded. A total of 1086 patients were included in the analysis: 68.4 % female, average age 45.0 ± 11.4 years with preoperative BMI 51.3 ± 9.5 kg/m^2. Race was not reported. The studies represented patients from a wide geographical distribution including the Netherlands, Spain, Portugal, Italy, Egypt, Czech Republic, Brazil, China, and the United States. The average body mass index (BMI) following SADI-S was 32.1 ± 6.7 kg/m^2. Mean total body weight (TBW) loss ranged from 11.3% to 17.3% at three months, 21.5% to 41.2% at 12 months, and 25.8% to 46.3% at 24 months. Mean excess body weight (EBW) loss ranged from 21.8% to 40.2% at three months, 60.9% to 91.0% at 12 months, and 44.3% to 86.0% at 24 months. Mean excess BMI (EBMI) ranged from 9.4% to 31.1% at three months, 17.9% to 86.6% at 12 months, and 19.5% to 80.8% at 24 months. The comorbidity resolution rates were 72.6% for diabetes mellitus (DM), 77.2% for dyslipidemia, 59% for hypertension (HTN), 54.8% for obstructive sleep apnea (OSA), and 25% for gastroesophageal reflux disease (GERD). Additionally, rates of improvement of comorbid conditions were 19.1% for DM, 27.1% for dyslipidemia, 31.7% for HTN, 28% for OSA, and 25% for GERD. The most common early (< 30 days) postoperative complications after SADI-S included the need for reoperation (3.1%), bleeding (1.1%), wound infection (1.0%), anastomotic leak (0.9%), and intrabdominal collection/abscess (0.6%). Late (> 30 days) postoperative complications were the need for reoperation (5.3%) and malnutrition/dumping syndrome (1.3%). Four deaths were noted: one in early postoperative period due to an anastomotic leak, three in the late postoperative period from cardiac arrest, untreated obstructed sleep apnea, and ventricular fibrillation. Only one study reported on the preoperative nutritional status of patients. All studies reported nutritional deficiencies postoperatively, specifically calcium, vitamin D, and PTH values. Additional abnormalities were observed in the total serum protein, albumin, zinc, selenium, and copper. Author noted limitations included heterogeneity in the technical aspects of the operations and reported outcomes; included studies were either retrospective cohort studies or case series, and short-term follow ups. SADI-S offers the benefits of a combined malabsorptive and restrictive bariatric operation, with fewer postoperative complications than the traditional standard biliopancreatic diversion with duodenal switch (BPD/DS).

Yashkov et al. (2021) conducted a retrospective review to compare the results of single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) and Hess-Marceau's BPD/duodenal switch (RY-DS) operations at five years in 754 patients. The group that received SADI-S (n=226) had an average age of 42 ± 11 years, 30.1% were males and presented with a preoperative BMI of 48.9 ± 9 kg/m^2. The RY-DS group (n=528) presented with an average age of 39 ± 9.9 years, 20.8% were males and had a preoperative BMI of 47.9 ± 7.3 kg/m^2. Race or ethnicity was not detailed, however surgeries were performed by a single surgeon in the Russian Federation. Data extracted included weight loss parameters including total weight loss (TWL%), excess BMI loss (EBMIL%), excess weight loss (EWL%); remission of diabetes mellitus type 2; complications; and revision rate in the SADI-S group and was compared with the results of RY-DS group. At 12 months, EWL% (77% vs 73.3%) and TWL% (39.4% vs 38.9%) were better in the SADI-S ($p< 0.01$, and $p<0.05$ respectively) than in the RY-DS group. EWL, TBWL, and EBMIL were comparable between the two groups at 24-36 months. RY-DS group had better weight loss (TBWL, EBMIL, EWL) in the fourth and fifth year. Diabetes remission occurred in 93.4% of SADI-S at three years and 98.6% of RY-DS patients at five years. Early complication rate was 2.65% in the SADI-S and 5.1% in the RY-DS groups. Protein deficiency (0.26% vs 0.55%) and small bowel obstruction rates (0.26% vs 0.4%) were lower after SADI-S, however bile reflux occurred in 7.5% of patients (n=17) and was a main reason (6 of 9) for revisions. No bile reflux occurred in the RY-DS group. Revisions occurred in 13.3% of RY-DS patients to improve results (n=31) and to treat side effects/complications (n=39). Author noted limitations of the study included the retrospective study design and that both surgeries were performed using an open technique. SADI-S was a simpler surgery to perform, had lower early complication rates, less protein deficiency, less small bowel obstruction rates and less revisions while providing similar weight loss and diabetes remission up to three years when compared to the RY-DS procedure.

Moon et al. (2019) conducted a retrospective review to compare the safety and effectiveness of single-anastomosis duodenal-ileal bypass (SADI-S) to the traditional double-anastomosis duodenal switch (DS) on 185 patients at a single institution in the United States. In the SADI-S group (n=111), the mean age was 41.5 ± 9.5 years, 81 were female and 30 were male with a mean preoperative body mass index (BMI) of 56.3 kg/m^2. The double-anastomosis DS patients (n=74) had a mean age of 40.8 ± 9.4 years with 57 female and 17 male patients with a mean BMI of 54.4 kg/m^2. The majority of patients in both groups were white at 67.6% (n=75) and 75.7% (n=56) for SADI-S and double anastomosis DS, respectively. Follow ups were conducted at one, three, six, 12 months and yearly thereafter. There was significant loss to follow up by 24 months (n=23). Weight loss was comparable for the two groups. In the SADI-S group, percentage of total weight loss (TWL) was 22.0%, 38.5%, and 44.2% at 6, 12, and 24 months, respectively. TWL in the double anastomosis group was 20.2%, 38.0%, and 48.4% for the same time frame. The majority of patients had normal levels of vitamin A and E, however vitamin D levels were low in 40-60%. At last follow up, remission of diabetes occurred in all in SADI-S (54/54) and all in double anastomosis DS (32/32). Readmission rate within 30 days was lower for double-anastomosis DS (n=4) than SADI-S (n=13). Author noted study limitations included retrospective study design with significant loss to follow up as time progressed. An additional study limitation was that the majority of subjects were white women.

Neichoy et al. (2018) conducted a retrospective analysis on 225 patients who underwent stomach intestinal pylorus-sparing (SIPS) procedure to evaluate safety and effectiveness of the procedure. SIPS is a modification of the Roux-en-Y duodenal switch (RYDS) procedure. The mean preoperative body mass index (BMI) was 52.4 ± 9.1 kg/m^2 and weight was 324 ± 71.7 pounds (lbs.). The majority of the patients were female (77%) with an average age of 49.3 ± 11.3 years. Race or ethnicity was not detailed. Follow ups were conducted at one, three, six, 12 months and yearly thereafter. Mean excess weight loss was 36.7% at three months, 50.6% at six months, 60.4% at nine months, 71.3% at 12 months, 81.1% at 18 months and 88.7% at 24 months. The average BMI points lost at 24 months was 26.6 ± 7.1. Comorbidity resolution occurred in 94.4% of those with sleep apnea, 88.8% with type 2 diabetes, 68.4% with hypertension, 78.7% with hyperlipidemia, and 86% with gastroesophageal reflux. Short term complications included leak from the duodenoileostomy (DI) (n=5, 2%), stricture at the DI (n=3, 1%), small bowel injury (n=1) and death related to surgery (n=2). Long term complications included stricture at the DI (n=1), peripheral edema (n=3), diarrhea (n=5), malnutrition (n=3), dysphagia (n=2), superior mesenteric venous thrombosis (n=1), liver abscess (n=1), and death related to surgery (n=2). Author noted study limitations included the retrospective study design, small patient population, and lack of long term follow up.

Surve et al. (2017) conducted a retrospective review to compare the outcomes of 182 patients who underwent either biliopancreatic diversion with duodenal switch (BPD-DS) (n=62) or stomach intestinal pylorus sparing surgery (SIPS) (n=120) at a single private institution. The majority of patients were female (BPD-DS 61%; SIPS 65%) with an average age of 51.7 ± 12.3 years for BPD-DS and 49.1 ± 14 years for SIPS. Race or ethnicity was not detailed. Operative time for BPD-DS group was 136.9 ± 35.5 minutes compared to 69.9 ± 15.8 minutes for SIPS. Length of hospital stay for BPD-DS was 4.1 ± 6.2 days while SIPS was 2 ± days. The percent excess weight loss (%EWL) and body mass index (BMI) lost for the BPD-DS group was 46.7% and 11.2 kg/m^2 at three months, 67.3% and 16.2 kg/m^2 at six months, 79.3% and 19.2 kg/m^2 at nine months, 86.6% and 21 kg/m^2 at 12 months, 92.7% and 22.7 kg/m^2 at 18 months, and 94.9% and 23.3 kg/m^2 at 24 months. The reported %EWL and BMI for the SIPS group was 44% and 10.2 kg/m^2 at three months, 62.1% and 14.3 kg/m^2 at six months, 72.7% and 16.8 kg/m^2 at nine months, 79.3% and 18.4 kg/m^2 at 12 months, 85% and 19.8 kg/m^2 at 18 months, and 87.1% and 20.3 kg/m^2 at 24 months. When comparing nutritional outcomes from baseline to 24 months, there was statistical difference (improvement) for glucose, HbA1C, insulin, cholesterol, triglyceride, vitamin D, and vitamin B1 for both procedures. There was no statistical difference between the two groups for postoperative nutritional data such as vitamins D, B1, B12, serum calcium, fasting blood glucose, glycosylated hemoglobin (HbA1C), insulin, serum albumin, serum total protein, and lipid panel. Short-term complication rate for the BPD-DS group was 20.9% and included intraabdominal abscess (n=2), anastomotic leak (n=2), sepsis (n=2), postoperative bleed (n=2), mild renal failure (n=2), duodenal stump leak (n=1), peritonitis (n=1), and small bowel obstruction (n=1). Short-term complication rate for the SIPS group was 1.6% and included acute blood loss anemia (n=1) and intraabdominal hematoma (n=1). Long-term complication rate for BPD-DS group was 32.2% and included diarrhea (n=7), malnutrition (n=5), hiatal hernia (n=3), sleeve stricture (n=2), liver failure (n=1) and common channel lengthening (n=1). Long term complication rate for the SIPS was 10.8% and included diarrhea (n=1), malnutrition (n=1), hiatal hernia (n=2), sleeve stricture (n=4), constipation (n=2), retrograde filling of the afferent limb (n=2), and common channel lengthening (n=1). No complications resulted in death. Author noted study limitations included the retrospective study design, small patient population, and lack of long term follow up. The SIPS is a simplified DS procedure. The SIPS eliminates one anastomosis and compared with BPD-DS has fewer perioperative and postoperative complications, shorter operative time and length of stay, and similar nutritional results at two years.

Cottam et al. (2015) conducted a retrospective review of a matched cohort of 108 patients who underwent either a Roux-en-Y gastric bypass (GBP) (n=54) or a single anastomosis loop duodenal switch (LDS) (n=54) to compare weight loss outcomes and complication rate. The cohort was matched based on gender and body mass index (BMI) within one point. The baseline BMI was 47.6 ± 8.8 kg/m^2 with 38 females and 16 males in each group. Average age for the GBP group was 46.7 ± 13.6 years and 51.9 ± 13 years for the LDS group. The percent of weight lost (%WL) for the GBP group was 19.5% at three months, 27.5% at six months, 32.7% at nine months, 36.1% at 12 months, 38.3% at 15 months and 39.6% at 18 months. The %WL for the LDS group was 19.2%, 26.8%, 32.3%, 36.3%, 39.1% and 41% at three, six, nine, 12, 15 and 24 months, respectively. The mean BMI at 18 months for the LDS group was 26.8 kg/m^2 compared to the GBP group with 29.5 kg/m^2. Short term complications for the GBP group included nausea (n=9), abdominal pain (n=4), diarrhea (n=1), incisional hernia (n=1), and diaphoresis (n=1). For the LDS group, short term complications reported were nausea (n=1) and abdominal wall spasms (n=1). Long term complications for the GBP group included nausea (n=17), ulcers (n=6), stricture (n=1), adhesions causing small bowel obstruction (n=3), perforation (n=1), intra-abdominal hemorrhaging (n=1), low pre-albumin (n=2), gastroesophageal reflux (GERD) (n=2), and renal failure (n=1). Reported long term complications for the LDS group included nausea (n=4), sleeve stricture (n=1), dilated fundus requiring reoperation (n=1), GERD (n=1), diarrhea (n=1), and miscounted small bowel requiring reoperation (n=1). Author noted study limitations included the retrospective study design, small patient population, lack of vitamin and mineral level analysis, lack of comorbidity analysis and short-term follow up. The LDS group had less short and term complications with statistically similar weight loss to the GBP group.

Professional Societies/Organizations

American Society for Metabolic and Bariatric Surgery (ASMBS): The ASMBS updated their guidelines in 2020 to endorse the SADI-S, a modification of classic Roux-en-Y DS, as an appropriate metabolic bariatric surgical procedure that meets appropriate standards for safety and benefit. The recommendation was based on current clinical knowledge, expert opinion and published peer-reviewed scientific evidence. The ASMBS reached the conclusion from the current review of the available peer-reviewed literature that SADI-S provides for similar outcomes to those reported after classic DS. The society states that concerns remain about intestinal adaptation, nutritional issues, optimal limb lengths, and long-term weight loss/regain after this procedure and recommends a cautious approach to the adoption of this procedure with attention to ASMBS-published guidelines on nutritional and metabolic support of bariatric patients (Kallies, et al, 2020).

International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): In 2020, the IFSO confirmed their position on and updated their recommendations regarding single anastomosis duodenal-ileal bypass with sleeve gastrectomy and one anastomosis duodenal switch (SADI-S/OADS) (Brown, 2020). The position statement was based on current clinical knowledge, expert opinion and published peer-reviewed scientific evidence. A systematic review of the literature, updating the previous review, was conducted to summarize the current evidence to provide the most up-to-date information to guide practice. All studies that included any data or reported experiences with single anastomoses pylorus-preserving procedures were included. All study designs (i.e., case reports, retrospective reviews), study sizes and follow-up time frames were accepted. The update included an additional 25 new case series and three case reports with follow ups up to five years in four primary case series. Thirty-four case series were included. The geographical locations included the United States, Germany, Taiwan, Chile, Spain, China, Netherlands, Portugal, Italy, and Australia. The majority of subjects for each study were women (50.6%–85%). In total, there were 4,540 subjects but this included overlapping patients. For follow ups that occurred between 12–24 months, mean total body weight loss (TBWL) ranged from 23.6%–39.0% at 12 months, 39.6%–42.9% at 18 months, and 22.8%–47.8% at two years. Mean excess weight loss (EWL) ranged from 62.4%–102% at 12 months. Three studies reported follow-ups at five years for TBWL ranging from 22% to 38% with the follow-up rate from 78%–100%. Changes in type 2 diabetes diagnosis and treatment were reported in 28 case series. There was a significant improvement in both HBA1c and requirement for hypoglycemic agents. Early complications were uncommon and included anastomotic leaks, bleeding and nausea. Longer term complications were gastroesophageal reflux disease (GERD), bile reflux, flatulence, dumping syndrome, and nutritional issues. Post-operative nutritional issues included malnutrition, hypoalbuminemia, vitamin D deficiency, hypocalcemia, hyperparathyroidism, and iron deficiency. The IFSO states there is current evidence now out to five years in four primary case series that confirm that SADI-S/OADS can help a person with morbid obesity achieve and maintain significant weight loss with an improvement in metabolic health. Based on the existing data, the IFSO recommended the following:

- "SADI-S/OADS offers substantial weight loss that is maintained into the medium term.
- SADI-S/OADS provides an improvement in metabolic health that is maintained into the medium term.
- Nutritional deficiencies are emerging as long-term safety concerns for the SADI-S/OADS procedure and patients undergoing this procedure need to be aware of this, and counseled to stay in long-term multidisciplinary care.
- Surgeons performing the SADI-S/OADS, as well as other bariatric/metabolic procedures, are encouraged to participate in a national or international registry so that data may be more effectively identified.
- IFSO supports the SADI-S/OADS as a recognized bariatric/metabolic procedure, but highly encourages randomized controlled trials in the near future."

National Institute for Health and Care Excellence (NICE): A 2016 NICE guidance on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity stated that the current evidence on the safety shows that there are well-recognized complications. Evidence on efficacy is limited in both quality and quantity. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE 2016).

Sleeve Gastrectomy (SG)

SG, also known as partial or vertical gastrectomy, is a restrictive procedure that is now being proposed as a definitive procedure for morbid obesity or as the first procedure in a staged surgical approach for those with very high BMI (BMI (>60 kg/m^2). Weight loss following SG is thought to reduce the risk of a subsequent, more extensive procedure, such as biliopancreatic diversion, in very high-risk patients. It has been suggested that the hormone ghrelin may play a role in the weight loss associated with SG. Although resection of the fundus may lower ghrelin levels by reducing the volume of ghrelin-producing cells, low levels of this hormone after surgery may be due to the paracrine effect of gastrointestinal hormones such as glucagon-like peptide-1 (GLP-1), GLP, ghrelin, and other hormones.

SG can be an open or laparoscopic procedure and involves the resection of the greater curvature of the stomach with the remainder resembling a tube or sleeve. The resulting decrease in stomach size inhibits distention of the stomach so that early satiety is achieved. Preservation of the pyloric sphincter prevents the dumping syndrome. Other advantages of this procedure include the lack of intestinal anastomosis and no implantation of a foreign body. Major complications associated with SG include staple-line leak and postoperative hemorrhage.

Literature Review

The percentage of excessive weight loss (%EWL) for laparoscopic sleeve gastrectomy (LSG) has been reported to vary from 33%–90% and to be sustained for up to three years. The rate of complications has ranged from 0%–29% (average 11.2%), and the mortality rate from 0–3.3%. Rates of resolution or improvement of comorbidities after SG have been found to range from 45%–95.3%. Safety and effectiveness are comparable to other established bariatric procedures, with %EWL at three years, comorbidity resolution, complication and mortality rates for RYGB being 66%, 65-84%, 9.5%, 0.56%, respectively, and for LAGB, 55%, 41-59%, 6.5%, 0.47%, respectively (Shi, et al., 2010). A number of studies including systematic reviews (Brethauer, et al., 2009), randomized controlled trials and multiple case series (Himpens, et al., 2010; Peterli, et al., 2009; Strain, et al., 2009; Arias, et al., 2009; Fuks, et al., 2009; Karamanakos, et al., 2008; Felberbauer, et al., 2008; Nocca, et al., 2008; Vidal, et al., 2007; Hamoui, et al., 2006; Silecchia, et al., 2006; Himpens, et al., 2006; Cottam, et al., 2006) support the safety and efficacy of SG. Shi et al. (2011) performed a systematic review of the literature (n=15 studies; 940 patients) analyzing outcomes of LSG compared to benchmark clinical data from LAGB and LRYGB. The %EWL for LSG varied from 33% to 90% and appeared to be sustained up to three years. The mortality rate was 0%–3.3% and major complications ranged from 0%–29% (average 12.1%). It was summarized that early, non-randomized data suggest that LSG is efficacious in the surgical management of morbid obesity. However, it is not clear if weight loss following LSG is sustainable in the long term.

Brethauer et al. (2009) performed a systematic review (n=36 studies) of the evidence on SG. Studies included a single nonrandomized matched cohort analysis, RCTs (n=2 studies) and uncontrolled case series (n=33 studies). The mean BMI in all 36 studies was 51.2 kg/m^2. The mean baseline BMI was 46.9 kg/m^2 for the high-risk patients (range 49.1–69.0) and 60.4 kg/m^2 for the primary SG patients (range 37.2–54.5). The follow-up period ranged from 3–60 months. The mean %EWL after SG reported in 24 studies was 33–85%, with an overall mean %EWL of 55.4%. The mean postoperative BMI was reported in 26 studies and decreased from a baseline mean of 51.2 kg/m^2 to 37.1 kg/m^2 postoperatively. Improvement or remission of type 2 diabetes was found in more than 70% of patients. Significant improvements were also seen in hypertension and hyperlipidemia, as well as in sleep apnea and joint pain. The major postoperative complication rate ranged from 0%–23.8%. The most frequent complications seen were leaks (2.2%) and bleeding requiring re-operation or transfusion (1.2%). Study data for high-risk staged and primary subgroups are listed in the following table:

Variable	High-risk patients/ Staged approach	Primary Procedure
Mean preoperative BMI	60.0	46.6
Mean postoperative BMI	44.9	32.2
Follow-up range	4-60 months	3-36 months
Mean %EWL	46.9%	60.4%
Mean Complication rate	9.4%	6.2%
Mortality rate	0.24%	0.17%

The authors summarized that although the long-term data are limited, based on the volume of available evidence, LSG is an effective weight loss procedure that can be performed safely as a first stage or primary procedure (Brethauer, et al., 2009).

The growing volume of studies in the published peer-reviewed medical literature suggests that the safety and effectiveness rates for SG are comparable to those for other accepted bariatric procedures such as RYGB and LAGB. There is sufficient evidence to support the use of SG as a stand-alone procedure or as the first of a two-stage procedure. Long-term data are needed to further define the role of SG for the treatment of morbid obesity.

Professional Societies/Organizations
American Society for Metabolic and Bariatric Surgery (ASMBS): The ASMBS updated position on sleeve gastrectomy (2017) stated that there is substantial, published long-term outcome data, including comparative studies, that confirm that sleeve gastrectomy (SG) provides significant and durable weight loss, improvements in medical co-morbidities, improved quality of life, and low complication and mortality rates for obesity treatment. SG and Roux-en-Y (RYGB) appear similar in terms of initial early weight loss and improvement of most weight-related co-morbid conditions. The effect of SG on gastroesophageal reflux disease (GERD), however, is less clear, because GERD improvement is less predictable and GERD may worsen or develop de novo. ASMBS recognized SG as an acceptable option for a primary bariatric procedure or as a first-stage procedure in high-risk patients as part of a planned, staged approach. Long-term weight regain can occur after SG and may require one or more of a variety of reinterventions. The guideline also discussed SG as a weight loss option for adolescents and stated that weight loss surgery (WLS) is becoming more accepted for this age group. Based on safety and efficacy data, there is a trend toward SG as the procedure of choice for adolescents, although both RYGB and SG are routinely performed in teen WLS programs. However, ASMBS noted that since there is almost no literature on the outcomes of adults who underwent WLS as teens, this area merits further study.

American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS): According to the AACE/TOS/ASMBS guidelines, a first-stage SG may be performed in high-risk patients to induce an initial weight loss (25 to 45 kg), with the possibility of then performing a second-stage RYGB or BPD/DS after the patient's operative risk has improved (Mechanick, et al., 2008). The 2013 update to these guidelines states that the LSG has become widely accepted as a primary bariatric operation and is no longer considered investigational (Mechanick, et al., 2013, updated 2020).

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES): The 2008 SAGES guideline for laparoscopic bariatric surgery stated that SG is validated as providing effective weight loss and resolution of comorbidities to 3–5 years.

Vertical Banded Gastroplasty (VBG)
This restrictive procedure uses both a band and staples to create a small stomach pouch. The pouch limits the amount of food that can be eaten at one time and slows passage of the food into the remainder of the stomach and gastrointestinal tract. VBG may be performed using an open or laparoscopic approach. Complications of VBG include esophageal reflux, leaking or rupture along the staple line, stretching of the stomach pouch from overeating.

Although reoperation rates have been reported to be higher for VBG, the available evidence in the form of RCTs, nonrandomized comparative trials, and case series (Miller, et al., 2007; Nocca, et al., 2007; Olbers, et al., 2005; Lee, et al., 2004; Morino, et al., 2003) report that substantial weight loss can be achieved with this restrictive procedure. VBG has been largely replaced by adjustable silicone gastric banding however**,** and is now rarely performed (Centers for Medicare and Medicaid Services [CMS], 2006).

Other Bariatric Surgical Procedures

Fobi-Pouch
The Fobi-Pouch, limiting proximal gastric pouch, has been proposed by one investigator as an alternative to traditional bariatric surgery. The procedure involves a small (less than 25 ml) vertical banded pouch, a Silastic® ring around the stomach creating a stoma, and a gastroenterostomy to a Roux-en-Y limb. Published evidence supporting the use of this procedure is in the form of one descriptive article (Fobi and Lee, 1998) and one case series (Fobi, et al., 2002; n=50). Current evidence available in the published, peer-reviewed scientific literature indicates that the safety and efficacy of this procedure have not been established.

Gastric Pacing/Gastric Electrical Stimulation (GES)
GES is being investigated as a treatment for morbidly obese patients. It is thought that GES may cause increased satiety resulting in decreased food intake and weight loss. The exact mechanism by which gastric pacing impacts eating and behavior is unclear. There is currently insufficient evidence in the literature to support the use of GES for the treatment of obesity. Please refer to the Gastric Pacing/Gastric Electrical Stimulation (GES) Coverage Policy for additional information.

Gastroplasty
Gastroplasty, also referred to as stomach stapling, is the prototypical restrictive procedure. A simple gastroplasty involves the stapling of the upper portion of the stomach horizontally. A small opening is left for food to pass through to the lower portion. The outlet of the pouch is restricted by a band, which slows emptying, allowing the person to feel full after only a few bites of food. It has been reported in the literature that those who have undergone this procedure seldom experience any satisfaction from eating, and tend to eat more, causing vomiting and tearing of the staple line. The available literature also reports that horizontal stapling alone has led to poor long-term weight loss. Because many simple gastroplasty patients have eventually required some type of revision operation in order to achieve successful weight loss, this procedure has largely been abandoned.

Intestinal/Jejunoileal Bypass
In a jejunoileal or intestinal bypass the proximal jejunum is joined to the distal ileum, bypassing a large segment of the small bowel. Various technical modifications of the jejunoileal anastomosis have been developed, all bypassing extensive length of small intestine and leading to inevitable malabsorption of protein, carbohydrate, lipids, and vitamins. However, unabsorbed fatty acids entering the colon has caused significant diarrhea in patients who have undergone this procedure. Other long-term complications have been observed in jejunoileal bypass patients, the most serious of which is irreversible hepatic cirrhosis (Morris, et al., 2017; Collins, et al., 2007). Because of these complications, jejunoileal bypass has fallen out of favor and is no longer one of the more commonly performed bariatric procedures.

Intragastric Balloon (IGB)
Treatment with the IGB has been proposed as a temporary aid for obese patients who have had unsatisfactory results in their medical management of obesity and for super-obese patients with higher surgical risk. The IGB technique allows the reduction of the gastric reservoir capacity, causing a premature sensation of satiety, facilitating the consumption of smaller amounts of food (Fernandes, et al., 2007). The balloon is typically removed within six months of insertion. Adverse effects associated with the intragastric balloon include gastric erosion, reflux, and obstruction. FDA approved balloons include: Orbera™ Intragastric Balloon System (Apollo Endosurgery Inc, Austin, TX, United States), the ReShape® Integrated Dual Balloon System (ReShape Medical, Inc., San Clemente, CA, United States, acquired by Apollo Endosurgery in 2018), Obalon (Obalon® Therapeutics, Inc., acquired by ReShape Lifesciences™, San Clemente, CA in July 2021) and the Transpyloric Shuttle/TransPyloric Shuttle Delivery Device (TPS) (BAROnove, Inc. San Carols, CA).

US Food and Drug Administration

In 2017 the FDA issued letters to health care provider regarding serious adverse events including spontaneous hyperinflation, acute pancreatitis and deaths from the use of liquid filled intragastric balloons (Obera and ReShape). In June 2018 the FDA reported that there had been five additional deaths with the Orbera and ReShape balloons. The FDA has approved new U.S. labeling for the Orbera and ReShape balloon systems with more information about possible death associated with the use of these devices (FDA, 2018). The FDA provided another update in April 2020 after the completion of the post-approval studies for the Orbera intragastric balloon regarding the potential risks of over-inflation (spontaneous hyperinflation), acute pancreatitis, and deaths. As of January 1, 2019, Apollo Endosurgery stopped selling and distributing the ReShape Balloon (FDA, 2020).

The Orbera™ Intragastric Balloon System (Apollo Endosurgery, Inc., Austin, TX) received a PMA approval from the U.S. FDA in August 2015. The Orbera is a weight loss system that uses a gastric balloon to occupy space in the stomach. The balloon is placed into the stomach through the mouth, using a minimally invasive endoscopic procedure. Once in place, the balloon is filled with saline until it expands into a spherical shape. The balloon can be filled with 400 cc–700 cc of saline to best align with the patient's anatomy. The FDA stated that the Orbera system is indicated for use as an adjunct to weight reduction for adults with obesity with a BMI ≥ 30 and ≤ 40 kg/m2 who have failed more conservative weight reduction alternatives (e.g., supervised diet, exercise, behavior modification). The system is to be used in conjunction with a long-term supervised diet and behavior modification program designed to increase the possibility of significant long-term weight loss and maintenance of that weight loss. The maximum placement period for Orbera is six months. Prior to FDA approval the Orbera was known as the BioEnterics® Intragastric Balloon (BIB® System) (INAMED Health, Santa Barbara, CA) and was introduced in the mid-1990s. In 2013, the BIB system was rebranded as Orbera™.

The Obalon Balloon System (ReShape Lifesciences™, San Clemente, CA) is also FDA PMA approved for the treatment of obesity. The FDA indications for use stated that the "Obalon Balloon System (the "System") is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30–40 kg/m^2) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed" Each balloon is contained within a porcine gelatin capsule, which is attached to a catheter. Prior to administration of an actual balloon capsule, patients must undergo a placebo capsule test to identify patients who may not be able to swallow the actual device. Then the catheter/capsule is swallowed by the patient. The catheter is then attached to the EzFill Dispenser that contains an EzFill Can containing nitrogen-sulfur hexafluoride gas mixture which is used to fill the balloon. After the patient swallows a balloon capsule, radiography (fluoroscopy or digital x-ray) must be done prior to inflation to ensure the balloon is below the gastroesophageal junction. A fully inflated single balloon is an ellipsoid with a volume of approximately 250 cc. Up to three balloons can be swallowed making a total balloon volume of 750 cc. There should be no less than 14 days between Balloon placements. After inflation is complete, the catheter is ejected from the balloon valve and removed, leaving each balloon free-floating in the patient's stomach. Proton Pump Inhibitors must be taken for the duration of the balloon implantation (FDA, 2016). According to the company's website, the Obalon Balloon System is currently not commercially available (ReShape Lifesciences, 2021).

The Transpyloric Shuttle/TransPyloric Shuttle Delivery Device (TPS) (BAROnove, Inc. San Carols, CA) was FDA PMA approved for obese adult patients with a Body Mass Index (BMI) of 35.0-40.0 kg/m^2 or a BMI of 30.0 to 34.9 kg/m^2 with an associated medical condition (for example, diabetes) who have been unable to lose weight on a diet and behavior modification program and exercise. It is intended to be used while a patient participates in a diet and exercise plan supervised by a health care provider (FDA, 2019). The TPS is placed into the stomach through the mouth during an endoscopic procedure. Once in place, the TPS is formed, using the TPS Delivery

Device, into a smooth large bulb connected to a smaller bulb by a flexible silicone tether. The large bulb remains in the stomach. The smaller bulb can remain in the stomach or cross the stomach into the small intestine to slow the time it takes for food to leave the stomach and enter the small intestine (gastric emptying). The TPS remains in the stomach for up to 12 months to help patients lose weight (FDA, 2019).

Other balloons being investigated include the SatiSphere (Endosphere, Columbus, OH), Spatz Adjustable Balloon System (Spatz Medical, NY, USA), Elipse (Allurion Technologies, Wellesley, M)A, Full Sense Bariatric Device (Baker, Foote, Kemmeter, Walburn [BFKW] LLC, Grand Rapids, MI), Heliosphere® (Helioscopie Medical Implants, Vienne, France), Silimed Gastric Balloon (Silimed, Rio de Janeiro, Brazil) and the Ullorex® Oral Intragastric Balloon (Phagia Technologies, Inc., Fort Lauderdale, FL). These devices are currently not FDA approved for use in the US (Bazerbachi, et al., 2017; Jirapinyo and Thompson, 2017; Kumar, 2016; Kumar, 2015).

Literature Review

Orbera: Ahmed and Ezzat (2018) conducted a randomized controlled trial to evaluate the effect of obesity on quality of life, and the influence of weight loss after insertion of BioEnteric balloon (Obera) (n=40 females) compared to Atkins diet (n=40 females). The weight lost in the first six months was highest in the treatment group in which 19 subjects (47.5%) lost 33 kg (p=0.00001), compared to the control group in whom 10 patients (25%) lost 17 kg of their body weight (p=0.00010). Patients in the both groups reported better quality of life following weight loss. Limitations of the study include the small, all female patient population, short-term follow-up and a shortage of the Atkins formula and foods in the area.

Fuller et al. (2013) conducted a randomized controlled trial (n=66) to evaluate the safety and efficacy of the Orbera IGB (n=31) compared to control (n=35) in obese individuals with metabolic syndrome. Eligible subjects were adults age 18–60 years with a BMI of 30-40 kg/m^2 for at least two years and had failed supervised weight reduction programs. Exclusion criteria included conditions of the gastrointestinal tract, prior gastric surgery or insertion of an IGB, hepatic or renal insufficiency, or psychiatric disorder. The primary outcome was percentage of weight loss at six months. Secondary outcomes included weight loss at 12 months and remission of metabolic syndrome. At 12 months, there was a significantly greater weight loss in the IGB group versus the control group (p=0.007) No significant difference in percentage of metabolic syndrome remission was found. Adverse events related to the gastrointestinal tract were common in the IGB group but predominantly resolved within two weeks.

The American Society for Gastrointestinal Endoscopy's (ASGE) Bariatric Endoscopy Task Force, a subcommittee of ASGE, conducted a systematic review and meta-analysis of the literature to evaluate endoscopic technologies for the treatment of obesity. The review included a meta-analysis of the available data on the Orbera. A total of 82 studies met inclusion criteria. Studies were primarily in the form of case series and retrospective reviews. Seven randomized controlled trials were also included. Based on a meta-analysis of 17 studies (n=1683 patients), the percentage of excess weight loss (%EWL) with the Orbera at 12 months was 25.44%. Three randomized, controlled trials compared %EWL in patients who received the Orbera (n=131) vs. control group (n=95). The mean difference in %EWL in patients who received the Orbera was significantly greater than controls at 26.9% (p≤0.001). The pooled percentage of total body weight loss (%TBWL) after Orbera implantation was 12.3%, 13.16%, and 11.27% at 3, 6, and 12 months, respectively. Subgroup analysis showed Orbera performed as well in higher BMI groups. The rates of adverse events pooled from 68 studies included 33.7% pain, 29% nausea, 18.3% gastrointestinal reflux disease (GERD), 12% erosion and 7.5% early removal. Serious side effects included 1.4% incidence of migration and 0.1% gastric perforation. Fifty percent (4/8) of gastric perforations occurred in patients who had undergone previous gastric surgeries. Four deaths were reported and were related to gastric perforation or an aspiration event. ASGE concluded that

Orbera met the thresholds as a primary or bridge procedure with a mean %EWL of 25% at one year. ASGE noted that these recommendations should not be taken to imply that these devices could be used on their own without appropriate screening, dietary, and lifestyle intervention support, nor should they be used without consideration of surgical therapy. Author-noted limitations of the meta-analyses included the high degree of heterogeneity among included studies, risk of bias in non-randomized studies, and different methods used among studies to report the %EWL (Metropolitan Life Tables vs. BMI 25 method) (ASGE Bariatric Endoscopy Task Force, et al., 2015).

Obalon: Studies investigating the safety and efficacy of the Obalon gastric balloon in children, adolescents and adults are primarily in the form of case series with small patient populations (n=10–17) (De Peppo, et al., 2017; Nobili, et al., 2015; Mion, et al., 2013).

Sullivan et al. (2018) conducted a randomized controlled trial to assess the safety and efficacy of the Obalon balloon. Patients were randomized to treatment with the balloon plus lifestyle therapy (n=198) or to the control group using sham plus lifestyle therapy (p=198). Adults aged 22–64 years who were weight stable for 12 months, with a BMI 30–40 kg/m^2 who made at least one attempt to lose weight through a medically or nonmedically supervised weight loss program without success were eligible for inclusion. Primary outcome measures were the difference in mean percentage of totally body weight loss (%TBWL). Secondary outcomes included weight loss maintenance from weeks 24–48 and changes in cardiometabolic risk factors from baseline to week 24. All balloons were removed at week 24. A total of 160 treatment group patients continued study participation through week 48 after unblinding, and 128 patients in the control group received the balloon and completed study testing through week 48. The %TWL and total weight loss was significantly more in the treatment group (p=0.0085; p<0.001, respectively). Body mass index changes in the treatment and control groups were 2.5 ± 1.8 and 1.3 ± 1.8 kg/m^2 (p<0.0001), respectively. The responder rate in the treatment group was 66.7% (p<0.0001). Weight loss maintenance in all patients at 48 weeks was 88.5%. Weight loss for the control patients who crossed over was 3.6 ± 4.4% at week 24 and 7.0 ± 6.2% at week 48 (n=128). Systolic blood pressure (p=0.020), plasma total cholesterol concentration (p=0.0214), plasma triglyceride concentration (p=0.0049), and plasma glucose concentration (p=0.008) were significantly improved in the treatment groups compared to controls. Adverse events in the balloon group included numerous gastrointestinal events (e.g., nausea, vomiting, dyspepsia, abdominal distention, diarrhea). There were 43 bleeding events. One balloon deflation occurred. The balloons used in this study used a different gas formulation than earlier balloons. The authors noted several limitations of the study including: the study was not powered to determine effects on metabolic outcomes; over 85% of participants in this study were women; short-term follow-up of six months; and the study did not investigate the mechanism of action of weight loss (weight loss increased after the third balloon placement).

TransPyloric Shuttle (TPS): The evidence includes one single-center feasibility study that investigated the safety and efficacy of TPS (n=20) (Marinos, et al., 2014).

Multiple Intragastric Balloons: The evidence evaluating the safety and efficacy of the IGB includes technology assessments, meta-analyses, RCTs and case series, primarily with relatively small sample sizes.

Zheng et al. (2015) performed a systemic review and meta-analysis of the evidence (n=11 RCTs) for the safety and efficacy of IGBs for the treatment of obesity. All studies incorporated conservative therapy with the IGB treatment. Sample sizes ranged from 22–128 patients, and mean baseline BMIs ranged from 35.0–50.4 kg/m^2. IGBs were compared to behavioral modification, pharmacotherapy, and observation without treatment. Results were calculated with weighted mean differences which favored IGB for weight loss (p<0.01). Statistically significant differences in favor of IGB were also found for excessive weight loss and BMI reduction. Adverse events were primarily vomiting and abdominal pain. No fatalities were reported. The results of this review are limited by the lack of blinding and the short term follow-ups. It was concluded that IGBs with conservative therapy are a safe and effective obesity treatment in the short term. However, well designed follow-up RCTs are needed to evaluate long-term safety and efficacy.

Imaz et al. (2008) performed a meta-analysis of 15 studies (n=3608) on IGB for the treatment of obesity. The efficacy at balloon removal was estimated with a meta-analysis of two RCTs (n=75 patients) that compared balloon versus placebo. The estimates for weight lost at balloon removal were 14.7 kg, 12.2% of initial weight, and 5.7 kg/m^2, 32.1% of excess weight. These differences in weight lost between the IGB and placebo groups were 6.7 kg, 1.5% of initial weight, 3.2 kg/m^2, and 17.6% of excess weight. The majority of complications were reported to be mild and the early removal rate was 4.2%. In the opinion of the authors, the available evidence demonstrates that IGB is an effective treatment to lose weight in the short-term, but does not verify the maintenance of this weight loss over the long term (Imaz, et al., 2008).

In a Cochrane review of the evidence for IGB, Fernandes et al. (2007) included nine randomized, controlled clinical trials (n=395) that compared IGB to no treatment, diet and a combination of balloon placement and diet. According to the authors, results indicated that compared with conventional management, the IGB did not show convincing evidence of a greater weight loss. Although few serious complications of intragastric balloon placement occurred, the relative risks for minor complications like gastric ulcers and erosions were significantly raised (Fernandes, et al., 2007).

A larger case series conducted by Genco et al. (2005) evaluated 2515 patients with a mean BMI of 44.4 who underwent intragastric balloon placement. The balloon was removed after six months. Mortality, complications, BMI, percentage excess weight loss (EWL), BMI loss and comorbidities were evaluated. The overall complication rate was reported to be 2.8%, including the death of two patients. Gastric perforation occurred in five patients (0.19%), four of whom had undergone previous gastric surgery. A total of 19 gastric obstructions (0.76%) presented in the first week after balloon positioning and were successfully treated by balloon removal. Preoperative comorbidities resolved in 617 (44.3%) of 1394 patients. After six months, mean BMI was 35.4 and the EWL was 33.9%. BMI loss was reported to be 4.9 (range 0–25). Despite the complications noted, it was concluded that intragastric balloon is an effective procedure with reduced comorbidities and satisfactory weight loss within a follow-up period of six months. Previous gastric surgery was noted to be a contraindication to intragastric balloon placement.

Currently, the available evidence in the published, peer-reviewed scientific literature is insufficient to establish the safety and efficacy of intragastric balloons.

Laparoscopic Greater Curvature Plication

Laparoscopic greater curvature plication, also referred to as gastric plication or gastric imbrication, is being investigated as a less invasive surgical procedure for obesity. The procedure is similar to laparoscopic sleeve gastrectomy (LSG), but does not involve removal of stomach tissue. The stomach is folded and sewn and therefore the procedure is theoretically reversible. A combination of gastric banding with greater curvature gastric plication has also been described in the literature. This procedure is similar to laparoscopic gastric plication but includes placement of the adjustable gastric band. This combined technique has been suggested to augment the early weight loss after gastric banding with possible decrease in the need for band adjustments (ASMBS, 2011; reviewed 2015).

Literature Review

Evidence evaluating the safety and effectiveness of laparoscopic greater curvature plication, with or without adjustable gastric banding, consists primarily of case series with patient populations ranging from 26-244 and follow-ups of 12 months to five years (Doležalova-Kormanova, et al. 2017; Kim, et al., 2015; Niazi, et al., 2013; Fried, et al., 2012; Taha, 2012; Talebpour, et al., 2012; Skrekas, et al., 2011; Ramos, et al., 2010). Outcomes of percentage of excessive weight loss (EWL), operative timeframes, and resolution of comorbidities have been reported. Limitations in these studies include lack of a randomized controlled design and short-term follow-up.

Talebour et al. (2018) conducted a randomized controlled trial (n=70) to compare the safety and effectiveness of laparoscopic gastric plication (LGP) (n=35) vs. laparoscopic sleeve gastrectomy (LSG) (n=35). Primary outcome measures were BMI reduction and the percentage of excess weight loss (%EWL) and total body weight loss (%TWL). Postoperative complications were the secondary outcome. At the 24 months' follow-up there was no significant difference in the lower BMI and mean %EWL between the two groups. The mean BMI was significantly lower in both groups compared to baseline ($p<0.05$). Seven patients in LSG and one in LGP were readmitted to the hospital ($p=0.024$). Readmissions in the LSG group were due to two cases of leakage, one case of a draining abscess, two cases of cholecystectomy, and two patients developed acute coronary syndrome. In the LGP group, one patient was readmitted to perform an abdominoplasty. Diarrhea was significantly more frequent in the LGP group (6 vs. 1, $p=0.046$). Serious events were more common in the LSG group including two cases of leakage and one case of draining abscess formation, whereas in the LGP group, one patient died from pulmonary thromboembolism. Hospital stay was 6.06 ± 1.53 days in the LGP group and 7.46 ± 1.93 days in the LSG group, statistically significant ($p=0.001$). Limitations of the study include the small patient population and short-term follow-up. Randomized controlled trials with larger patient populations and long-term follow-up are needed to establish the safety and efficacy of LGP.

Ye et al. (2017) conducted a systematic review to compare the safety and efficacy of laparoscopic sleeve gastrectomy (LSG) and laparoscopic greater curvature plication (LGCP). Three randomized controlled trials, four retrospective studies, and one prospective study (n=536) met inclusion criteria. This meta-analysis showed a significantly greater percentage of weight loss (%EWL) after LSG compared to LGCP at 3 months ($p=0.02$), six months ($p<0.01$), 12 months ($p<0.01$) and three years ($p<0.01$). Based on five studies LSG was associated with a significantly shorter postoperative hospital stay ($p<0.01$). No significant differences were found in operation time ($p=0.06$), adverse events ($p=0.06$), and the resolution of obesity-related hypertension ($p=0.57$) and diabetes mellitus (p-0.31). Adverse events were defined as postoperative major morbidities, including leaks, stenosis, bleeding, and any other reason of reoperation. Author-noted limitations of this analysis included: possible publication bias due to the inclusion of only the eight studies; the heterogeneity of included patients, the surgeons' experience, and the duration of observation which might have reduced the reliability of the effect size; and five studies were non-randomized, controlled trials, which may have caused selection and detection bias. A multicenter randomized controlled trial with long-term follow-up is needed to validate these findings.

A systematic review (n=521 patients) by Kourkoulos et al. (2012) included prospective case series (n=8 studies) and case reports (n=2 studies). Inclusion criteria in five studies were age over 18 years old and BMI > 40 or BMI > 35 with at least one comorbidity. Inclusion criteria were not defined in the one study with a minimum BMI of 36, as well as a second study in which minimum BMI was 30. The inclusion criteria for the remaining study included age 18–62 years, BMI of 32–35 kg/m^2, and a history of GERD and obesity for more than five years with unsuccessful attempts at conservative weight-loss therapy. This study was aimed at demonstrating the efficacy of LGCP with Nissen fundoplication in obese patients with GERD. Universal exclusion criteria included pregnancy, previous bariatric or gastric surgery, hiatal hernia, uncontrolled diabetes, cardiovascular risks, a history of eating disorders (e.g., bulimia), medical therapy for weight loss within the previous two months, or any other condition that constituted a significant risk of undergoing the procedure. A BMI > 50 was defined as an exclusion criterion in two studies. Outcomes of weight loss and complications were assessed. Reported percentage of excessive weight loss in all studies was found to be approximately 50% at six months, 60–65% at 12 months, and 60–65% at 24 months. The total complication rate was 15.1%. The reoperation rate was 3% and the rate of conversion to another procedure was 0.2%. Mortality was zero at 24 months. The authors concluded that the literature on gastric plication and its modifications is limited. More data are required and randomized control trials must be completed in order to reach safe conclusions.

Another systematic review (n=307 patients) by Abdelbaki et al. (2012) also included prospective case series (n=5 studies) reviewed by Kourkoulos et al. (2012) as described above, and case reports (n=2 studies). The age range of patients was 23 to 59 years. At 12 months of follow up, excess weight loss (EWL) ranged from 23.3% to 67%. Patients were followed for more than two years in two studies with EWL rates of 57% and 65%. One study showed inadequate weight loss (<EWL 50 %) in 29/135 subjects (21.48%) and failure (<EWL 30%) of weight loss in 8/135 (5.9%). Complications including gastric leaks and perforations, developed in 25/307 patients (8%), with a complication rate range of 7%–15.3%. Prospective randomized controlled trials with long-term follow-up comparing gastric plication to other well-established bariatric procedures are needed to prove the reliability and metabolic effectiveness of this new procedure.

There is insufficient evidence in the published, peer-reviewed medical literature demonstrating safety and effectiveness of gastric plication. Well-designed studies with larger patient populations comparing this technique to established bariatric procedures are needed to draw firm conclusions regarding the overall safety, efficacy and impact on health outcomes.

Professional Societies/Organizations

American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS): According to the 2013 updated guidelines from the from the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS), while there are several short-term studies demonstrating relative safety and effectiveness of greater curvature plication with outcomes intermediate between LAGB and SG, more robust comparative data and conclusive data evaluating the durability of this procedure will be needed before specific recommendations can be made (Mechanick, et al., 2013, updated 2020).

American Society for Metabolic and Bariatric Surgery (ASMBS): The ASMBS (2011; reviewed 2015) policy statement on laparoscopic gastric plication explained that the quantity (n=4 studies, <300 patients) and quality (prospective or retrospective case series) of the available data is insufficient to draw any definitive conclusions regarding the safety and efficacy of this procedure. The Society supports the following recommendations regarding gastric plication alone or in combination with adjustable gastric band placement for the treatment of obesity:

1. Gastric plication procedures should be considered investigational at this time. This procedure should be performed under a study protocol with third party oversight (local or regional ethics committee, Institutional Review Board, Data Monitoring and Safety Board, or equivalent authority) to ensure continuous evaluation of patient safety and to review adverse events and outcomes.
2. Reporting of short- and long-term safety and efficacy outcomes in the medical literature and scientific meetings is strongly encouraged. Data for these procedures should also be reported to a program's center of excellence database.
3. Any marketing or advertisement for this procedure should include a statement to the effect that this is an investigational procedure.

4. The ASMBS supports research conducted under an IRB protocol as it pertains to investigational procedures and devices. Investigator meetings held to facilitate research are necessary and supported, as is the reporting of all data through BOLD, Bariatric NSQIP or a specific research database. The ASMBS does not support CME courses on investigational procedures and devices held for bariatric surgeons for the purpose of use of investigational procedures outside an IRB research protocol.

National Institute for Clinical Excellence (NICE): The 2012 NICE (United Kingdom) guideline indicates that while the evidence on laparoscopic gastric plication for severe obesity raises no major safety concerns in the short term, there is inadequate evidence about safety in the long-term, specifically with regarding to the reversibility of the procedure and how it affects the safety of any further gastric surgery that may be necessary.

Mini-Gastric Bypass/One Anastomosis Gastric Bypass (OAGB)/Loop Gastric Bypass
The mini-gastric bypass, also called the Omega loop gastric bypass and single- or one-anastomosis gastric bypass (OAGB), has been proposed as a bariatric surgery method. The controversial procedure is performed laparoscopically and is similar to the Roux-en-Y. An endoscopic stapler is used to divide the stomach into two parts, and a new, narrow stomach pouch is formed. The larger part of your stomach remains in the body and continues to produce digestive juices to help with digestion but will no longer come in contact with food. Once the new stomach is formed, it is connected (anastomosed) to a two-meter loop of bowel consisting of the duodenum and part of the jejunum. By bypassing two meters of the small intestine, the food passes from the small stomach pouch directly into the small bowel where it meets the digestive juices from the detached portion of the stomach. Complications include biliary reflux and esophagitis. Ongoing concerns following mini-gastric bypass include gastric and esophageal bile reflux, marginal ulcer, poor follow-up and remnant gastric cancer (Wang, et al., 2017). Some patients who undergo loop gastric bypass develop symptomatic bile reflux gastritis and esophagitis, necessitating conversion to RYGB (Salameh, 2006). The loop gastric bypass as developed years ago has generally been abandoned by many bariatric surgeons.

Literature Review
Evidence supporting the use of the mini-gastric bypass is primarily in the form of retrospective reviews (n=1200–1520) and small case series (Carbajo, et al., Jan 2017; Carbajo, et al., May 2017; Taha, et al., 2017).

The Omega Loop Versus Roux-en-Y Gastric Bypass (YOMEGA) was a multicenter, randomized controlled trial conducted by Robert et al. (2018) to compare the safety and efficacy of one anastomosis gastric bypass (OAGB) (n=129) to Roux-en-Y gastric bypass (RYGB) (n=124). Patients were eligible for inclusion if they were aged 18–65 years, had a BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² with at least one comorbidity (e.g., type 2 diabetes, high blood pressure, obstructive sleep apnea, dyslipidemia, arthritis) and had undergone a multidisciplinary evaluation by the bariatric team. Exclusion criteria were a history of esophagitis, Barrett's esophagus, severe gastro-esophageal reflux disease resistant to proton-pump inhibitors, and previous bariatric surgery. The primary outcome measure was the percentage excess BMI loss two years after surgery. Secondary outcomes included: weight and BMI, early and late complications, mean length of hospital stay; duration of surgery; quality of life within two years of surgery; the incidence of gastro-esophageal reflux disease and diarrhea, steatorrhea at six months, dumping syndrome at each follow-up visit, metabolic profile, and histological modifications of gastric and esophageal mucosa. Two years postoperatively, the mean percentage excess BMI loss was –87.9% (SD 23.6) in the OAGB group and –85.8% (SD 23·1) in the RYGB group. The mean difference of percentage excess BMI loss was –3·3% in favor of OAGB. The mean operative time was significantly shorter in the OAGB group (p<0.001). The median duration of hospital stay was five days for both groups. There was no significant difference between the groups in HbA1C at two years. The mean decrease in HbA1C at two years was significantly greater in the OAGB group (p=0.0037). The proportions of type 2 diabetes remission were not significantly different between the treatment groups (p=0.28). There was no significant difference between the groups in the values and decrease of fasting glycemia, triglycerides, LDL cholesterol, HDL cholesterol, and total cholesterol. The incidence of diarrhea was significantly higher in the OAGB group (p=0.04), as was median steatorrhea at six months (p=0.0002). There was no significant difference in dumping syndrome at two years (p=0.82). The improvement in quality of life was not significantly different between the groups. Intraoperative complications occurred in four (3%) RYGB patients (three hemorrhages; one bowel injury) compared with eight (7%) OAGB patients (four hemorrhages; two bowel injuries; two stapling of the nasogastric tube). A total of 66 serious adverse events associated with surgery were reported. There were significantly more serious adverse events in the OAGB group vs. the RYGB group (42 vs. 24, respectively) (p=0.042) and nutritional complications (nine vs. no patients, respectively) (p=0.0034). A limitation of the study includes the number of patients lost to follow-up. Five patients did not undergo their assigned surgery, and after undergoing their surgery, 14 patients were excluded from the per-protocol analysis. There were four revisions from OAGB to RYGB. Additional limitations include the initial small patient population and the short-term follow-up of two years. The results of this study showed that OAGB was not inferior to RYGB in terms of percentage excess BMI loss at two years, using a 200 cm biliopancreatic limb in the OAGB group and a 150 cm alimentary limb and 50 cm biliopancreatic limb in the RYGB group. However, there were more serious adverse events following OAGB including nutritional complications. Prospective studies with long-term follow-up are needed to conclusively identify the safety and efficacy of OAGB.

Wang et al. (2018) conducted a systematic review and meta-analysis of the literature to compare the safety and efficacy of mini gastric bypass (MGB) (n=4558) vs. Roux-en-Y (RYGB) (n=3934). Ten cohort studies and one randomized controlled trial were included. A significant difference was seen in favor of MGB vs. RYGB in the one-year excess weight loss percentage (%EWL) (p=0.007) (five studies); two-year %EWL (p=0.003) (two studies); type 2 diabetes remission rate (p=0.002), and shorter operative time (p<0.00001) (four studies). There were no significant differences in remission rate of hypertension (p=0.57) (four studies), mortality (p=0.43) (four studies), leakage rate (p=0.48) (four studies), gastroesophageal reflux disease (p=0.47) (three studies) and hospital stay (p=0.89) (three studies). Limitations of the study included: the lack of randomized controlled trial, possible selection bias of studies, small patient populations, high heterogeneity between studies, and the short-term follow-ups. The authors cautioned that due to the small sample sizes and biased data, the results of this analysis should be treated with caution. Larger sample size and multi-center RCTs are needed to compare the safety and efficacy of these two procedures.

One randomized open comparison study (n=80) compared mini-gastric bypass to laparoscopic Roux-en-Y (Lee, et al., 2005). The authors reported similar efficacy in terms of excess weight loss (EWL) at two years. Based on a retrospective review (n=2678) intraoperative and early complication rates were 0.5% and 3.1%, respectively. Follow-ups that occurred at five years was 62.6%. Adverse events included perioperative bleeding, postoperative duodenal-gastro-esophageal reflux, gastric or anastomotic leak, and abscess or infection (Musella, et al., 2017). Comparative studies with large patient populations and long-term follow-up are needed to support the safety and effectiveness of mini-gastric bypass.

Wang et al. (2017) conducted a systematic review and meta-analysis to investigate the safety and effectiveness of laparoscopic mini-gastric bypass (MGB) versus laparoscopic sleeve gastrectomy (SG). Comparative studies, patients aged 20–70 years, with at least one of the desired outcome measures were included. Two randomized controlled trials and 12 cohort studies met inclusion criteria. The primary endpoints were one-year percentage excess weight loss (%EWL), five-year %EWL, and remission rate of comorbidities (type 2 diabetes, hypertension, obstructive sleep apnea [OSA], osteoarthritis). The secondary endpoints included overall early complications rate, leakage rate, postoperative bleeding rate, overall late complications rate, ulcer rate, vomiting rate, anemia rate, GERD rate, hospital stay, and revision rate. The last endpoint was operation time. Meta-analysis included 1998 MGB patients and 1864 SG patients. Two studies included patients with a preoperative BMI > 50 kg/m^2 and three studies included type 2 diabetics. Results of meta-analyses included the following:

- MGB one-year %EWL ranged from 58%–79.3%; SG ranged from 45%–71.4%
- MGB five year %EWL ranged from 68%–78.2%; SG ranged from 51.2%–68.7%
- MGB had a higher one-year %EWL than SG group (p=0.005) (seven studies)
- MGB had a higher five-year %EWL (p>0.001) (two studies)
- MGB had a higher remission rate of type 2 diabetes (p=0.002) (eight studies)
- MGB had a higher remission rate of hypertension (p=0.02) (six studies)
- MGB had a higher remission rate of OSA (p=0.03) (three studies)
- MGB had a lower remission rate of osteoarthritis (p=0.008) (two studies)
- MGB's overall comorbidity remission rates were 86% for type 2 diabetes, 75% for hypertension, 93% for OSA and 68% for osteoarthritis; SG's overall comorbidity remission rates were 65% for type 2 diabetes, 60% for hypertension, 76% for OSA and 88% for osteoarthritis.
- There were no significant differences in overall early complication rates (six studies), bleed rates (p=0.095) (six studies), vomiting rates (p=0.36) (three studies), anemia rates (p=0.17) (two studies) and operation times (p=0.58) (four studies).
- MGB had a lower leakage rate (p=0.02) (five studies), lower overall late complication rate (p=0.02) (three studies), lower GERD rate (p=0.006) (four studies), shorter hospital stay (p=0.05) and a lower revision rate (p<0.001) (five studies).
- MGB had a higher ulcer rate (p=0.001) (six studies)

The authors noted that due to the biased data, small patient populations, short-term follow-ups and heterogeneity of the studies, the results may be unreliable. Multicenter randomized controlled trials with large patient populations and long-term follow-ups are needed to compare the effectiveness and safety between mini-gastric bypass and sleeve gastrectomy. Future studies should also investigate the rate of bile reflux and remnant gastric cancer following MGB.

The American Society for Metabolic and Bariatric Surgery (ASMBS) (2018) conducted a literature review on the one-anastomosis gastric bypass (OAGB) or mini gastric bypass. Eleven review articles and 58 clinical studies of which 93% were retrospective reviews were included. A mean follow-up of 60 months was reported in 86% of the studies. Four randomized controlled trials (RCT) involving 341 patients were also included. From the review, ASMBS concluded that OAGB had a relatively short operative time, low complication rate, and excellent weight loss outcomes. However, the retrospective nature of the studies and lack of long-term follow-up data limited the current evidence regarding OAGB, particularly in regard to concerns about long-term nutritional deficiencies due to the hypoabsorptive nature of the procedure, as well as issues specific to the loop gastroenterostomy configuration, such as bile reflux and its potential long-term carcinogenic effects. Well-designed prospective studies with long-term follow-ups are needed to establish the safety and efficacy of OAGB.

Natural Orifice Transluminal Endoscopic Surgery (NOTES)
NOTES, also referred to as endoscopic (oral)-assisted, endoluminal, or transoral incisionless surgery, involves the use of natural orifice access (e.g., mouth, anus) to perform a surgical procedure which potentially reduces or eliminates the trauma of access incisions. The NOTES technique is currently being investigated for use in a range of procedures including bariatric procedures such as gastric bypass (Schauer, et al., 2007).

In 2005, representatives from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Gastrointestinal Endoscopy (ASGE) formed a Working

Group on Natural Orifice Translumenal Endoscopic Surgery. The Working Group, now called Natural Orifice Surgery Consortium for Assessment and Research™ (NOSCAR®), is developing a guidance document for Natural Orifice Translumenal Endoscopic Surgery (NOSCAR, 2021). NOSCAR stated that research on the safety and efficacy of NOTES has generally been confined to animal studies, but human studies are being performed.

Gys et al. (2019) conducted a systematic review and meta-analysis of the published literature to evaluate the efficacy and safety of endoscopic gastric plication or gastroplasty for morbid obesity. Endoscopic gastroplasty is a natural orifice transluminal endoscopic surgery (NOTES) which is considered a minimally invasive and mostly restrictive procedure. Twenty two studies (n=2475 patients, mean age 41.2 years, mean baseline BMI 37.8 ± 4.1 kg/m^2) met the inclusion criteria of a clinical trial with the primary intervention of endoscopic gastroplasty. Seven different techniques were used among the 22 studies. Eight studies (n=1721) used the OverStitch Endoscopic Sleeve Gastroplasty (ESG). Five studies (n=465) used primary obesity surgery endoluminal (POSE™). Four studies (n=128) used the transoral (vertical) gastroplasty (TOGa®) technique. One study (n=64) used endoluminal vertical gastroplasty (EVG Bard EndoCinch™ suturing system). One study (n=18) used transoral gastric volume reduction (TGVR RESTORe Suturing System). One study (n=17) used the 360°, fully flexible articulating circular endoscopic stapler (ACE). Two studies (n=62) used the endoluminal suturing device (Endomina). Studies were excluded if weight loss was not a primary outcome, had indications other than morbid obesity or concomitant surgical procedures were performed. The primary outcome measured was weight loss at six months or more after the procedure. The secondary outcome was the occurrence of adverse events or complications including insufficient weight loss or regain. The mean follow-up was 13 months. The procedures included in the meta-analysis were endoscopic sleeve gastroplasty (ESG) and the primary obesity surgery endolumenal (POSE™). The average pooled percentage excess weight loss (%EWL) at six months (p = 0.02) and 12 months (p = 0.04) favored POSE™. The %EWL for ESG was 57.9 ± 3.8% at six months and 44.4 ± 2.1% at 12 months. %EWL for POSE™ was 68.3 ± 3.8% at six months and 44.9 ± 2.1% at 12 months. The TOGa® studies reported 35 %EWL after six months and 43 %EWL after 12 months. The EVG Bard EndoCinch™ suturing system reported 58.1 ± 19.9 %EWL after 12 months. TGVR RESTORe Suturing System reported 27.7 ± 21.9 %EWL after 6–12 months follow-up. ACE reported a median %EWL of 34.9 after 12 months. Endomina reported 32%EWL at six months and 29% EWL at 12 months. ESG reported adverse events were pneumothorax (n=2), perigastric collection (n=8), pulmonary embolism (n=2), intraluminal bleeding (n=5), and leakage (n=1). POSE™ adverse events included intraluminal bleeding (n=2), extra gastric bleeding (n=1), and hepatic abscess (n=1). TOGa® studies reported post-procedural COPD exacerbation as the only major adverse event. The EVG Bard EndoCinch™, TGVR RESTORe Suturing System, ACE, and Endomina reported no major adverse events. Other frequent adverse events reported for any device used include abdominal pain, sore throat, and/or nausea with or without vomiting. Minor adverse events not requiring intervention included superficial phlebitis, temporomandibular dysfunction, pharyngitis, esophagitis, (mild) mouth trauma, and self-limiting intraluminal bleeding. An author-noted limitation of the review was that the devices used varied in techniques. Limitations of the study include the small patient populations and relatively short-term follow-up. High quality studies with larger patient populations and long-term follow-up are needed to determine efficacy and safety of these devices.

Khan et al. (2019) conducted a systematic review and meta-analysis to evaluate and compare the efficiency of three endoscopic procedures for the treatment of obesity (endoscopic sleeve gastroplasty [ESG], AspireAssist [AA], primary obesity surgery endolumenal [POSE]). Twelve studies (n=1149 patients) met the inclusion criteria. Studies were included if they used one of the three endoscopic procedures (ESG, POSE, or AA), reported on either percent excess weight loss (%EWL) or percent total body weight loss (%TBWL), had follow-ups of six months or more, and a minimum of ten patients in the study. Studies were excluded if they were suspected of patient overlap based on inclusion dates reported. Primary outcomes measured were percent excess weight loss (%EWL) and percent total body weight loss (%TBWL) and were reported at six, 12, and 24 months. Four observational studies (n=369) evaluated the performance of ESG. Pooled mean %EWL was 49.67 ($p=0.22$) at six months, 52.75 at 12 months, and 60.40 at 24 months. Pooled mean %TBWL was 16.01 ($p<0.001$) at six months, 17.41 at 12 months, and 19.61 at 24 months. Two randomized control trials (RCT) and two observational studies evaluated the AA (n=307). Pooled mean %EWL at six and 12 months was 43.25 and 50.85, respectively. Pooled mean %TBWL was 15.37 at 12 months and 20.10 at 24 months. Two RCT and two observational studies evaluated POSE (n=447). Pooled mean %EWL was 43.79 and 44.91 at six and 12 months. Pooled mean %TBWL at six months 13.82 ($p=0.12$) and 12 months 10.98 ($p<0.001$). ESG showed more weight loss than POSE at six and 12 months. No differences in weight loss between ESG and AA at 12 and 24 months was reported. There was no difference in weight loss between AA and POSE at 12 months. The most common adverse events reported were abdominal pain, nausea and vomiting. Adverse events for AA included peristomal infections and granulation tissue formation. Adverse events for ESG were reported in one patient each with pulmonary embolism, pneumoperitoneum, and perigastric fluid collection. Author-noted limitations included: heterogeneity of the studies, inclusion of small studies and inability to evaluate effects on comorbidities such as diabetes, hypertension and lipid profiles. Well-controlled studies with larger patient populations are needed to support the current limited evidence on weight loss in both the short- and long-term, as well as safety for these devices.

Restorative Obesity Surgery, Endoluminal (ROSE): ROSE is an endoscopic–assisted procedure that is being investigated for the treatment of weight regain following gastric bypass surgery that is caused by a gradual expansion of the gastric pouch. The stomach is accessed orally via an endoscope and the stomach pouch is reduced in size using a device such as the StomaphyX™ endoluminal fastener and delivery system (EndoGastric Solutions, Inc., Redmond, WA). StomaphyX is described as a non-invasive weight loss procedure to reduce the size of a patient's stomach without any incisions.

StomaphyX: The StomaphyX is inserted endoscopically and used to create permanent folds (plications) by repeatedly suctioning and fastening parts of the stomach wall using H-shaped durable fasteners. The folds make the area within the stomach smaller, reducing the amount of food the patient can eat. The folds can also serve to slow the draining of food into the lower part of the stomach, prolonging feelings of fullness to further facilitate weight loss.

US Food and Drug Administration
StomaphyX was granted marketing approval by the FDA via the 510(k) process on March 9, 2007 because it was considered substantially equivalent to another device already on the market. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the StomaphyX prior to marketing the device. The StomaphyX system is FDA approved for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract. The 510(k) summary stated that the StomaphyX is substantially equivalent to LSI Solutions Flexible Suture Placement Device and the Bard Endoscope Suturing System/Bard Endocinch. The Bard suturing systems were FDA 510(k) approved for endoscopic placement of sutures in the soft tissue of the esophagus and stomach and for approximation of tissue for the treatment of symptomatic GERD.

Literature Review
Evidence investigating the safety and efficacy of StompahyX is lacking.

Professional Societies and Organizations
American Society for Metabolic and Bariatric Surgery (ASMBS): According to ASMBS there are currently a number of endoluminal innovations and novel devices and technologies in different

stages of development or application for the treatment of obesity, including provisional interventions. The Society noted that the theoretical goals of these therapies include decreasing the invasiveness, risk, and barriers to acceptance of effective treatment of obesity. However, these outcomes cannot be assumed and must be proven. The Society stated that the use of novel technologies should be limited to clinical trials done in accordance with the ethical guidelines and designed to evaluate the risk and efficacy of the intervention (ASMBS, 2009a; reviewed 2013).

Duodenal-jejunal Bypass Liner: The duodenojejunal bypass liner (DJBL) is an endoscopically placed and removable intestinal liner. The EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Lexington, MA) is described as a non-surgical, physical barrier that enables food to bypass portions of the intestine. This device is proposed for bariatric preoperative weight loss but has not been approved by the FDA.

Literature Review
Evidence in the published peer reviewed medical literature evaluating the safety and effectiveness of the endoscopic duodenal-jejunal bypass liner is limited to few studies with small sample sizes and short-term follow-up. Koehestanie et al. (2014) conducted a multicenter RCT of obese patients with T2DM assigned to treatment with DJBL implantation (n=38) versus control (n=39). Patient eligibility criteria included adults between 18 and 65 years of age, BMI between 30 and 50 kg/m2, and T2DM for less than 10 years. Exclusion criteria were weight loss of more than 4.5 kg within 12 weeks before screening, anticoagulation therapy, and weight loss medication. After six months' follow-up, a statistically significant decrease in body weight was observed in favor of the DJBL group (p<0.05). EWL was also greater in the DJBL versus control group (p<0.05). HbA1c levels decreased to 7.0% in the DJBL group compared with 7.9% in the control group (p< 0.05). In the DJBL group, 76.3% of the patients had at least one adverse event (e.g., gastrointestinal complaints) compared to 59% of the patients in the control group. Although study results suggest DBJL implantation may be effective in improving HbA1c levels and may result in EWL, the study is limited by its small sample size and short term follow-up.

An RCT (n=41) by Schouten et al. (2010) compared patients who received the endoscopically placed duodenal-jejunal bypass sleeve or EndoBarrier Gastrointestinal Liner (n=30), to a diet control group (n=11). Successful implantation occurred in 26 patients. Mean EWL after three months was 19.0% for device patients versus 6.9% for control patients (p<0.002). All patients had at least one adverse event, primarily abdominal pain and nausea during the first week after implantation.

Professional Societies/Organizations
American Society for Gastrointestinal Endoscopy (ASGE): The Bariatric Endoscopy Task Force, a subcommittee of ASGE, conducted a systematic review and meta-analysis of the literature to evaluate endoscopic technologies for the treatment of obesity. The review included a meta-analysis of the available data on the EndoBarrier duodenal jejunal bypass sleeve (DJBS). Regarding EndoBarrier DJBS, six randomized controlled trials and six prospective studies met inclusion criteria. Three studies (n=105) reported 35.3% excess weight loss (EWL) at 12 months following implantation. Four randomized controlled trials compared 12–24 weeks of treatment with EndoBarrier (n=90) vs. sham or control (n=84). The mean %EWL difference compared with a control group was significant at 9.4%. The studies were associated with a high degree of heterogeneity. Compared to baseline, the EndoBarrier demonstrated a significant improvement in HBA1C from -0.7 at 12 weeks (p=0.16), -1.7 at 24 weeks (p<0.001) weeks and -1.5 at 52 weeks (p<0.001) following implantation. There was a statistically significant improvement in HBA1C when EndoBarrier was compare to controls (p=0.001). Adverse events included 58.7% pain, 39.4% nausea/vomiting, 18.37% early removal, 4.93% migration, 3.9% GI bleeding and 3.47% sleeve obstruction. The Task Force noted that enrollment in the multicenter U.S. pivotal trial was placed on hold in March 2015 by the U.S. Food and Drug Administration after four cases of hepatic

abscess occurred among the 325 patients already enrolled. Author-noted limitations of the meta-analyses included the high degree of heterogeneity among included studies, risk of bias in non-randomized studies, and different methods used among studies to report the %EWL (Metropolitan Life Tables vs. BMI 25 method) (ASGE Bariatric Endoscopy Task Force, et al., 2015). Randomized controlled trials with larger patient populations and long-term data are necessary to support the safety and efficacy of EndoBarrier DJBS.

National Institute for Health and Care Excellence (NICE): According to the 2013 NICE (United Kingdom) guidance on the use of duodenal–jejunal bypass sleeves, the current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass sleeve for managing obesity was limited in quality and quantity. NICE stated that this procedure should only be used in the context of research. Well-controlled studies are needed to support the current limited evidence on weight loss in the short term.

Transoral Gastroplasty (TG): Transoral gastroplasty, also known as vertical sutured gastroplasty or endoluminal vertical, involves the use of endoscopically guided staplers that create a stapled restrictive pouch along the lesser curvature of the stomach. The TOGA® system (Satiety Inc., Palo Alto, CA) developed for this procedure has not been FDA-approved. Currently there is insufficient evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of this procedure.

Endoscopic Closure Devices: Endoscopic closure devices such as the Overstitch (Apollo Endosurgery, Inc., Austin, Texas), are used in a variety of surgical procedures including bariatric surgery. The devices are proposed for endoscopic closure of acute and chronic gastrointestinal (GI) wall defects, including spontaneous and iatrogenic perforations, anastomotic leaks, and chronic fistulae. They may also allow closure of enterotomies created for NOTES procedures. In August 2008, the Apollo Endosurgery OverStitch Endoscopic Suture System received PMA approval from the FDA. According to the FDA the Apollo Overstitch is intended for endoscopic placement of suture(s) and approximation of soft tissue and provides physicians the ability to perform several different types of tissue apposition within the gastrointestinal tract and peritoneal cavity (FDA, 2008). The ASGE (2014) stated that further prospective studies are needed to define the role of these devices in the closure of GI wall defects.

Currently there is insufficient evidence in the peer-reviewed medical literature to support the use of transluminal endoscopic surgical procedures and devices including the ROSE procedure, StomaphyX, transoral gastroplasty, DJBL, and endoscopic closure devices for the management of severe obesity. Studies investigating the OverStitch Endoscopic Suturing System are primarily in the form of retrospective reviews and prospective case series with small patient populations (n=4–77) and short-term follow-ups (6–20 months) (Kumar, et al., 2018; Abu Dayyeh, et al., 2017; Pauli, et al., 2013).

Endoscopic sleeve gastroplasty (ESG): Endoscopic sleeve gastroplasty is a procedure in which the volume of the stomach is reduced by approximately 70% through plication of the greater curvature of the stomach using an endoscopic suturing device (OverStitch, Apollo Endosurgery, Austin, TX).

Literature Review

Currently there is insufficient evidence in the peer-reviewed medical literature to support the use of ESG. Evidence investigating the safety and efficacy of ESG is limited to retrospective reviews and case series. Comparative studies are lacking. Hedjoudje et al. (2020) conducted a systematic review and meta-analysis to evaluate the safety and efficacy of endoscopic sleeve gastroplasty (ESG) for the treatment of obesity. Eight studies (n=1772) met inclusion criteria including three retrospective studies and five prospective case series. The patient's mean age was 38.3 ± 10.9

years, 62.6% were male with baseline body mass index (BMI) of 33.3 ± 4.5 kg/m^2 and 43.0 ± 8.9 kg/m^2. The pooled mean total body weight loss (TBWL) was 8.8% ($p \leq 0.01$) at one month, 11.2% ($p \leq 0.01$) at three months, 15.1% ($p<0.01$) at six months, 16.1% ($p=0.08$) at nine months, 16.5% ($p<0.01$) at 12 months, and 17.1% ($p=0.03$) at 18-24 months. The pooled decrease in BMI was 3.0 kg/m^2 ($p<0.01$) at one month, 3.9 kg/m^2 ($p<0.01$) at three months, 5.6 kg/m^2 ($p<0.01$) at six months, 5.7 kg/m^2 ($p=0.12$) at nine months, 6.1 kg/m^2 ($p<0.01$) at 12 months, and 6.5 kg/m^2 ($p<0.01$) at 18-24 months. The pooled relative excess weight loss (EWL) was 32.4% ($p<0.01$) at one month, 47.1% ($p<0.01$) at three months, 57.7% ($p=0.01$) at six months, 66.2% ($p=0.07$) at nine months, 61.8% ($p<0.01$) at 12 months, and 66.9% ($p=0.04$) at 18-24 months. The pooled estimate of post-ESG severe adverse event rate was 2.2%. No deaths were reported. The pooled rates of reported severe adverse events included 1.08% (n=18) pain or nausea requiring hospitalization, 0.56% (n=9) upper gastrointestinal bleeding, 0.48% (n=8) perigastric leak or collection, 0.06% (n=1) pulmonary embolism, and 0.06% (n=1) pneumoperitoneum. Author-noted limitations of the meta-analyses included the high degree of heterogeneity among included studies, risk of bias in non-randomized studies, short term follow-up, lack of evaluation of comorbidities, lack of reporting of mild adverse events, and different methods used among studies to report the %EWL.

Transoral outlet reduction (TORe): Transoral outlet reduction (TORe) is an endoscopic procedure used in patients with weight gain post Roux-en-Y gastric bypass (RYGB). Weight regain after Roux-en-Y gastric bypass (RYGB) correlates with dilated gastrojejunal anastomosis (GJA). Endoscopic sutured transoral outlet reduction (TORe) has predominantly been performed by either placing interrupted sutures at the GJA or the creation of a purse-string suture. This procedure has also been performed using various techniques including plication devices (Stomaphyx; Endogastric Solutions, California, United States), suction based superficial suturing devices (Endocinch; C.R. Bard, Murray Hill, New Jersey, United States) or with the full thickness suturing devices (Overstitch; Apollo Endosurgery, Texas, United States) (Dhindsa, et al. 2020).

Literature Review

Evidence in the published peer reviewed medical literature evaluating the safety and effectiveness of transoral outlet reduction is insufficient to support its use. The evidence consists of retrospective reviews and case series with small patient populations (n=20–44) and short-term follow-ups (9–12 months) (Fayad, et al., 2019; Laterza, et al., 2017; Catalano, et al., 2016; Goyal, et al., 2015)

Roux-en-Y Gastric Bypass (RYGB) Combined with Gastric Banding

The combination of RYGB with a banding procedure is being investigated as a treatment to enhance weight loss and avoid weight regain. The evidence evaluating this combined procedure is currently limited. A prospective randomized double-blind trial (n=90) by Bessler et al (2007) compared banded and nonbanded open gastric bypass for the treatment of super obesity. No significant differences were found in the overall number of complications, resolution of co-morbidities, or % excess weight loss (EWL) at six, 12, and 24 months (43.1% versus 24.7%, 64.0% versus 57.4%, and 64.2% versus 57.2%, respectively) postoperatively. The banded patients had achieved a significantly greater %EWL at 36 months (73.4% versus 57.7%; $p<0.05$). The incidence of intolerance to meat and bread was greater in the banded group.

The available evidence for gastric bypass combined with simultaneous gastric banding is insufficient to support safety and efficacy for the treatment of obesity, and to demonstrate a clinical benefit with improved long-term outcomes.

Stomach Aspiration Therapy

Aspiration therapy is being investigated as a weight loss method for patients with Class II and III obesity. This therapy involves the endoscopic percutaneous placement of a gastrostomy tube which drains gastric contents after meal consumption. Aspiration therapy requires the use of the AspireAssist system that allows instillation of fluid into the stomach and partial aspiration of ingested meals (Sullivan, 2016).

U.S. Food and Drug Administration
On June 14, 2016 Aspire Bariatrics, Inc. (King of Prussia, PA) received FDA PMA approval for the AspireAssist® System. The device consists of the A-Tube™ which connects to a port (Skin-Port) outside of the abdomen, a water reservoir for infusion, and a "gravity" flow director system through which patients aspirate (drain) gastric contents about 20 to 30 minutes after consumption of a meal. The AspireAssist is used after the three (3) major meals each day, takes about 5-10 minutes to complete, and typically removes about 30% of the calories consumed. According to the FDA, the AspireAssist is intended to assist in weight reduction of obese patients. It is indicated for use in adults aged 22 or older with a BMI of 35-55 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for a long-term duration of use in conjunction with lifestyle therapy and continuous medical monitoring. Contraindications include the following:

- previous abdominal surgery that significantly increases the medical risks of gastrostomy tube placement
- esophageal stricture, pseudo-obstruction, severe gastroparesis or gastric outlet obstruction
- inflammatory bowel disease
- history of refractory gastric ulcers
- ulcers, bleeding lesions, or tumors discovered during endoscopic examination
- uncontrolled hypertension (blood pressure >160/100)
- history or evidence of serious pulmonary or cardiovascular disease, including acute coronary syndrome, heart failure requiring medications, or NYHA (New York Heart Association) class III1 or IV2 heart failure

The pivotal study for FDA-approval was an RCT (n=207) published by Thompson et al (2017). In this study, patients were randomized to receive treatment with aspiration therapy plus lifestyle counseling (n=137) or lifestyle counseling alone (n=70). Inclusion criteria were age 21–65 years old and a BMI of 35.0–55.0 kg/m^2. Exclusion criteria included previous bariatric surgery, serious cardiovascular disease, use of medications that cause clinically significant weight gain or loss, and a history of an eating disorder. The first co-primary end point was mean percentage of excessive weight loss (% EWL) at 52 weeks, with success defined as at least a 10% difference in %EWL between the AspireAssist and Lifestyle Counseling groups. The second co-primary end point was the proportion of participants who achieved at least a 25% EWL at 52 weeks. Success was defined as at least 50% of the AspireAssist group achieving at least 25% EWL. Secondary end points included change in percentage of total body weight from baseline and the proportion of participants who achieved a reduction in total body weight of 10% or more. After enrollment, 29 AspireAssist and 29 Lifestyle Counseling participants withdrew from the study leaving 82 AspireAssist (74% of those enrolled) and 31 Lifestyle Counseling participants (52% of those enrolled) who completed the entire 52-week study. Both co-primary end points were met: 1) % EWL in the AspireAssist group was 22% greater than the %EWL achieved in the Lifestyle Counseling only group, and 2) 59% of the AspireAssist group lost at least 25% of EBW. Adverse events were primarily associated with the gastrostomy tubes and included the development of peristomal granulation tissue (40.5%) and abdominal pain (37.8%). Serious adverse events were severe abdominal pain, peritonitis, pre-pyloric ulcer, and A-tube replacement due to Skin-Port malfunction, each occurring in one patient (0.9%). Acknowledged study limitations include the lack of blinding which was not possible, the short-term follow-up period, and the number of patients lost to follow-up (28%). Study results suggested that aspiration therapy may be effective in achieving weight loss. However, safety issues surround the required gastrostomy tube placement and additional well-designed studies with longer follow-up are needed to define the role of this weight-loss therapy.

Literature Review
Nystrom et al. (2018) conducted a post-market registry/observational study (n=201) to evaluate the safety and efficacy of the AspireAssist System at five European centers. Subjects were age ≥◦18 years with a BMI of 35.0–70.0 kg/m^2 and had failed conservative weight loss methods. Following AspireAssist implantation lifestyle/cognitive behavior therapy was provided and varied from center to center. Follow-ups occurred monthly or as medically warranted during the first year. After the first year follow-ups occurred every
3–6 months with some visits conducted electronically or telephonically. Mean weight loss outcomes included: 18.2% ± 9.4% (n=155) at one year; 19.8% ± 11.3% (n=82) at two years; 21.3% ± 9.6% (n=24) at three years and 19.2% ± 13.1% (n=12) at four years. Clinically significant reductions at year one were observed in glycated hemoglobin (HbA1C) ($p<0.0001$) (n=57), triglycerides ($p<0.001$) (p=53), total cholesterol ($p<0.01$) (n=53) and blood pressure. Of the 199 successful gastrostomies, 47 participants discontinued aspiration therapy and had their gastrostomy tubes removed along with 17, 18, 9, 2, and 1 subjects in the first, second, third, fourth, and fifth year, respectively. Reasons for discontinuing the therapy included: achievement of weight loss, lack of weight loss, inability or unwillingness to adhere to therapy, discomfort and/or fatigue with the therapy. Five subjects pursued other bariatric surgeries. Periprocedural complications included pain, possible/actual wound infections, and benign pneumoperitoneum. Postoperative complications included: gastric leakage, stomal irritation/granulation tissue; infection/possible infection; buried bumper; and A-Tube rotation. Author-noted limitations of the study included: lack of a control group; only two centers reported cardiometabolic data; short-term follow-up; and number of subjects lost to follow-up. Another limitation was the variation in the lifestyle/cognitive behavior therapy at each center. Randomized controlled trials with large patient populations and long-term follow-up are needed to support the safety and efficacy of the AspireAssist.

Norén and Forssell (2016) conducted a prospective observational study (n=25) the AspireAssist system for treatment of obesity, and its effect on patient's quality of life. Inclusion criteria were BMI ≥ 35.0 kg/m^2 and age from 25 to 65 years. Exclusion criteria were myocardial infarction during the last three months, known malignancy, chronic liver or kidney disease, prior major surgery in the upper gastrointestinal tract, psychiatric disease including substance abuse, or eating disorder, Participants had the option to continue therapy for an additional year. Follow-up of 12 months was completed by 20/25 patients. The mean extreme weight loss (EWL) was 54.4% at 12 months and 61.5% at 24 months. In diabetic patients (n=7), there was a significant reduction in HbA1c level from a median of 47to a median of 42 ($p=0.03$). The primary adverse effect was moderate to severe pain. Quality of life measured by EQ-5D and VAS was reported to significantly increase during treatment. Study limitations include the non-randomized controlled design, small patient population, and short-term follow-up.

A randomized controlled pilot study (n=18 subjects) by Sullivan et al. (2013) assigned obese subjects in a 2:1 ration to undergo aspiration therapy for one year plus lifestyle therapy (n=11) or lifestyle therapy alone (n=7). Lifestyle intervention comprised a 15- session diet and behavioral education program. Adults with a BMI between 40.0 and 50.0 kg/m^2 or between 35.0 and 39.9 kg/m^2 with comorbidities were selected. Exclusion criteria were evidence of an eating disorder or major depression, history of gastrointestinal disease or previous gastric surgery that would increase the risk of A-Tube placement, uncontrolled hypertension, sleep apnea, fasting serum glucose level ≥ 105 mg/dL, diabetes, serum triglyceride level > 400 mg/dL or pregnancy/lactation. One-year follow-up was completed by 10/11 aspiration therapy subjects and 4/7 subjects who received lifestyle therapy only. The percentage of weight loss and excess weight loss (EWL) in the aspiration therapy group was significantly greater than in the lifestyle therapy group (p=0.02, p=0.036 respectively) at 52 weeks. No significant change in the percentage of weight loss or EWL occurred from week 52 to week 104 in the subjects (n=7) who continued aspiration therapy. The use of aspiration therapy was not reported to induce any adverse eating behaviors. The adverse events included peristomal pain and irritation. No serious adverse events occurred in either group. These study results indicate that aspiration therapy may be associated with weight loss in obese patients. However it is difficult to draw conclusions regarding safety and efficacy due to the small number of patients included and lack of long-term follow-up.

There is a paucity of evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of stomach aspiration therapy. Studies primarily include small patient populations and short-term follow-ups. Additional well-designed, long-term studies are needed to support this treatment for Class II and III obesity.

Vagus Nerve Blocking

Vagus nerve blocking (VNB) or vagal blocking therapy is has been investigated as a treatment for obesity. In vagal blocking for obesity control (VBLOC) (e.g., Maestro) an implanted neurogenerator discharges high-frequency, low-energy electrical pulses to block vagus nerve signals in the abdominal region, inhibiting gastric motility and increasing satiety (feeling full). The procedure involves the placement of two leads around the vagal nerve trunks via laparoscopy. An external device programs the generator. Early clinical trial results suggest that VNB may achieve excess weight loss (EWL) that is comparable to approximately half of that achievable by LAGB.

U.S. Food and Drug Administration

On January 14, 2015 EnteroMedics, Inc. (St. Paul, MN) received PMA device approval for the Maestro® Rechargeable System. The device consists of implantable (i.e., rechargeable neuromodulator, anterior and posterior leads), and external components which include the clinician programmer, and clinician and patient transmit coils. The system sends pulses of energy to vagal nerve trunks at a high frequency, which keeps the nerve fibers in a refractory state and suppresses the natural impulses that are sent from the stomach to the brain. According to the FDA, the Maestro system is "indicated for use in weight reduction in patients aged 18 years through adulthood who have a Body Mass Index (BMI) of 40 to 45 kg/m2, or a BMI of 35 to 39.9 kg/m^2 with one or more obesity related co-morbid conditions, and have failed at least one supervised weight management program within the past five years." Contraindications are as follows:

- cirrhosis of the liver, portal hypertension, esophageal varices or a clinically significant hiatal hernia
- planned magnetic resonance imaging (MRI)
- planned ultrasound diathermy
- high risk for surgical complications
- permanently implanted, electrical powered medical device, or gastrointestinal device or prosthesis (e.g., pacemakers, implanted defibrillators, or neurostimulators)

Potential adverse of the device include allergic reaction to the implanted material and damage to the vagal nerve trunks. The FDA-approval was based on one pilot and two pivotal studies (i.e., EMPOWER, ReCharge) (FDA, 2015).

Literature Review

Evidence in the published peer-reviewed medical literature evaluating vagus nerve blocking (VNB) for severe obesity consists of RCTs and case series. Morton et al. (2016) conducted an RCT (n=84) to evaluate the safety and efficacy of vagal blocking device (vBloc) in patients with moderate obesity and comorbidities. This sub-group from the FDA ReCharge trial was randomized to vBloc (n=53) or sham (n=31). Obesity-related comorbidities included dyslipidemia (73%), hypertension (58%), sleep apnea (33 %), and type 2 diabetes (8 %). The vBloc group achieved a

33% excess weight loss (EWL) compared to 19% EWL in the sham group at 12 months ($p<0.0001$). Common adverse events of vBloc through 12 months of follow-up were heartburn/dyspepsia and implant site pain; the majority of events were reported as mild or moderate.

Ikramuddin et al. (2014) conducted the ReCharge trial, a multicenter randomized, double-blind, sham-controlled study (n=239) of patients implanted with a nerve block device (Maestro Rechargeable System) using active (n=162) versus sham treatment (n=77). Inclusion criteria were a BMI of 40-45 or 35-40 with at least one obesity-related condition. The co-primary endpoints were percentage of excess weight loss (% EWL) at 12 months and the percentage of patients achieving ≥ 20% EWL and ≥ 25% EWL. At 12 months, 52% of patients in the vagal nerve block group achieved 20% or more excess weight loss and 38% achieved 25% or more excess weight loss. In the sham group 32% of subjects achieved 20% or more loss and 23% achieved 25% or more loss. Efficacy endpoints were not met. A total of eight patients in the active therapy group required a revision procedure. Therapy-related serious adverse event rate in the vagal nerve block group was 3.7%, and included mild to moderate heartburn, dyspepsia, and abdominal pain. Acknowledged limitations include homogeneity of the patient population and a low rate of common metabolic comorbidities such diabetes. Study results indicate no significant difference in %EWL between active vagal nerve block therapy and treatment with a sham device.

Apovian et al. (2017) reported on the two-year follow-up of the ReCharge study on the subjects who were randomized to vBloc and continued open-label with the therapy. At 24 months subjects (n=103) had a mean excess weight loss (EWL) of 21%; mean total weight loss (TWL) of 8%; 58% had ≥ 5% TWL; and 34% had ≥ 10% TWL. Compared to screening values, significant improvements ($p<0.05$) were seen in mean LDL, HDL, triglycerides and systolic and diastolic blood pressures. Patients in the sham group who did not cross-over had a mean 4% EWL. Adverse events included heartburn, dyspepsia and implant site pain. There were four additional revisions between 12 and 24 months of which two were due to pain at the neuroregulator site and one each due to twisted leads and a device that would not recharge. Limitations of the study include the small patient population, short-term follow-up, missing data and lack of a control group.

Sarr et al. (2012) conducted the EMPOWER study, a multicenter double-blind, prospective RCT (n=294) of patients implanted with a vagal blocking system and randomized to the treatment (n= 192) or control (n=102) group. Male or female obese subjects, 18-65 years of age, with a BMI of 40-45 kg/m^2 or 35-39.9 kg/m^2 with one or more obesity-related, comorbid condition were included. The primary effectiveness objective was to demonstrate a significantly greater %EWL at 12 months in the treated group compared to the control group. At the end of the blinded, 12-month follow-up period, all subjects received open-label VBLOC Therapy and will be followed for an additional four years. The secondary effectiveness objective was to determine if a significantly greater percent of subjects in the treated group achieved 25% EWL compared to control subjects. Neither endpoint statistically differed between active and sham treatment groups. There were a total of 35 adverse events including infection and pain, with 14 subjects requiring a revision procedure due to an adverse event or to make the device operational. Limitations of the study included compliance issues related to wearing an external device versus a completely implantable system, and the study inclusion of dietary counseling, behavior modification, and exercise training, which may have contributed to the % EWL.

Camilleri et al. (2009) conducted an open-label multicenter study (n=31) to assess the effects of a vagal blocking device on EWL, safety, dietary intake, and vagal function. Electrodes were implanted laparoscopically near the esophagogastric junction to provide intermittent vagal blocking in patients with a BMI range of 35-50 kg/m^2. The mean EWL at six months follow-up was 14.2% ($p<0.001$). Calorie intake decreased by > 30% at six months ($p\leq$ 001), with earlier satiation ($p<0.001$) and reduced hunger ($p=0.005$). There were no deaths or device-related serious adverse events. The study is limited by its small sample size and lack of randomization. Additional well-designed studies are needed to further evaluate the role of this therapy in the treatment of obesity.

Evidence evaluating the safety and effectiveness of VNB is limited, not supportive of safety and efficacy at this point, and is therefore insufficient to support use of the procedure for the treatment of obesity.

Professional Societies/Organizations
The American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on VNB for obesity stated that the quantity of the current data and the length of follow-up indicate adequate safety and efficacy in the short term. More prospective studies with longer follow-up are required to establish the clinically significant efficacy and patient tolerance of this device (Papasavas, et al., 2015).

Vagus Nerve Stimulation (VNS)
VNS provides intermittent electrical stimulation to the tenth cranial nerve, which influences certain patterns of brain activity. The vagus nerve is a major connection between the brain and the rest of the body and as such, carries sensory information from the body to the brain and motor commands from the brain to the body. A potential use of VNS concerns the regulation of brain satiety signals. The brain knows that the stomach is empty or full, largely on the basis of information transmitted by the vagus nerve. Based on the theory the vagus signal could be altered to modify eating behavior, VNS has been proposed as a treatment for obesity. Currently the literature regarding the use of VNS for obesity is limited and therefore conclusions about safety and efficacy cannot be made at this time. Please refer to the Vagus Nerve Stimulation (VNS) Coverage Policy for additional information.

Bariatric Surgery in Adolescents
Two bariatric procedures are established treatment options for those adolescents (age 11–17 years) who have morbid obesity and have been unresponsive to medical and pharmacological management. Consistent low to moderate quality of evidence has shown that Roux-en-Y or sleeve gastrectomy result in significant weight reduction and improvement in co-morbidities postoperatively. Data support the use of these two procedures in adolescents with a BMI ≥ 40 kg/m^2 or 140% of the 95^{th} percentile (class 3 obesity) (whichever is lower) or a BMI of 35–39.9 kg/m^2 or 120% of the 95th percentile (class 2 obesity) (whichever is lower) with at least one clinically significant obesity-related comorbidity (e.g., coronary artery disease, diabetes mellitus, idiopathic intracranial hypertension, obstructive sleep apnea, hypertension, gastroesophageal reflux, nonalcoholic steatohepatitis [NASH]). Current data suggest that weight loss outcomes at three years postoperatively are comparable between SG and RYGB in adolescents. Bariatric surgery has been shown to improve risk factors and decrease morbidity and mortality in this age group. However, long-term data are lacking (Inge, 2023; Pratt, 2018; Inge, et al., 2017).

Literature Review
Inge et al. (2017) reported 5–12 year outcomes (n=58) of the Follow-up of Adolescent Bariatric Surgery at 5 Plus Years (FABS-5+) extension study for severe adolescent obesity (BMI ≥ 40 kg/m^2). The original prospective, noncomparative study included 74 young people aged 13–21 who underwent Roux-en-Y gastric bypass for clinically severe obesity. At baseline, the mean age of the cohort was 17.1 years and mean BMI was 58.5 kg/m^2. Inclusion criteria in the original study were adolescents aged ≤ 21 years with a mean BMI of 60.2 kg/m^2 who underwent Roux-en-Y gastric bypass surgery. All but two procedures were laparoscopic. Exclusion criteria were an inability to complete self-report forms because of developmental delay, or death before the long-term study visit. The primary outcome measure was the change in BMI over time. Secondary outcomes measures were prevalence of diabetes, hypertension, and dyslipidemia. Secondary

safety outcomes were micronutrient levels and clinical events postoperatively. At the mean follow-up of eight years (range 5.4–12.5 years), the mean age was 25.1 years, mean BMI was 41·7 kg/m^2 and the mean change in BMI was –29.2%. From baseline to long-term follow-up, there was significant improvements in the prevalence of elevated blood pressure (p=0·001), dyslipidemia (p<0·0001), and type 2 diabetes (p=0·03). At follow-up, 25 (46%) patients had mild anemia which required no intervention, 22 (45%) had hyperparathyroidism, and eight (16%) had low amounts of vitamin B12. Although, on average, patients had improvements in bodyweight and health status over time, most patients remained obese (n=36/57) having a BMI ≥ 35 kg/m^2. Limitations of the study included the small patient population, lack of a control group, larger number of females vs. males, and the number of patients lost to follow-up, The authors noted that surgical intervention soon after the diagnosis of severe obesity (e.g, BMI 35–40 kg/m^2) might result in more complete reversal of severe obesity and cardiometabolic risks than when surgery is offered to adolescents who have progressed to higher BMI values. The recommendation for consideration of surgery in adolescents at BMI values of 35–40 kg/m^2 with other clinical indications is consistent with advice contained in peer-reviewed clinical practice guidelines.

Rajjo et al. (2017) conducted a systematic review of randomized controlled trials (RCTs) (n=133) to evaluate the effectiveness of various medical and surgical interventions for reducing excess body weight in children and adolescents. The RCTs were taken from 16 systematic reviews. RCTs that had enrolled overweight or obese children, age > 2 years; evaluated interventions used to treat pediatric obesity (medication, surgery, lifestyle interventions, and community based interventions); compared the interventions to usual care or each other; and had a follow-up of at least six months were included. Outcomes included the change in absolute and percentage of change in body mass index (BMI) and weight. Changes in metabolic outcomes were also reviewed. Outcome data revealed the following:

- Multisport and aerobic exercise reduced systolic blood pressure and fasting glucose (low to moderate quality of evidence).
- Low-carbohydrate diets had a similar effect to low-fat diets in terms of body mass index (BMI) reduction (moderate quality of evidence).
- Education-based interventions (compared with usual care) significantly lowered diastolic blood pressure (moderate quality evidence), BMI (low quality evidence), and waist circumference (low quality evidence) but did not substantially reduce systolic blood pressure (very low quality evidence).
- Pharmacotherapy (metformin, sibutramine, orlistat) reduced BMI and waist circumference (sibutramine, orlistat) and increased high-density lipoprotein cholesterol (sibutramine) but also raised systolic and diastolic blood pressure (sibutramine).
- Surgical interventions resulted in an average BMI difference of -13.5 kg/m^2 from baseline to one year. The BMI loss was greater after Roux-en-Y compared with laparoscopic adjustable gastric banding. Overall, surgical interventions have been mainly restricted to advanced cases with multiple comorbidities and refractory to nonsurgical interventions.
- A combined approach of education and physical activity significantly reduced the BMI (low quality evidence). A Combined approach of dietary modification, physical activity, behavioral therapy, and education substantially reduced systolic and diastolic blood pressure, BMI, and triglycerides but not low-density lipoprotein cholesterol (low quality evidence).
- Family-based interventions, including both the parent and the child, compared with parent-only interventions, did not yield substantial differences in BMI (low quality evidence).

The authors concluded that although several childhood obesity interventions are effective, a comprehensive multicomponent intervention appears to yield the best overall outcomes.

A prospective RCT (n=50) by O'Brien et al. (2010) compared the outcomes of adolescents between the ages of 14 and 18 with a BMI > 35 who were assigned either to a supervised lifestyle intervention or to undergo gastric banding. In the gastric banding group 24/25 participants completed the study versus 18/25 subjects in lifestyle group. An excess weight loss of 78.8% (95% CI, 66.6%-91.0%) was reported in the gastric banding group compared to an excess weight loss of 13.2% (95% CI, 2.6%-21.0%) in the lifestyle group. At 24 months, none of the gastric banding group had the metabolic syndrome (p=0.008) compared to 4/18 (22%) in the lifestyle group (p=0.13). There were no perioperative adverse events. However, surgical revision was required in seven patients for proximal pouch dilatation or tubing injury during follow-up.

Treadwell et al. (2008) performed a systematic review and meta-analysis of the evidence on pediatric obesity and bariatric surgery. Included studies evaluated laparoscopic adjustable gastric banding (LAGB) (n=8 studies; 352 patients), Roux-en-Y gastric bypass (RYGB) (n=6 studies; 131 patients), and other bariatric procedures (n=5 studies; 158 patients). The average patient age was 16.8 years (range, 9-21 years). Meta-analyses of BMI reductions at longest follow-up indicated sustained and clinically significant BMI reductions for both LAGB and RYGB. Comorbidity resolution was infrequently reported, but surgery appeared to resolve some conditions such as diabetes and hypertension. For LAGB, band slippage and micronutrient deficiency were the most frequently reported complications, with sporadic cases of band erosion, port/tube dysfunction, hiatal hernia, wound infection, and pouch dilation. For RYGB, more severe complications have been documented, such as pulmonary embolism, shock, intestinal obstruction, postoperative bleeding, staple line leak, and severe malnutrition.

A case series (n=73) by Nadler et al. (2008) reported outcomes for adolescents, ages of 13–17 years, who underwent LABG. The mean preoperative BMI was 48. The percentages of excess weight loss at six-, 12- and 24-month follow-ups were 35% +/- 16%, 57% +/- 23%, and 61% +/- 27%, respectively. Gastric perforation after a reoperation for band replacement occurred in one patient. Band slippage occurred in a total of six patients, and three patients developed symptomatic hiatal hernias. Two patients were lost to follow-up in the first year, and 3 patients were lost to follow-up in the second year, for an overall compliance rate of at least 89.5%.

Professional Societies/Organizations

American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): In a 2022 joint statement the indications for metabolic and bariatric surgery, the ASMBS and IFSO recommend consideration of metabolic and bariatric surgery (MBS) in children/adolescents with BMI >120% of the 95th percentile (class II obesity) and major co-morbidity, or a BMI >140% of the 95th percentile (class III obesity) (Eisenberg, et al., 2022).

European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN): A 2015 ESPGHAN position statement evaluated the indications and limitations of bariatric surgery in children with severe obesity with attention to the comorbidity of nonalcoholic steatohepatitis (NASH). The ESPGHAN outlined the following clinical indications for bariatric surgery in adolescents with complicated obesity:

- BMI > 40 kg/m^2 with severe comorbidities:
  - type 2 diabetes mellitus
  - moderate-to-severe sleep apnea
  - pseudotumor cerebri
  - NASH with advanced fibrosis

- BMI > 50 kg/m^2 with mild comorbidities including:
  - hypertension
  - dyslipidemia
  - mild obstructive sleep apnea
  - chronic venous insufficiency

- panniculitis
- urinary incontinence
- impairment in activities of daily living
- NASH
- gastroesophageal reflux disease
- severe psychological distress
- arthropathies related to weight

Additionally, the child or adolescent should have attained 95% of adult stature, and have failed to reach a healthy weight with previously organized behavioral/medical treatments. According to the ESPGHAN, there is evidence to suggest that bariatric surgery can reduce the grade of steatosis, hepatic inflammation, and fibrosis in NASH. However uncomplicated nonalcoholic fatty liver disease (*NAFLD*) is not an indication for bariatric surgery. Roux-en-Y gastric bypass (RYGB) and laparoscopic adjustable gastric banding (LAGB) are the two surgical procedures that have been commonly used in pediatric obesity, with RYGB being considered a safe and effective option for adolescents with extreme obesity, as long as appropriate long-term follow-up is provided (Nobili, et al., 2015).

American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee: Based on a systematic review of the literature, ASMBS (2018) updated the 2012 Pediatric Metabolic and Bariatric Surgery (MBS) guidelines. The Society states that MBS is a proven, effective treatment for severe obesity in adolescents and should be considered standard of care. The World Health Organization's (WHO) defines adolescents as age 10-19 years. However ASMBS states that younger children who meet the other criteria could be considered when benefit outweighs risk. The review included meta-analyses, randomized controlled trials, cohort studies, case reports, and expert opinions. The 2018 guidelines included the following:

- Vertical Sleeve Gastrectomy (VSG) has become the most used and most recommended operation in adolescents with severe obesity due to the near equivalent weight loss to the Roux-en-y Gastric Bypass (RYGB) as well as fewer reoperations, better iron absorption, and near equivalent effect on comorbidities. However, given the more extensive long-term data available for RYGB, the Society recommends the use of either RYGB or VSG in adolescents. Long term outcomes of GERD after VSG are still not well understood.
- There are no data that the number of weight loss attempts correlates with success after metabolic and bariatric surgery. Compliance with a multidisciplinary preoperative program may improve outcomes after MBS but prior attempts at weight loss should be removed as a barrier to definitive treatment for obesity.
- Use of the most up to date definitions of childhood obesity: a) BMI cut offs of 35 kg/m^2 or 120% of the 95th percentile with a co-morbidity or b) BMI > 40kg/m^2 or 140% of the 95th percentile without comorbidity (whichever is less). Requiring adolescents with a BMI over 40 to have comorbidity puts children at a significant disadvantage to attaining a healthy weight. Earlier surgical intervention (at a BMI less than 45 kg/m^2) can allow adolescents to reach a normal weight and avoid lifelong medication therapy and end organ damage from co-morbidities. ASMBS stated that there is no data to suggest that a youth's puberty status as measured by Tanner staging, or linear growth, as measured by height, are adversely affected by MBS.
- Certain co-morbidities should be considered in adolescents, specifically the psychosocial burden of obesity, the orthopedic diseases specific to children, GERD, and cardiac risk factors. Given the poor outcomes of medical therapies for type 2 diabetes in children, these comorbidities may be considered an indication for MBS in younger adolescents or those with lower obesity percentiles.
- Regarding when to refer the patient, ASMBS states that since MBS results in better weight loss and resolution of comorbidities in adolescents at lower BMI's with fewer comorbidities, referrals should occur early, as soon as a child is recognized to suffer from severe obesity

disease (BMI > 120% of the 95th percentile or BMI of 35). Prior weight loss attempts, tanner stage and bone age should not be considered when referring patients for bariatric surgery.

Contraindications for adolescent MBS include:

- a medically correctable cause of obesity
- an ongoing substance abuse problem (within the preceding year)
- a medical, psychiatric, psychosocial, or cognitive condition that prevents adherence to postoperative dietary and medication regimens
- current or planned pregnancy within 12 to 18 months of the procedure (Pratt, et al., 2018)

Endocrine Society Task Force: The 2017 Endocrine Society Task Force guidelines on pediatric obesity recommended that bariatric surgery be considered only under the following conditions:

- The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
- The patient has a BMI > 40 kg/m^2 and significant, severe comorbidities.
- Extreme obesity and co-morbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy.
- Psychological evaluation confirms the stability and competence of the family unit (psychological distress due to impaired quality of life from obesity may be present, but the patient does not have an underlying untreated psychiatric illness).
- Patient has access to an experienced surgeon in a pediatric bariatric surgery center of excellence providing the necessary infrastructure for patient care, including a team capable of long-term follow-up of the metabolic and psychosocial needs of the patient and family.
- The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

In the 2017 update of the guidelines, the Society placed more emphasis on contraindications in the use of bariatric surgery in growing children and immature teenagers. The Society noted that procedures should only be carried out in those mature pubertal individuals with severe comorbidities of obesity in the presence of a motivated and compliant patient and family and only in the hands of an experienced surgeon with a dedicated and experienced support team.

The Task Force recommended against bariatric surgery for preadolescent children, for pregnant or breastfeeding adolescents, and for those planning to become pregnant within two years of surgery and in any patient who has not mastered the principles of healthy dietary and activity habits; and/or has unresolved substance abuse, eating disorder or untreated psychiatric disorder.

American Academy of Pediatrics (AAP): The American Academy of Pediatrics first Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity (Hampl, et al., 2023) made the following Key Action Statements:

- "Pediatricians and other pediatric health care providers (PHCPs) should measure height and weight, calculate body mass index (BMI), and assess BMI percentile using age- and sex-specific Centers for Disease Control (CDC) growth charts or growth charts for children with severe obesity at least annually for all children 2 to 18 years of age to screen for overweight (BMI ≥ 85th percentile to <95th percentile), obesity (BMI ≥ 95th percentile), and severe obesity (BMI ≥ 120% of the 95th percentile for age and sex).
- Pediatricians and other PHCPs should evaluate children 2 to 18 years of age with overweight (BMI ≥ 85th percentile to <95th percentile) and obesity (BMI ≥ 95th percentile) for obesity related comorbidities by using a comprehensive patient history, mental and behavioral health screening, social determinants of health (SDoH) evaluation, physical examination, and diagnostic studies.

- In children 10 years and older, pediatricians and other PHCPs should evaluate for lipid abnormalities, abnormal glucose metabolism, and abnormal liver function in children and adolescents with obesity (BMI ≥ 95th percentile) and for lipid abnormalities in children and adolescents with overweight (BMI ≥ 85th percentile to <95th percentile).
- Pediatricians and other PHCPs should treat children and adolescents for overweight (BMI ≥ 85th percentile to <95th percentile) or obesity (BMI ≥ 95th percentile) and comorbidities concurrently.
- Pediatricians and other PHCPs should evaluate for dyslipidemia by obtaining a fasting lipid panel in children 10 years and older with overweight (BMI ≥ 85th percentile to <95th percentile) and obesity (BMI ≥ 95th percentile) and may evaluate for dyslipidemia in children 2 through 9 years of age with obesity.
- Pediatricians and other PHCPs should evaluate for prediabetes and/or diabetes mellitus with fasting plasma glucose, 2-hour plasma glucose after 75-gram oral glucose tolerance test (OGTT), or glycosylated hemoglobin (HbA1c).
- Pediatricians and other PHCPs should evaluate for nonalcoholic fatty liver disease (NAFLD) by obtaining an alanine transaminase (ALT) test.
- Pediatricians and other PHCPs should evaluate for hypertension by measuring blood pressure at every visit starting at three years of age in children and adolescents with overweight (BMI ≥ 85 to <95th percentile) and obesity (BMI ≥ 95th percentile).
- Pediatricians and other PHCPs should treat overweight (BMI ≥ 85th percentile to <95th percentile) and obesity (BMI ≥ 95th percentile) in children and adolescents, following the principles of the medical home and the chronic care model, using a family-centered and nonstigmatizing approach that acknowledges obesity's biologic, social, and structural drivers.
- Pediatricians and other PHCPs should use motivational interviewing (MI) to engage patients and families in treating overweight (BMI ≥ 85th percentile to <95th percentile) and obesity (BMI ≥ 95th percentile).
- Pediatricians and other PHCPs should provide or refer children six years and older (Grade B) and may provide or refer children 2 through 5 years of age (Grade C) with overweight (BMI ≥ 85th percentile to <95th percentile) and obesity (BMI ≥ 95th percentile) to intensive health behavior and lifestyle treatment. Health behavior and lifestyle treatment is more effective with greater contact hours; the most effective treatment includes 26 or more hours of face-to-face, family-based, multicomponent treatment over a 3 to 12-month period.
- Pediatricians and other PHCPs should offer adolescents 12 years and older with obesity (BMI ≥ 95th percentile) weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to health behavior and lifestyle treatment.
- Pediatricians and other PHCPs should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery centers."

A 2019 policy statement issued by the American Academy of Pediatrics (Armstrong et al., 2019) makes the following Practice-Level Recommendations:

- "Recognize that severe obesity (BMI ≥35 or ≥120% of the 95th percentile for age and sex, whichever is lower) places the adolescent at higher risk for liver disease, type 2 diabetes mellitus, dyslipidemias, sleep apnea, orthopedic complications, and mental health conditions even when compared with milder degrees of obesity.
- Seek high-quality multidisciplinary centers that are experienced in assessing risks and benefits of various treatments for youth with severe obesity, including bariatric surgery, and provide referrals to where such programs are available.

- Understand the efficacy, risks, benefits, and long-term health implications of the common metabolic and bariatric surgery procedures so that pediatricians can effectively help in family medical decision-making concerning surgical options to manage severe obesity.
- Identify pediatric patients with severe obesity who meet criteria for surgery (Table 1), and provide timely referrals to comprehensive, multidisciplinary, pediatric-focused metabolic and bariatric surgery programs.
- Coordinate pre- and postoperative care with the patient, family, and multidisciplinary, anesthesia, and surgical teams.
- Monitor patients postoperatively for micronutrient deficiencies and consider providing iron, folate, and vitamin B12 supplementation as needed.
- Monitor patients postoperatively for risk-taking behavior and mental health problems."

The AAP went on to make System-Level recomenations for pediatricians to advocate for increased access for pediatric patients of all racial, ethnic, and socioeconomic backgrounds to multidisciplinary programs that provide high-quality pediatric metabolic and bariatric surgery.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN): In their 2017 Clinical Practice Guideline Summary: Diagnosis and Treatment of Nonalcoholic Fatty Liver Disease in Children, NASPGHAN stated that bariatric or weight loss surgery can lead to clinically meaningful weight loss in severely obese adolescents (minimum body mass index (BMI) of ≥35 kg/m^2. Within one to two years, this reduction in BMI results in improvement or resolution of many obesity-related comorbid conditions, including dyslipidemia, high blood pressure, insulin resistance, diabetes, and sleep apnea. These conditions are often associated with nonalcoholic fatty liver disease (NAFLD). Because studies in adults have suggested up to 89% of nonalcoholic steatohepatitis (NASH) resolution, it has been proposed as a criterion for adolescent weight loss surgery. NASPGHAN recommends that bariatric surgery be considered for selected adolescents with BMI ≥35 kg/m^2 , who have noncirrhotic NAFLD and other serious comorbidities (Vos, et al., 2017).

Systematic Reviews on Bariatric Surgery

Agency for Healthcare Research and Quality (AHRQ) Evidence Report: AHRQ (2018) conducted a technology assessment on short- and long-term outcomes of bariatric surgery in the Medicare population. Studies that included patients age ≥ 65 years were included. Of the 126 eligible studies, 83 described safety and efficacy of bariatric surgery, and 43 described predictors of body weight loss or absolute body weight following surgery. No randomized controlled trials including Medicare-eligible patients were found. There were few direct (head-to-head) comparisons between different surgical procedures with sufficient evidence in nonrandomized studies and none for endoscopic procedures. Studies were primarily observational in design and very few utilized an appropriate design and/or analytical approach that could yield unbiased estimates of causal treatment effects including weight loss and non-weight-loss outcomes. AHRQ stated that "bariatric surgery overall, and in particular the procedures of Roux-en-Y gastric bypass, sleeve gastrectomy, and adjustable gastric banding, resulted in improvements in weight loss outcomes beyond one year after surgery and Roux-en-Y gastric bypass performed better when compared to sleeve gastrectomy or adjustable gastric banding for metabolic, cardiovascular outcomes, renal function outcomes and for postoperative complications; Roux-en-Y gastric bypass also performed better for weight loss outcomes". According to AHRQ, there are large gaps in regard to comparisons of individual bariatric surgical procedures to each other, and very limited evidence in regard to patient-centered outcomes following including quality of life.

Cochrane Reviews: A systematic review and meta-analysis by Colquitt et al. (2014) evaluated surgical procedures for weight loss in adults. The review included 22 RCTs (n=1798 participants), with sample sizes ranging from 15-250. Most studies followed participants for 12, 24 or 36 months; the longest follow-up was 10 years. A total of seven RCTs compared surgery to nonsurgical interventions and found benefits of surgery on measures of weight change at one to two years follow-up. Improvements for some aspects of health-related quality of life (n=2 RCTs) and diabetes (n=5 RCTs) were also found. The overall quality of the evidence was moderate. Five studies reported data on mortality, no deaths occurred. Serious adverse events, reported in four studies, ranged from 0% to 37% in the surgery groups and 0% to 25% in the no surgery groups. Between 2% and 13% of participants required reoperations in the five studies that reported these data. Outcomes were found to be similar between Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy, with both procedures having better outcomes than adjustable gastric banding. For people with very high BMI, biliopancreatic diversion with duodenal switch (BPD/DS) resulted in greater weight loss than RYGB. Based on one small RCT, duodenojejunal bypass with sleeve gastrectomy and laparoscopic RYGB had similar outcomes. Based on one trial, sleeve gastrectomy led to better weight-loss outcomes than adjustable gastric banding after three years follow-up. Weight-related outcomes were similar between laparoscopic gastric imbrication and laparoscopic sleeve gastrectomy in one trial. Across all studies adverse event rates and reoperation rates were generally poorly reported. It was noted that due to the small number of studies included in the meta-analyses, only limited conclusions can be drawn from them. Also, the long-term effects of surgery remain unclear because the follow-up period in most trials was only one or two years.

O'Brien and Colleagues: O'Brien et al. (Aug 2006) conducted a systematic review of studies evaluating medium-term weight loss after bariatric surgical procedures. Procedures examined in the 43 studies included laparoscopic adjustable gastric banding (LAGB) (n=18), biliopancreatic diversion (BPD) with and without duodenal switch (DS) (n=7), and Roux-en-Y gastric bypass (RYGB) (n=18). Of the LABG reports, 12 provided data on the LAP-BAND, five on the Obtech® band (Ethicon Endo-Surgery, Inc., Cincinnati, OH), and one study included both devices. Pooled data for all procedures showed a mean excess weight loss in the range of 54–67% with no evidence of loss of effect at 10 years. It was concluded that all current bariatric operations lead to major weight loss in the medium term. BPD and banded RYGBP appear to be more effective than both RYGBP and LAGB, which are equal in the medium term (O'Brien, et al., Aug 2006).

__Bariatric Surgery Impact on Health Outcomes__

The potential benefits of bariatric surgery on health outcomes include the following:

- The increase in reported morbidity associated with obesity is thought to be mediated primarily by insulin resistance, diabetes, hypertension and lipid disturbances (Sjöstrom, et al., 2004).
- Diet therapy alone in the absence of surgery is relatively ineffective in treating obesity over the long term (Buchwald, et al., 2004).
- Severely obese patients who undergo bariatric surgery achieve greater short-, intermediate- and long-term (i.e., 10 years) weight loss, more physical activity and lower energy intake than severely obese patients treated with conventional medical interventions, such as very low-calorie diets and pharmacotherapy (Sjöstrom, et al., 2004; Buchwald, et al., 2004).
- Intermediate- and long-term (i.e., 10 years) incidence rates of recovery from risk factors such as diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, hyperlipidemia and hyperuricemia are more favorable in surgically-treated patients than in nonsurgical, severely obese patients (Sjöstrom, et al., 2004; Buchwald, et al., 2004).
- Bariatric surgery reverses, eliminates or significantly improves risk factors of diabetes, hyperlipidemia, hypertension and obstructive sleep apnea (Buchwald, et al., 2004).
- Severely obese diabetic individuals treated with bariatric surgery have shown an 80% reduction in mortality (Sjöstrom, et al., 2004).
- Weight-loss surgery has been reported to reduce the relative risk of death by 89% with an absolute mortality reduction of 5.49% (Christou, et al., 2004).

- Gastric bypass has been reported to result in more favorable overall health outcomes (i.e., weight loss, risk factor recovery/reduction) relative to other surgical interventions, such as banding procedures (Buchwald, et al., 2004).

Buchwald et al. (2009) performed a meta-analysis of 19 studies with 43 treatment arms and 11,175 patients to determine the impact of bariatric surgery on type 2 diabetes mellitus in association with the procedure performed and the weight reduction achieved. The included studies reported both weight loss and diabetes resolution separately for the 4070 diabetic patients. At baseline, the mean age was 40.2 years with a mean BMI of 47.9 kg/m^2, and 10.5% had previous bariatric procedures. Meta-analysis of weight loss was 38.5 kg or 55.9% excess weight loss (EWL). Overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion with duodenal switch (BPD/DS), followed by gastric bypass, and least for banding procedures. In the studies reporting only diabetic patients, 82% of patients had resolution of the clinical and laboratory manifestations of diabetes in the first two years after surgery, and 62% remained free of diabetes more than two years after surgery (80% and 75% for the total group) (Buchwald, et al., 2009).

Sjöström et al. (2007) conducted a prospective, matched, surgical interventional trial, referred to as the Swedish Obese Subjects study, which involved 4047 obese subjects. Of these subjects, 2010 underwent bariatric surgery (surgery group) and 2037 received conventional treatment (matched control group). A total of 376 subjects underwent nonadjustable or adjustable banding, 1369 underwent vertical banded gastroplasty, and 265 received gastric bypass. For adjustable banding, the Swedish adjustable Gastric Band was used. Outcome measures included weight change and overall mortality during an average of 10.9 years of follow-up. Vital status was known for all but three subjects at the time of the analysis. In the surgery group, participation rates of subjects at follow-up examination at two, 10, and 15 years were 94%, 84%, and 66%, respectively. Corresponding rates for subjects in the control group were 83%, 75% and 87%. The average weight change in control subjects was less than +/-2% during the period of up to 15 years during which weights were recorded. At 10 years, the weight losses from baseline were stabilized at 25% after gastric bypass, 16% after vertical-banded gastroplasty, and 14% after banding. There were 129 deaths in the control group and 101 deaths in the surgery group. The most common causes of death were myocardial infarction which occurred in 25 subjects in the control group and 13 subjects in the surgery group. Cancer was the most common cause of death from noncardiovascular causes (control group [n=47]; surgery group [n=29]). The main limitation of the study is the lack of randomization, however it is questionable whether randomization is feasible in bariatric surgery trials designed to study mortality. Although study results indicated that bariatric surgery is associated with a reduction in overall mortality, it is undetermined whether the favorable survival effect is explained by weight loss or by other beneficial effects of the surgical procedure (Sjöström, et al., 2007).

The National Institutes of Diabetes and Digestion and Kidney Disease (NIDDK) sponsored the Longitudinal Assessment of Bariatric Surgery (LABS) program. This program involves six clinical centers that have expertise in relevant fields including bariatric surgery, obesity research, endocrinology, epidemiology, and outcomes research. The purpose of the LABS program is to plan and conduct studies that will analyze the risks and benefits of bariatric surgery and its impact on the health and well-being on patients with severe obesity as well as to identify the types of patients who are most likely to benefit from bariatric surgery (NIDDK, 2022). The seven year reported results included:

- Weight loss of an average of 28.4% of body weight was experienced after gastric bypass surgery and 14.9% after laparoscopic gastric band surgery

- Most particpants maintained the weight loss. Gastric bypass surgery patients that regained weight at three to seven years post surgery, regained an average of 3.9% of their body weight, while gastric band surgery patients regained an average of 1.4%.
- High cholesterol was less common after both gastric bypasss and gastric band surgery
- Diabetes and high blood pressure were less common after gastric bypass surgery with a small number of patients experiencing a reoccurance of diabetes over time
- Alcohol use disorders increased after gastric bypass surgery but not after gastric band surgery
- Pain and physical function improved after bariatric surgery

Reoperation/Revisional Bariatric Surgery

Revisional bariatric surgery (RBS) includes a variety of abdominal operations performed on patients who have complications, weight loss failure and/or weight regain, or poor resolution of comorbidities after bariatric surgery for severe obesity. Approximately 10%–17% of patients who undergo bariatric surgery experience complications and approximately 7% undergo RBS. Previous bariatric operative approaches may fail for functional or technical reasons, causing inadequate weight loss or severe complications. The literature indicates that re-operative procedures may be required for severe gastroesophageal reflux disease *(*GERD), staple line breakdown, esophageal mobility issues, metabolic complications of jejunoileal bypass, obstruction, alkaline or acid reflux esophagitis, band erosion, stricture, anastomatic ulcer, or gastric pouch dilatation following gastric restrictive procedures. Following Roux-en-Y the most frequent complications concern the gastrojejunal anastomosis with anastomotic stenoses and marginal ulcers being the most common complications (Ellsmere, 2023; Lim, et al., 2018; Fringeli, et al., 2005).

Weight loss and comorbidity resolution following a bariatric operation is typically rapid in the first year. After this initial period of success, there is a gradual increase in weight and a new balance is reached at a somewhat higher threshold over the next two to three years, but at a level that still contributes to good resolution of comorbidity and improved quality of life. Some patients do not achieve satisfactory weight loss after the primary operation. In others, weight regain occurs with return of comorbid conditions after initial success, requiring re-evaluation for additional surgical intervention. Such failure may be the result of a leak in the band, a large stomach pouch, or a gastrogastric fistula that can be corrected with a reoperation. Although noncompliance with diet and exercise regimens plays a role, weight gain and recurrence of comorbid conditions may occur despite patient compliance due to individual biology. In these cases, a more aggressive bariatric procedure may be indicated to provide effective therapy (Sudan, et al., 2015).

There are three main categories of revisional bariatric surgery (Brethauer et al., 2014):

- Conversion: a change from one type of procedure to a different type.
- Corrective: a procedure that attempts to remedy complications or incomplete treatment effects of a previous bariatric operation.
- Reversal: a procedure that restores the original anatomy.

The type of revisional bariatric surgery procedure performed is determined by factors such as type of primary procedure, patient anatomy, medical history and indications for RBS. Weight loss and comorbidity outcomes of laparoscopic adjustable gastric banding (LAGB) patients converted to Roux-en-Y Gastric bypass (RYGB), sleeve gastrectomy (SG), and biliopancreatic diversion with duodenal switch (BPD/DS) have been reported to have results similar to the outcomes for primary bariatric procedures. Conversion to RYGB or BPD/DS has been performed for patients who need additional therapy for weight loss or regain weight after SG (Sharples, et al., 2017; Brethauer et al., 2014). Less commonly performed is the revision of a gastric bypass via placement of an adjustable gastric band. This revision, referred to as "band over bypass" or "salvage banding", is a less invasive option to control pouch size compared to the other limited options such as a conversion to a longer limb bypass procedure with the associated adverse effect of severe malnutrition. Further weight loss after salvage banding has been reported in the literature as varying from 55.9%–94.2% excess body mass index loss (EBMIL) after 12–42 months of follow-up (Vijgen, et al., 2012). Similarly, banded sleeve gastrectomy or "band over sleeve" has been proposed as an option to counteract sleeve dilatation and ameliorate weight loss over time (Karcz, et al., 2014). There is insufficient evidence in the published peer-reviewed medical literature to support the safety and effectiveness of band over bypass or band over sleeve procedure.

Reoperation by surgical reversal (i.e., "takedown") or surgical revision of bariatric surgery is generally considered to be medically necessary at any time following the original surgery when the patient experiences complications from the original surgery, such as stricture, obstruction, pouch dilatation, erosion or band slippage.

Bariatric Surgery for the Treatment of Other Conditions

Type 2 Diabetes Mellitus: Bariatric surgery is currently being evaluated as a treatment and potential cure for Type 2 Diabetes Mellitus (T2DM). Studies reporting the results of bariatric surgery on T2DM have primarily included morbidly obese patients (i.e., a BMI ≥ 40 or a BMI 35–39.9 with a clinically significant obesity-related comorbidity) and have demonstrated that obese diabetic patients who undergo bariatric surgery experience complete T2DM remission. As an example, Roux-en-Y gastric bypass (RYGB) reduces the storage capacity of the stomach, induces malabsorption, and causes hormonal changes which may lead to improvement in diabetic symptoms. Sleeve gastrectomy (SG) is surgical reduction of the stomach only, which is proposed to improve T2DM by inducing weight loss, some hormonal changes, and modification of gastrointestinal motility, bile acids, and gut microbiota. Few studies have investigated the safety and efficacy of bariatric surgery, also referred to as metabolic surgery, in patients with a BMI < 35 (class I obesity). Although bariatric surgery has also been proposed as a potential treatment for type 1 diabetes mellitus (T1DM), the published peer-reviewed medical literature contains limited evidence regarding T1DM.

Literature Review-Type 2 Diabetes Mellitus:
Schauer et al. (2014) published an RCT (n=150) of obese patients with uncontrolled T2DM randomized to receive either intensive medical therapy alone (n=40) or intensive medical therapy plus Roux-en-Y gastric bypass (n=48) or sleeve gastrectomy (n=49). The Surgical Treatment and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trial included patients between the ages of 20–60 years, with a glycated hemoglobin level > 7.0%, and a BMI of 27–43. The primary outcome was a glycated hemoglobin level of 6.0% or less, with or without the use of diabetes medications. A total of 91% of the patients completed 36 months of follow-up. At three years, the criterion for the primary end point was met by 5% of the patients in the medical-therapy group, compared to 38% of those in the gastric-bypass group (p<0.001) and 24% of those in the sleeve-gastrectomy group (p=0.01). Study results indicated that for obese patients with uncontrolled type 2 diabetes, bariatric surgery was associated with improved glycemic control and weight reduction compared to intensive medical therapy alone. It was noted that limitations to the study included an inadequate sample size and duration to detect differences in the incidence of diabetes complications, such as myocardial infarction, stroke, or death. The study protocol specifies further follow-up at years for all patients, which should allow additional assessment of even longer-term efficacy (Schauer, et al., 2014). Schauer et al. (2017) published five-year outcomes for the STAMPEDE trial. At five years, the criterion for the primary end point was met by 2/38 patients (5%) who received medical therapy alone versus 14/49 patients (29%) who underwent gastric bypass (p=0.01), and 11/47 patients (23%) who underwent sleeve gastrectomy (p=0.03). Patients who underwent surgical procedures had a greater mean percentage reduction from baseline in glycated hemoglobin level than did patients who received

medical therapy alone (p=0.003). A single major late surgical complication (i.e., reoperation) was reported.

Maglione et al. (2013) performed an Agency for Healthcare Research and Quality (AHRQ) review of the evidence (n=24 studies) on efficacy, safety, and comparative effectiveness of various types of bariatric surgery for treating adult patients with a body mass index (BMI) of 30.0 to 34.9 kg/m^2 and diabetes or impaired glucose tolerance (IGT). The review compared effectiveness of surgery versus nonsurgical interventions in this population. Included studies were primarily observational (n=19 studies). Two trials comparing different procedures (n=2 studies), and three trials comparing surgical versus nonsurgical interventions were also included. Studies for the analysis had to report on laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD/DS), sleeve gastrectomy, or nonsurgical treatment, and had to include patients with a BMI of at least 30 kg/m^2 but less than 35 kg/m^2 with diabetes or IGT. Excluded were nonsurgical studies already included in previous systematic reviews or with less than one year follow-up; those with no outcomes of efficacy, effectiveness, or safety/adverse events; and studies with a sample size of less than three. Outcomes measured were weight and blood glucose levels. Based primarily on glucose control outcomes, moderate strength evidence of efficacy of bariatric surgery in treating diabetes in patients with a BMI of at least 30 but less than 35 kg/m^2 in the short term was found. At one-year follow-up, surgery patients showed much greater weight loss than usually seen in studies of diet, exercise, or other behavioral interventions. The overall evidence was rated as moderate due to paucity of data. Observational data, which start as low strength evidence, were upgraded due to consistency of results regarding BMI and blood sugar. The strength of evidence of efficacy for RYGB, LAGB, and SG in treating diabetes and IGT in patients with a BMI of between 30 and 35 in the short term (i.e., up to 2 years) was rated as moderate. For BPD, both the number of studies and their sample sizes are much lower; thus the strength of evidence of efficacy for this procedure was rated low. Evidence on comparative effectiveness of surgical procedures is insufficient. The strength of evidence for short-term harms was low for all four surgical procedures and insufficient for long-term adverse events. It was concluded that the literature on bariatric surgery for diabetes or IGT patients with BMI of at least 30 kg/m^2 and less than 35 kg/m^2 has many limitations. There is minimal data on long-term efficacy and safety, as few studies of this target population have long-term follow-up. No evidence was found on major clinical endpoints such as all-cause mortality, cardiovascular mortality or morbidity, or peripheral arterial disease. The studies of bariatric surgery in this population have measured only intermediate or surrogate endpoints regarding glucose control. While control of glucose is certainly important, the available evidence from the diabetes literature indicates it may be premature to assume that controlling glucose to normal or near normal levels completely mitigates the risk of microvascular and macrovascular events. Thus, claims of a "cure" for diabetes based on glucose control within one or two years require longer term data before they can be substantiated.

Ikramuddin et al. (2013) conducted a multicenter unblinded randomized trial (n=120) to compare Roux-en-Y gastric bypass with lifestyle and intensive medical management (n=60) with intensive management alone (n=60). Subjects with a hemoglobin A1c (HbA1c) level of ≥ 8.0%, BMI 30.0–39.9, C peptide level of > 1.0 ng/mL, and type 2 diabetes for at least six months were included. The primary end-point was a composite goal of HbA1c < 7.0%, low-density lipoprotein cholesterol < 100 mg/dL, and systolic blood pressure < 130 mm Hg. Secondary outcome measures included weight loss, medication use, and adverse events. After 12-months of follow-up, 28 participants (49%) in the gastric bypass group and 11 (19%) in the lifestyle-medical management group achieved the primary end points (p<0.01). Participants in the gastric bypass group required 3.0 fewer medications and lost 26.1% vs 7.9% of their initial body weight compared with the lifestyle-medical management group. There were 22 serious adverse events in the gastric bypass group, including a single cardiovascular event, and 15 in the lifestyle-medical management group. The gastric bypass group experienced more nutritional deficiency than the lifestyle-medical management group. Study limitations include the small patient population and short-term follow-up.

Schauer et al. (2012) conducted a randomized non-blinded, single-center trial (n=150) to assess the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in obese patients with uncontrolled type 2 diabetes. The mean BMI was 36; 51/150 patients had a BMI less than 35. The average glycated hemoglobin level was 9.2 ± 1.5%. The primary end point was the proportion of patients with a glycated hemoglobin level of ≤ 6.0% 12 months after treatment. Of the 150 patients, 93% completed 12 months of follow-up. The proportion of patients with the primary end point was 12% (5 of 41 patients) in the medical-therapy group versus 42% (21 of 50 patients) in the gastric-bypass group (p=0.002) and 37% (18 of 49 patients) in the sleeve-gastrectomy group (p=0.008). Glycemic control improved in all three groups, with statistical significance in the gastric-bypass (p<0.001), and sleeve-gastrectomy (p=0.003) groups. The wide range of BMI levels and short-term follow-up limit the ability to draw conclusions that are specific to class I obese patients.

Lee et al. (2011) randomized 60 patients with T2DM, HbA1c > 7.5%, c-peptide ≥ 1.0, and a BMI > 25 and < 35 kg/m^2 to either gastric bypass (n=30) or sleeve gastrectomy (n=30) performed laparoscopically. The primary outcome was remission of diabetes defined as HbA1c < 6.5% and fasting glucose < 126 mg/dL on no diabetes medications at the one-year follow-up. Follow-up was 100% in both groups at one year. The average age of participants was 45 years, with an average BMI of 30 kg/m^2 (range 25-34), and an average HbA1c of 10.0%. The diabetes remission rate was higher in the RYGB group (93% versus 47%, p=0.02). The average reduction in HbA1c at one year was also higher in the RYGB group (4.2% versus 3.0%, p<0.001). At the one year follow-up, the average HbA1c was lower in the RYGB group (5.7% versus 7.2%, p<0.001), as was the average fasting glucose level (99 versus 140, p<0.001), the LDL-cholesterol (97 versus 137, p<0.001), and BMI (22.8 versus 24.4, p=0.009). This study is limited by the small number of participants and short-term follow-up.

Dixon et al. (2008) conducted an unblinded randomized controlled trial to determine if surgically induced weight loss resulted in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control. This study included 60 obese patients with a BMI range of 30–40, recently diagnosed (i.e., < 2 years) type 2 diabetes, and with no evidence of renal impairment or diabetic retinopathy. The surgical group (n=30) underwent laparoscopic adjustable gastric banding (LAGB) along with conventional diabetes care and the conventional-therapy group received diabetes therapy with a focus on weight loss by lifestyle change. The primary outcome measure was remission of type 2 diabetes demonstrated by a fasting glucose level <126 mg/dL [7.0 mmol/L] and glycated hemoglobin [HbA1c] value <6.2% while taking no glycemic therapy. Secondary measures included weight and components of the metabolic syndrome. Of the 60 patients enrolled, 55 (92%) completed the two-year follow-up. Remission of type 2 diabetes was achieved by 22 (73%) in the surgical group (n=30) and four (13%) in the conventional-therapy group (p<0.001). Relative risk of remission for the surgical group was 5.5 (95% confidence interval, 2.2-14.0). The surgical group achieved a mean 20% body weight loss at two years compared to a 1.4% body weight loss among the conventional-therapy group (p<0.001). The reduction in metabolic syndrome was significant in the surgical group (p<0.001), but not in the conventional-therapy group (p=0.23). It was noted that although study results suggested that patients who received surgical intervention were more likely to achieve remission of type 2 diabetes through greater weight loss, these results need to be confirmed in a larger study with a more diverse population and an assessment of long-term efficacy.

Case series with patient populations ranging from 18–42 and follow-up periods of 12–24 months have also demonstrated promising results, with reversal rates of type 2 diabetes mellitus ranging from 62%–88%. However these studies are limited by their design, small patient populations and short-term follow-ups (Gianos, et al., 2012; Abbatini, et al., 2012; Huang, et al., 2011; Boza, et al., 2011; Serrot, et al., 2011).

Gastroesophageal reflux disease (GERD): Gastroesophageal reflux disease is a condition that occurs when the contents of the stomach come up into the esophagus. Symptoms can be mild or severe and range from heartburn, regurgitation, dysphagia, chest pain, water brash, globus sensation, odynophagia, extraesophageal symptoms (e.g. chronic cough, hoarseness, wheezing) and nausea (Kahrilas, Jul 2022). Medical management includes lifestyle and dietary modifications, and pharmacologic therapy (Kahrilas, Sep 2022). Refractory GERD is diagnosed when patients continue to have reflux symptoms or endoscopic evidence of esophagitis despite pharmacologic treatment. GERD is associated with obesity. For morbidly obese patients with GERD, the reported surgical treatment of choice is Roux-en-Y gastric bypass (RYGB) (Schwaitzberg, 2021). Bariatric surgery has been proposed to treat refractory gastroesophageal reflux disease in the absence of morbid obesity. There is insufficient evidence in the peer reviewed literature demonstrating the safety and efficacy of bariatric surgery for the treatment of GERD when there is an absence of morbid obesity.

Gastroparesis: Gastroparesis is when the stomach is delayed in emptying solid contents when there is no mechanical obstruction. Symptoms include nausea, vomiting, early satiety, belching, bloating and/or upper abdominal pain. Initial therapy includes dietary modification, hydration, glycemic control and pharmacologic therapy. Patients with refractory symptoms may be treated with a jejunostomy and venting gastrostomy tube (Camiller, 2023). Bariatric surgery has also been proposed to treat gastroparesis in the absence of morbid obesity. Studies in the peer reviewed literature investigating the safety and efficacy of bariatric surgery for this condition are lacking.

Professional Societies/Organizations
American Diabetes Association: The 2023 American Diabetes Association Standards of Medical Care in Diabetes discusses metabolic surgery for the treatment of diabetes. In the discussion of obesity management, the ADA recommendations include the following:

- "Metabolic surgery should be recommended as an option to treat type 2 diabetes in screened surgical candidates with BMI ≥ 40 kg/m^2 (BMI ≥ 37.5 kg/m^2 in Asian American individuals), and in adults with BMI 35.0–39.9 kg/m^2 (32.5–37.4 kg/m^2 in Asian American individuals) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with reasonable nonsurgical methods.
- Metabolic surgery may be considered as an option to treat type 2 diabetes in adults with BMI 30.0–34.9 kg/m^2 (27.5–32.4 kg/m^2 in Asian American individuals) who do not achieve durable weight loss and improvement in comorbidities (including hyperglycemia) with reasonable nonsurgical methods.
- Metabolic surgery should be performed in high-volume centers with multidisciplinary teams knowledgeable about and experienced in managing obesity, diabetes and gastrointestinal surgery.
- People who undergo metabolic surgery should receive long-term medical and behavioral support and routine micronutrient, nutritional, and metabolic status monitoring.
- People being considered for metabolic surgery should be evaluated for comorbid psychological conditions and social and situational circumstances that have the potential to interfere with surgery outcomes.
- If postbariatric hypoglycemia is suspected, clinical evaluation should exclude other potential disorders contributing to hypoglycemia, and management includes education, medical nutrition therapy with a dietitian experienced in postbariatric hypoglycemia, and medication treatment, as needed. Continuous glucose monitoring should be considered as

- an important adjunct to improve safety by alerting patients to hypoglycemia, especially for those with severe hypoglycemia or hypoglycemia unawareness.
- People who undergo metabolic surgery should routinely be evaluated to assess the need for ongoing mental health services to help with the adjustment to medical and psychosocial changes after surgery.

ADA noted that although metabolic surgery has been shown to improve the metabolic profiles of morbidly obese patients with type 1 diabetes, establishing the role of metabolic surgery in such patients will require larger and longer studies.

The ADA states that "health disparities adversely affect people who have systematically experienced greater obstacles to health based on their race or ethnicity, socioeconomic status, gender, disability, or other factors. Overwhelming research shows that these disparities may significantly affect health outcomes, including increasing the risk for obesity, diabetes and diabetes-related complications (ADA, 2023)."

In the discussion of children and adolescents, ADA stated that type 2 diabetes disproportionately impacts youth of ethnic and racial minorities and can occur in complex psychosocial and cultural environments, which may make it difficult to sustain healthy lifestyle changes and self-management behaviors. ADA stated that small retrospective studies and a nonrandomized study suggest that bariatric surgery may have similar benefits in obese adolescents with type 2 diabetes compared to outcomes in adults. However, no randomized trials have compared the safety and effectiveness of surgery to conventional treatment options. The 2023 ADA Standards of Medical Care in Diabetes for children and adolescents recommendations state:

- "metabolic surgery may be considered for the treatment of adolescents with type 2 diabetes who have severe obesity (BMI >35 kg/m^2) and who have elevated A1C and/or serious comorbidities despite lifestyle and pharmacologic intervention.
- 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, dietitian nutritionist, behavioral health specialist, and nurse."

American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): In a 2022 joint statement on the indications for metabolic and bariatric surgery (Eisenberg, et al., 2022), the ASMBS and IFSO make the following recommendations:

- metabolic and bariatric surgery (MBS) is recommended for individuals with a body mass index (BMI) ≥35 kg/m^2, regardless of presence, absence, or severity of co-morbidities.
- BMI thresholds be adjusted in the Asian population such that a BMI ≥25 kg/m^2 suggests clinical obesity, and individuals with BMI ≥27.5 kg/m^2 should be offered MBS
- MBS is recommended in patients with type 2 diabetes (T2D) and BMI ≥30kg/m^2

American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS): The 2013 update (updated 2019) of the AACE/TOS/ASMBS practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient included the following recommendations:

- Patients with a BMI ≥ 40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for one of the procedures.
- Patients with a BMI ≥ 35 kg/m^2 and one or more severe obesity-related co-morbidities, including type 2 diabetes (T2DM), high risk for T2D (insulin resistance, prediabetes, and/or metabolic syndrome), hypertension, hyperlipidemia, obstructive sleep apnea (OSA),

obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of OSA and OHS), nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), idiopathic intracranial hypertension, gastroesophageal reflux disease (GERD), venous stasis disease, severe urinary incontinence, debilitating arthritis, impaired mobility due to obesity, or considerably impaired quality of life, may also be offered a bariatric procedure.

- Patients with BMI of 30–34.9 kg/m^2 with diabetes or metabolic syndrome may also be offered a bariatric procedure. The current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.
- There is insufficient evidence for recommending bariatric surgery specifically for glycemic control alone, lipid lowering alone or cardiovascular disease risk reduction alone, independent of BMI criteria. In their discussion, the Society stated that there were no compelling studies that supported recommending bariatric surgery for management of T2DM in the absence of obesity (BMI < 30 kg/m^2).
- Preoperative weight loss or medical nutritional therapy may be used in selected cases to improve co-morbidities, reduce liver volume and/or help improve the technical aspects of the surgery.

Regarding the various procedures, the Societies stated that in general, laparoscopic bariatric procedures are preferred in order to lower early postoperative morbidity and mortality. Laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (RYGB), and laparoscopic biliopancreatic diversion (BPD), BPD/duodenal switch (BPD-DS), or related procedures are primary bariatric and metabolic procedures that may be performed in patients requiring weight loss and/or metabolic control (Mechanick, et al., 2013, updated 2020).

American Society for Metabolic and Bariatric Surgery (ASMBS): ASMBS published a 2018 updated position statement on class I obesity (e.g., BMI 30-35 kg/m^2). The review included systematic reviews, randomized controlled trials, observational studies and retrospective reviews that investigated bariatric surgery for patients with a BMI < 35 kg/m^2. ASMBS' updated recommendations included the following:

- Current nonsurgical treatments for class I obesity are often ineffective at achieving major, long-term weight reduction and resolution of co-morbidities.
- For patients with BMI 30-35 kg/m^2 and obesity-related co-morbidities who do not achieve substantial, durable weight loss and co-morbidity improvement with reasonable nonsurgical methods, bariatric surgery should be offered as an option for suitable individuals. In this population, surgical intervention should be considered after failure of nonsurgical treatments.
- Particularly given the presence of high-quality data in patients with type 2 diabetes, bariatric and metabolic surgery should be strongly considered for patients with BMI 30 to 35 kg/m^2 and type 2 diabetes.
- The safety and efficacy of adjustable gastric banding (AGB), sleeve gastrectomy (SG), and Roux-en-Y gastric bypass (RYGB) in low-BMI patients appear to be similar to results in patients with severe obesity and well-tolerated, effective treatments.
- The best evidence for bariatric and metabolic surgery for patients with class I obesity and co-morbid conditions exists for patients in the 18 to 65 age group.

American Association of Clinical Endocrinologists (AACE)/The Obesity Society (TOS)/American Association of Clinical Endocrinologists (AACE): The Societies updated their joint bariatric surgery guidelines in 2013. This guidance stated that patients with BMI of 30-34.9 kg/m^2 with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit. There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria (Mechanick, et al., 2013). Clinical practice guidelines issued by the AACE and American College of Endocrinology (ACE) in 2016 reaffirm these findings (Garvey, et al., 2016). In 2019, the Societies updated their guidance stating that there is an increasing body of evidence supporting a sustained improvement in glycemic control concomitant with reductions in diabetes medications in patients with BMI 30 to 34.9 kg/m^2; however, the current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit. The authors noted that future studies will need to elucidate the differential impact of multiple current surgical treatments for efficacy and safety. (Mechanick, et al., 2020). Additional studies are needed to validate these findings.

International Diabetes Organizations: Recommendations from a 2016 joint position statement by the International Diabetes Organizations include the following (Rubino, et al., 2016):

- Metabolic surgery should be a recommended option to treat T2D in appropriate surgical candidates with class III obesity (BMI > 40 kg/m^2), regardless of the level of glycemic control or complexity of glucose-lowering regimens, as well as in patients with class II obesity (BMI 35.0–39.9 kg/m2)with inadequately controlled hyperglycemia despite lifestyle and optimal medical therapy.
- Metabolic surgery should also be considered to be an option to treat T2D in patients with class I obesity (BMI 30.0–34.9 kg/m^2) and inadequately controlled hyperglycemia despite optimal medical treatment by either oral or injectable medications (including insulin).
- All BMI thresholds should be reconsidered depending on the ancestry of the patient. For example, for patients of Asian descent, the BMI values above should be reduced by 2.5 kg/m^2.
- Metabolic surgery should be performed in high-volume centers with multidisciplinary teams that understand and are experienced in the management of diabetes and GI surgery.
-

It was further noted that "although additional studies are needed to further demonstrate long-term benefits, there is sufficient clinical and mechanistic evidence to support inclusion of metabolic surgery among antidiabetes interventions for people with T2D and obesity" (Rubino, et al., 2016).

Gastric bypass or other bariatric procedures performed as a treatment for diabetes mellitus in the absence of obesity has not been adequately studied. The risk/benefit ratio of surgery in less obese (BMI 30-35 kg/m^2) populations has also not been fully explored in the long term. There is currently insufficient evidence to support the safety and effectiveness of bariatric surgery solely as a treatment for T2DM in individuals with a BMI less than 35. There is no evidence to suggest that bariatric surgery is a safe and effective treatment for T1DM.

Cholecystectomy, Liver Biopsy, Herniorrhaphy, Prophylactic Vena Cava Filter Placement, or Upper Endoscopy

Cholecystectomy at the Time of Bariatric Surgery

It has been shown that there is a moderate correlation between obesity and the development of gallstones, with the risk of cholelithiasis rising as BMI increases. Furthermore, evidence in the scientific literature suggests that the rapid weight loss which occurs following certain bariatric surgical procedures increases cholesterol load, thereby increasing the risk for gallstone formation. For these reasons, some surgeons advocate the routine removal of asymptomatic normal gallbladders at the time of bariatric surgery (specifically gastric bypass procedures). It has been suggested that patients undergoing gastric bypass are at a greater risk than with other procedures, such as gastric banding, due to the malabsorption and early and rapid postoperative weight loss associated with this procedure. The issue of performing routine prophylactic cholecystectomy concurrently with bariatric surgery continues to be debated. Many experts contend that performing cholecystectomy on non-diseased, normal-appearing gallbladders is not recommended and places unnecessary risk on the patient (Sreenarasimhaiah, 2004; Villegas, et al., 2004). Combining procedures increases operative time and has been reported to lengthen hospital stay significantly (Hamad, et al., 2003). Additionally, many of these individuals who do form gallstones do not develop symptoms that will ultimately lead to the need to remove the gallbladder. O'Brien and Dixon (2003) reported that 6.8% of patients undergoing laparoscopic adjustable gastric banding (LAGB) developed symptomatic gallstones necessitating cholecystectomy. Rather than surgical removal of the non-symptomatic gallbladder, some surgeons support the prophylactic use of ursodiol, a bile acid which prevents gallstone formation.

Literature Review
Fuller et al. (2007) reported on 144 consecutive patients undergoing Roux-en-Y gastric bypass (RYGB) who were routinely screened for cholelithiasis by ultrasound. The mean age was 43 years and the mean BMI was 46 kg/m^2. A total of 29 patients had a history of prior cholecystectomy. Cholelithiasis was diagnosed preoperatively in 22 of the remaining 115 patients. Of those 22 patients, nine (41%) were symptomatic and underwent concurrent cholecystectomy and RYGB. The remaining 13 patients (59%) had asymptomatic cholelithiasis preoperatively but did not undergo cholecystectomy at the time of surgery. Patients who did not have cholecystectomy were managed with ursodiol for six months postoperatively. Only one of these asymptomatic patients subsequently developed symptoms requiring cholecystectomy at up to one-year follow-up. This incidence did not reach statistical significance ($p=0.59$), suggesting that the relative risk of requiring a cholecystectomy after RYGB in the absence of preoperative symptoms is small.

Caruana et al. (2005) reported on a series of 125 patients who underwent Roux-en-Y gastric bypass (RYGB) and were not treated with ursodiol postoperatively. These patients had no palpable gallstones at the time of surgery and were followed for at least 16 months (range 16–48 months) after RYGB. Cholecystectomy for symptomatic stones was performed in 4.9% of patients during the first year of follow-up and in an additional 5% of patients within the second year of follow-up. There were no serious complications from the stones or the cholecystectomy. It was noted that prophylactic cholecystectomy would have been unnecessary in 115 of the 125 patients in this particular study group (Caruana, et al., 2005).

Villegas et al. (2004) attempted to determine the incidence of gallstone formation requiring cholecystectomy following laparoscopic Roux-en-Y. Of the 289 patients studied, 189 patients had no stone formation when examined intraoperatively. Of these 189 individuals, 151 patients had postoperative ultrasounds at six-month follow-up. A total of 33 patients developed gallstones (22%), and 8% had biliary sludge. Only 11 patients experienced gallstone-related symptoms requiring cholecystectomy (Villegas, et al., 2004).

The published, peer-reviewed scientific literature indicates that the prophylactic removal of a normal gallbladder (i.e., no evidence of gallstones or biliary sludge demonstrated on ultrasound or other diagnostic testing) is not considered medically necessary when performed concurrently with bariatric surgery, including gastric bypass. The impact on health outcomes has not been established through well-designed studies. Cholecystectomy performed concurrently with bariatric surgery is considered medically necessary when there is preoperative or intraoperative evidence of gallstones or biliary sludge on diagnostic study or when there is a recent history of cholecystitis.

Professional Societies/Organizations
American Society for Metabolic and Bariatric Surgery (ASMBS): ASMBS stated that the gallbladder should not be routinely removed unless clinically indicated. ASMBS noted that removal of normal and asymptomatic gallbladders at the time of bariatric surgery has not been shown to be necessary and may expose a patient to possible risk of complications without proven benefit. The Society also recommends avoiding an open approach for bariatric procedures due to the

advantages of laparoscopy (e.g., shorter hospital length of stay, decreased morbidity and mortality) (Leyva-Alvizo, et al., 2020).

Routine Liver Biopsy at the Time of Bariatric Surgery
Nonalcoholic fatty liver disease (NAFLD) refers to the presence of hepatic steatosis without any other causes for secondary hepatic fat accumulation (e.g., heavy alcohol consumption). NAFLD may progress to cirrhosis and is likely an important cause of cryptogenic cirrhosis. NAFLD is subdivided into nonalcoholic fatty liver (NAFL) and nonalcoholic steatohepatitis (NASH). In NAFL, hepatic steatosis is present without evidence of significant inflammation, whereas in NASH, hepatic steatosis is associated with hepatic inflammation that may not be histologically distinguishable from alcoholic steatohepatitis. Most patients with NAFLD are asymptomatic, although some may complain of fatigue, malaise, and vague right upper abdominal discomfort. NAFLD often comes to attention because laboratory testing revealed elevated liver aminotransferases or hepatic steatosis was detected incidentally on abdominal imaging. A definitive diagnosis of NAFLD requires the following (Sheth and Chopra, 2022):

- demonstration of hepatic steatosis by imaging or biopsy
- exclusion of significant alcohol consumption or other causes of hepatic steatosis
- absence of coexisting chronic liver disease

The exact role of NASH as an independent predictor in advanced liver disease has not been clearly established. It has been suggested that there may be several clinical triggers needed for NASH to progress to advanced liver disease including, but not limited to, type 2 diabetes, high BMI, liver toxins, and alcohol consumption. Liver biopsy may be used to confirm the diagnosis of NAFLD and to differentiate between NAFLD and NASH. However there are no clear guidelines as to when and in whom liver biopsy is necessary (Duvnjak, et al., 2007).

Literature Review
Dolce et al. (2009) presented a series of 108 patients undergoing bariatric surgery who had routine intraoperative liver biopsy. The aim of this study was to determine the relationship between the intraoperative liver appearance and the histopathologic findings during laparoscopic bariatric surgery. An intraoperative liver visual score was recorded according to the size, tan-speckling, and contour. The liver histologic findings were categorized into 3 groups: (1) normal; (2) bland steatosis; and (3) nonalcoholic steatohepatitis (NASH). The liver visual score was compared with the liver histologic findings. The prevalence of NASH was found to be 23% (n=25). Of the 25 patients with NASH, 12 (48%) had normal-appearing livers. Of the 50 normal-appearing livers, 12 (24%) had NASH and 14 (28%) had bland steatosis. The authors noted that the correlation between the general appearance of the liver and the presence of NASH is poor, limiting the sensitivity of selective liver biopsy.

Shalhub et al. (2004) analyzed prospective data on 242 patients who underwent open and laparoscopic Roux-en-Y gastric bypass (RYGB) to determine the role of routine liver biopsy in managing bariatric patients. The same pathologist graded all liver biopsies as mild, moderate or severe steatohepatitis. NASH was defined as steatohepatitis without alcoholic or viral hepatitis. Consecutive liver biopsies were compared to those liver biopsies selected because of grossly fatty livers. Selective liver biopsies were performed in 86 of the first 174 patients and routine liver biopsies were done in the remaining 68 consecutive patients. The two groups were reported to have to have similar findings of steatosis, but more patients were categorized as having moderate and severe NASH based on routine liver biopsy compared to selective biopsy ($p<0.05$). Both groups had a similar prevalence of cirrhosis. There was no correlation found between BMI, abnormal liver tests, and the severity of NASH. Study results indicate that liver biopsy is the gold standard for diagnosing NASH. However, additional data from well-designed RCTs are needed to support the need for routine liver biopsy during bariatric surgical procedures.

Some surgeons support the use of concurrent routine liver biopsy in all patients undergoing bariatric surgery. Like prophylactic cholecystectomy, routine liver biopsy in the absence of clinical findings at the time of bariatric surgery continues to be debated. Just what role routine liver biopsy plays in patients undergoing bariatric surgery is not known. Impact on health outcomes has not been established through well-designed clinical trials. At this time, there is not sufficient evidence to support routine liver biopsy in patients undergoing bariatric surgery.

Professional Societies/Organizations

American Association for the Study of Liver Diseases (AASLD): The 2023 updated practice guidance on the diagnosis and management of nonalcoholic fatty liver disease stated that metabolic abnormalities such as insulin resistance, dyslipidemia, central obesity, and hypertension precede the development of nonalcoholic fatty liver disease (NAFLD). The entire spectrum of obesity, ranging from overweight to obese and severely obese, is associated with NAFLD and disease progression. According to the guidelines, in patients with severe obesity undergoing bariatric surgery, > 95% will have NAFLD. There is also a very high prevalence of NAFLD in individuals with type 2 diabetes mellitus. The recommendations included the following:

- Liver biopsy should be considered in patients with NAFLD who are at increased risk of having steatohepatitis and/or advanced fibrosis.
- The presence of metabolic syndrome (MetS), NAFLD fibrosis score (NFS) or fibrosis-4 index (FIB-4), or liver stiffness measured by vibration controlled transient elastography (VCTE) or MR elastography (MRE) may be used for identifying patients who are at risk for steatohepatitis and advanced fibrosis.
- Liver biopsy should be considered in patients with suspected NAFLD in whom competing etiologies for hepatic steatosis and the presence and/or severity of coexisting chronic liver diseases cannot be excluded without a liver biopsy.
- Bariatric surgery can be considered in otherwise eligible obese individuals with NAFLD or NASH.
- It is premature to consider bariatric surgery as an established option to specifically treat nonalcoholic steatohepatitis (NASH).
- The type, safety, and efficacy of bariatric surgery in otherwise eligible obese individuals with well-compensated NASH cirrhosis due to NAFLD are not established. In otherwise eligible patients with compensated NASH or cryptogenic cirrhosis, bariatric surgery may be considered on a case-by-case basis by an experienced bariatric surgery program.

Hiatal Hernia Repair at the Time of Bariatric Surgery

Hiatal or hiatus hernia refers to the protrusion of an organ, typically the stomach, through the esophageal opening in the diaphragm into the chest. Hiatal hernia is often associated with obesity and gastroesophageal reflux disease (GERD) and its complications. Hiatal hernias are broadly divided into two main types, sliding and paraesophageal. However, the most comprehensive classification of hiatal hernia includes the following:

- Type I are sliding hiatal hernias, where the gastroesophageal junction migrates above the diaphragm. There is a widening of the muscular hiatal tunnel and circumferential laxity of the phrenoesophageal membrane, allowing a portion of the gastric cardia to herniate upward. The stomach remains in its usual longitudinal alignment and the fundus remains below the gastroesophageal junction.
- Type II are pure paraesophageal hernias (PEH). The gastroesophageal junction remains in its normal anatomic position but a portion of the fundus herniates through the diaphragmatic hiatus adjacent to the esophagus. The gastric fundus then serves as the leading point of herniation.

- Type III are a combination of Types I and II, with both the gastroesophageal junction and the fundus herniating through the hiatus. With progressive enlargement of the hernia through the hiatus, the phrenoesophageal membrane stretches, displacing the gastroesophageal junction above the diaphragm, thereby adding a sliding element to the type II hernia. The fundus lies above the gastroesophageal junction.
- Type IV hiatal hernias are associated with a large defect in the phrenoesophageal membrane, allowing other organs, such as colon, spleen, pancreas and small intestine to enter the hernia sac.

Typically, type 1 hiatal hernias are asymptomatic. However, with a large hernia the patient may have symptoms of gastroesophageal reflux disease (GERD) (e.g., heartburn, regurgitation, dysphagia). Many patients with a type II hernia are either asymptomatic or have only vague, intermittent symptoms. When present, symptoms are generally related to ischemia or partial or complete obstruction. The most common symptoms of type II hernia are epigastric or substernal pain, postprandial fullness, substernal fullness, nausea, and retching. A type II hernia can progressively enlarge so that the entire stomach eventually herniates, with the pylorus juxtaposed to the gastric cardia, forming an upside-down, intrathoracic stomach. Paraesophageal hernias are associated with abnormal laxity of structures normally preventing displacement of the stomach (gastrosplenic and gastrocolic ligaments). As the hernia enlarges, the greater curvature of the stomach rolls up into the thorax. Because the stomach is fixed at the gastroesophageal junction, the herniated stomach tends to rotate around its longitudinal axis resulting in an organoaxial volvulus. Gastric volvulus may lead to acute gastric obstruction, incarceration, and perforation (Kahrilas, 2023; Society of American Gastrointestinal and Endoscopic Surgeons [SAGES], 2013; Kahrilas et al., 2008)

Diagnosis is based on symptoms of GERD, surgical history (e.g, esophagomyotomy, partial gastrectomy), and diagnostic studies (e.g., upper endoscopy, barium swallow, endoscopy, esophageal manometry). Some physicians evaluate patients prior to bariatric surgery with an esophagogastroduodenoscopy or upper gastrointestinal study to detect conditions such as hiatal hernias and esophageal mucosal abnormalities related to gastroesophageal reflux (Mechanick, et al., 2008).

Symptoms of GERD are medically managed with medications that neutralize or reduce stomach acid. Surgery is generally reserved for emergency situations and for those who are not responsive to medications. Surgical repair of hiatal hernia by laparoscopy, laparotomy or thoracotomy is often combined with surgery for GERD. Nissen fundoplication is one method of repair used to treat GERD when it is caused by a hiatal hernia. Surgical repair of a paraesophageal hernia is typically not performed because the annual risk of developing acute symptoms requiring emergent surgery is less than 2% and the risk decreases exponentially after 65 years. The mortality rate from elective paraesophageal hernia repair is approximately 1.4%. Some propose that younger and healthier patients with a life expectancy of >10 years should consider surgery to prevent both the risk of acute gastric volvulus and potentially progressive symptoms. Elective surgical repair of paraesophageal hernia is indicated in patients with subacute symptoms such as gastroesophageal reflux disease (GERD) refractory to medical therapy, dysphagia, early satiety, postprandial chest or abdominal pain, anemia, or vomiting. Emergent repair is required in patients with a gastric volvulus, uncontrolled bleeding, obstruction, strangulation, perforation, and/or respiratory compromise secondary to the hernia. The underlying surgical principles for successful repair include reduction of hernia contents, removal of the hernia sac, closure of the hiatal defect, and an antireflux procedure (Kahrilas, 2023; SAGES, 2013; Schieman, et al., 2009; Kahrilas et al., 2008). Hiatal hernia repair performed at the time of the primary bariatric procedure is considered integral to the procedure.

Literature Review

The few studies investing the effectiveness and long-term outcomes of hiatal hernia repair performed at the time of bariatric surgery are primarily in the form of retrospective reviews, case reports and case series with small patient populations and short-term follow-ups. In some cases simultaneous hiatal hernia repair and bariatric surgery were proposed to prevent postoperative GERD. Studies included patients who were diagnosed preoperatively and those who were diagnosed intra-operatively (Mahawar, et al., 2015). There is insufficient evidence to support hiatal hernia repair in conjunction with bariatric surgery in an asymptomatic patient. Patient selection criteria for simultaneous procedures have not been established.

Professional Societies/Organizations

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES): Based on a systematic review of the literature SAGES (2013) developed guidelines for the management of hiatal hernia. The guidelines included the following strong recommendations for surgical intervention for hiatal hernias:

- Repair of a type I hernia in the absence of reflux disease is not necessary. The indication for repair of a sliding (Type I) hiatal hernia is gastroesophageal reflux disease. The hernia is not the indication for the procedure, but must be repaired. A fundoplication to address the reflux disease is mandatory. Outside of this situation, Type I sliding hiatal hernias have been thought to be almost inconsequential and not warranting surgical repair.
- All symptomatic paraesophageal hiatal hernias should be repaired particularly those with acute obstructive symptoms or which have undergone volvulus.
- Acute gastric volvulus requires reduction of the stomach with limited resection if needed.

Two weak recommendations by the Society stated that routine elective repair of completely asymptomatic paraesophageal hernias may not always be indicated. Consideration for surgery should include the patient's age and co-morbidities. Secondly, during operations for Roux-en-Y gastric bypass, sleeve gastrectomy and the placement of adjustable gastric bands, all detected hiatal hernias should be repaired because of the association with gastroesophageal reflux symptoms. This advice must be tempered by other reports which show that placement of an adjustable gastric band may relieve reflux symptoms, even without reduction of a hiatal hernia. Retrospective reviews and small case series suggested possible benefits of hiatal hernia repair combined with other types of bariatric surgery (e.g., adjustable gastric band placement; gastric bypass and sleeve gastrectomy).

<u>Vena Cava Filter Placement at the Time of Bariatric Surgery</u>

Obesity and general surgery are risk factors for venous thromboembolism. Patients undergoing bariatric surgery are generally considered to be at moderate to high risk for lower extremity deep vein thrombosis (DVT). Pulmonary embolus (PE) may be the first manifestation of venous thromboembolism (VTE) and is a leading cause of mortality in after bariatric surgery. Obese patients undergoing bariatric surgery should receive preventive measures in the perioperative period. Early postoperative ambulation and perioperative use of lower extremity sequential compression devices are safe and suggested for all bariatric patients when feasible. Unless contraindicated, chemoprophylaxis using various anticoagulant regimens is an important adjunct to these methods and may be routinely administered to bariatric surgery patients. The possible role of inferior vena cava (IVC) filters remains controversial. Because of the long-term complications of permanent IVC filters, retrievable IVC filters may be an option for selected patients in whom an elevated risk of thromboembolism is limited to the early postoperative period. (ASMBS, 2022; Hamad and Bergqvist, 2006).

Literature Review

The evidence evaluating the safety and effectiveness of prophylactic IVC filter placement with bariatric surgery is primarily in the form of small, uncontrolled studies and retrospective reviews. Trigilio-Black et al. (2007) evaluated IVC filter use for PE risk reduction in high-risk super morbidly obese bariatric surgery patients. In this cohort of patients (n=41) had a mean BMI of 64.2 +/- 12 kg/m^2 (range 47-105). IVC filters were inserted at the time of bariatric surgery according to the patient's risk factors, including immobility, previous DVT/PE, venous stasis, and pulmonary compromise. No instances of PE were documented, and no immediate or late complications related to filter placement occurred. DVT occurred in one patient, and one patient, with a BMI 105 kg/m^2, died secondary to rhabdomyolysis. Study limitations include the lack of randomization and small sample size. The authors noted that additional studies are needed to confirm the efficacy of IVC filter placement for PE risk reduction and related mortality in the super morbidly obese.

Halmi and Kolesnikov (2007) reported on 27 of 652 mini-open Roux-en-y gastric bypass (RYGB) patients who were at high risk for PE and received preoperative retrievable IVC filters placed by the interventional radiology two hours before bypass surgery. The mean BMI was 48.7 +/- 4.2 kg/m^2 (range 38-75). The indications for filter placement were previous DVT/PE, thrombophlebitis, a hypercoagulable state, pulmonary hypertension, an inability to ambulate, a body mass index >65 kg/m^2, and the presence of severe sleep apnea. Of the 27 filters, 26 were successfully removed during an outpatient procedure 18-21 days postoperatively. No thromboembolic complications occurred in this high-risk group. One retrievable filter was not removed because of prolonged hospitalization secondary to small bowel obstruction. Of the 625 patients who did not receive IVC filters preoperatively, two developed clinically significant PE and seven developed lower extremity DVT. It was noted that additional studies on larger clinical series are needed to prove the effectiveness of retrievable IVC filters in bariatric surgery (Halmi and Kolesnikov, 2007).

Professional Societies/Organizations

American Association of Clinical Endocrinologists, The Obesity Society, and the American Society for Metabolic and Bariatric Surgery (AACE/TOS/ASMBS): The AACE/TOS/ASMBS guidelines for the bariatric surgery patient stated “although randomized trials to support this action are lacking, prophylactic vena cava filter should be considered for patients with a history of prior PE, prior iliofemoral DVT, evidence of venostasis, known hypercoagulable state, or increased right-sided heart pressures” (Mechanick, et al., 2008). In the 2013 update to the guidelines it is stated that patients with a history of DVT or cor pulmonale should undergo an appropriate diagnostic evaluation for DVT as an element of medical clearance for bariatric surgery. According to the AACE/TOS/ASMBS, prophylactic vena cava filter may present a greater risk than benefit in patients with a history of prior pulmonary embolus or DVT given the risks of filter-related complications including thrombosis (Mechanick, et al., 2013). In the 2019 updated guidelines, routine placement is discouraged but prophylactic placement can be considered in select patients after evaluating risks and benefits (Mechanick, et al., 2020).

There is insufficient evidence in the published peer-reviewed medical literature to support routine prophylactic placement of IVC filters in all patients undergoing bariatric surgery. However, there is some evidence in the form of case series and professional society guidance to suggest that the procedure is appropriate in those bariatric surgery patients who are determined to be at high risk for venous thromboembolism (VTE) (e.g., deep vein thrombosis, hypercoagulable state, increased right-sided heart pressures, pulmonary embolus).

<u>Upper Endoscopy at the Time of Bariatric Surgery</u>

The role of routine upper endoscopy in obese patients prior to bariatric surgery is controversial. The rationale for performing an upper endoscopy before bariatric surgery is to detect and/or treat lesions that might potentially affect the type of surgery performed, cause complications in the immediate postoperative period, or result in symptoms after surgery (American Society for Gastrointestinal Endoscopy [ASGE], 2015).

The American Association of Clinical Endocrinologists, The Obesity Society, and the American Society for Metabolic and Bariatric Surgery (AACE/TOS/ASMBS) guidelines for bariatric surgery stated that all gastrointestinal symptoms should be evaluated and treated before bariatric surgery. According to these guidelines, although it is commonplace for surgeons to perform a routine upper gastrointestinal study or endoscopy to screen for peptic ulcer disease before many other types of surgical procedures, this practice has been questioned for bariatric surgery. After bariatric surgery, upper intestinal endoscopy is the preferred diagnostic procedure for the evaluation of persistent and severe gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain). In many circumstances, upper endoscopy can also incorporate a therapeutic intervention with transendoscopic dilation of a recognized stricture (Mechanick, et al., 2008; updated 2020).

The 2015 updated guideline on the role of endoscopy in the bariatric surgery patient by the American Society for Gastrointestinal Endoscopy (ASGE) in conjunction with representatives from the Society of Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Metabolic and Bariatric Surgery (ASMBS) included the following statements:

- "We recommend water-soluble contrast radiography rather than endoscopy as the initial investigation in the postoperative bariatric patient suspected of having a leak or fistula.
- We recommend endoscopy as a first-line diagnostic study in the evaluation of the postoperative bariatric patient with abdominal pain, nausea, or vomiting. In the immediate postoperative period consultation with the surgeon is recommended.
- We recommend that endoscopic dilation of symptomatic stomal stenoses be planned in accordance with the type of anastomosis created during the original bariatric operation. Generally, dilation should be limited to 15 mm and should be avoided after LAGB and VBG procedures".

The guideline does not discuss any indications for upper endoscopy performed during bariatric surgery

Professional society guidance suggests that upper endoscopy is warranted when performed in symptomatic patients prior to bariatric surgery. Well-designed prospective studies are needed to further evaluate the utility of preoperative routine upper endoscopy in bariatric surgery patients. Upper endoscopy performed at the time of bariatric surgery is not supported in the peer-reviewed medical literature, and is not considered medically necessary.

Professional Societies/Organizations

Society of American Gastrointestinal Endoscopic Surgeons (SAGES): According to the 2008 Sages guideline for clinical application of laparoscopic bariatric surgery, preoperative weight loss may be useful to reduce liver volume and improve access for laparoscopic bariatric procedures, but mandated preoperative weight loss does not affect postoperative weight loss or comorbidity improvements. Laparoscopic Roux-en-y gastric bypass (LRYGB), gastric banding by vertical banded gastroplasty or adjustable gastric banding, and biliopancreatic diversion with and without duodenal switch are established and validated bariatric procedures that provide effective long-term weight loss and resolution of co-morbid conditions. Laparoscopic sleeve gastrectomy (LSG) is validated as providing effective weight loss and resolution of comorbidities to 3-5 years. Laparoscopic revisional procedures may be performed safely, but with more complications than primary bariatric procedures, therefore the relative risks and benefits of laparoscopy should be considered on a case-by-case basis.

Use Outside of the US

The 2014 (updated 2022) National Institute for Health and Care Excellence (NICE) (United Kingdom) guidance on obesity management in adults and children stated that bariatric surgery is recommended as a treatment option for people with obesity if all of the following criteria are fulfilled:

- the person has a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (e.g., type 2 diabetes or high blood pressure) that could be improved if they lost weight
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anesthesia and surgery
- the person commits to the need for long-term follow-up

Bariatric surgery is also recommended as a first-line option instead of lifestyle interventions or drug treatment for adults with a BMI of more than 50 kg/m^2 in whom surgical intervention is considered appropriate (NICE, 2014, updated 2022).

In 2004, the European Association for Endoscopic Surgery (EAES) published evidence-based guidelines for obesity surgery. According to the EAES, adjustable gastric banding (AGB), vertical banded gastroplasty (VBG), Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch (BPD/DS) are all effective in the treatment of morbid obesity. There is evidence that the laparoscopic approach is advantageous for LAGB, VBG, and RYGB. Preliminary data suggest that the laparoscopic approach may also be preferable for BPD/DS if surgical expertise is available, but further studies are needed. The report concluded that in terms of excess weight loss (EWL) percentages, BPD/DS is superior to RYGB which, in turn, yields greater EWL than VBG and AGB. However, the greater degree of EWL resulting from BPD/DS is at the expense of other outcomes (Sauerland, et al., 2005).

In 2019, the European Association for Endoscopic Surgery (EAES) updated their 2004 guidelines for obesity surgery. It was noted that Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy offer similar mid-term weight loss and control/remission of metabolic comorbidities. Biliopancreatic diversion with duodenal switch (BPD/DS) and RYGB have shown no difference in mid-term weight loss. However, EAES stated that BPD/DS is superior to RYGB for control/remission of type 2 diabetes. (Di Lorenzo, et al., 2020). Recommendations included:

- Laparoscopic bariatric surgery should be considered for patients with BMI ≥ 40 kg/m^2, BMI ≥ 35–40 kg/m^2 with associated comorbidities that are expected to improve with weight loss, and for BMI ≥ 30–35 kg/m^2 and type 2 diabetes and/or arterial hypertension with poor control despite optimal medical therapy.
- Sleeve gastrectomy may be preferred over adjustable gastric banding (AGB) for weight loss and control/resolution of metabolic comorbidities as AGB surgeries are associated with a high rate of reoperations for complications or conversion to another bariatric procedure for insufficient weight loss in the long term.
- RYGB should be preferred over AGB, gastric plication (greater weight loss and control/remission of insulin resistance and type 2 diabetes) and sleeve gastrectomy (in patients with severe gastroesophageal reflux disease and/or severe esophagitis).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (100.1)	9/24/2013
LCD	Novitas	Bariatric Surgical Management of Morbid Obesity (L35022)	5/13/2021

	Contractor	Determination Name/Number	Revision Effective Date
LCD	Palmetto	Laparoscopic Sleeve Gastrectomy for Severe Obesity (L34576)	5/12/2022
LCD	First Coast	Surgical Management of Morbid Obesity (L33411)	10/01/2019

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
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
43659†	Unlisted laparoscopy procedure, stomach
43770†	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band 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 or less) Roux-en-Y gastroenterostomy
43847†	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43999†	Unlisted procedure, stomach
44238†	Unlisted laparoscopy procedure, intestine (except rectum)
44799†	Unlisted procedure, small intestine

†<u>Note</u>: Considered Experimental/Investigational/Unproven when used to report any procedure listed in this policy as Experimental/Investigational/Unproven for the treatment of morbid obesity

HCPCS Codes	Description
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
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Considered Experimental/Investigational/Unproven when used to report any procedure listed as Experimental/Investigational/Unproven for the treatment of morbid obesity:

CPT®* Codes	Description
43289	Unlisted laparoscopy procedure, esophagus
43499	Unlisted procedure, esophagus
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
44238	Unlisted laparoscopy procedure, intestine (except rectum)
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64999†	Unlisted procedure, nervous system
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming (Code deleted 12/31/2022)
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator (Code deleted 12/31/2022)
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator (Code deleted 12/31/2022)
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed (Code deleted 12/31/2022)

†<u>Note</u>: Considered Experimental/Investigational/Unproven when used to report any procedure for vagus nerve blocking (e.g., Maestro®)

<u>Reoperation and Revisional Bariatric Surgery (Adults)</u>

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
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
43659	Unlisted laparoscopy procedure, stomach
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 or 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 gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
43999	Unlisted procedure, stomach
44799	Unlisted procedure, small intestine

<u>Initial Bariatric Surgery Procedures (Adolescents)</u>

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43843††	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43846††	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847††	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption

HCPCS Codes	Description
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

††Note: Considered Experimental/Investigational/Unproven when used to report any procedure listed in this policy as Experimental/Investigational/Unproven for the treatment of morbid obesity

Reoperation and Revisional Bariatric Surgery (Adolescents)

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
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
43659	Unlisted laparoscopy procedure, stomach
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy

Adults and Adolescents

Bariatric Surgery for the Treatment of Diabetes Mellitus

Considered Experimental/Investigational/Unproven when performed solely for the treatment of diabetes mellitus with a BMI < 35:

CPT®* Codes	Description
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 or 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 gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

HCPCS Codes	Description
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

HCPCS Codes	Description
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Cholecystectomy, Liver Biopsy, Herniorrhaphy, Prophylactic Vena Cava Filter Placement, or Upper Endoscopy

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed

Considered integral to the primary bariatric procedure when gastrointestinal endoscopy is concurrently performed to assess a surgical anastomosis or to establish anatomical landmarks:

CPT®* Codes	Description
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)

Considered integral when simple suture repair (i.e., without mesh) of a diaphragmatic defect for a hiatal hernia is performed as part of a bariatric surgery procedure:

CPT®* Codes	Description
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh

Considered Not Medically Necessary when performed in conjunction with a bariatric surgery in the absence of signs or symptoms of disease:

CPT®* Codes	Description
47000	Biopsy of liver, needle; percutaneous
47001	Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (List separately in addition to code for primary procedure)
47379†	Unlisted laparoscopic procedure, liver
47562	Laparoscopy, surgical; cholecystectomy
47563	Laparoscopy, surgical; cholecystectomy with cholangiography
47564	Laparoscopy, surgical; cholecystectomy with exploration of common duct
47600	Cholecystectomy;
47605	Cholecystectomy; with cholangiography

CPT®* Codes	Description
47610	Cholecystectomy with exploration of common duct;

†**<u>Note</u>: Considered Not Medically Necessary when used to report laparoscopic liver biopsy performed in conjunction with a bariatric surgery in absence of signs or symptoms of liver disease**

References

1. Abbatini F, Capoccia D, Casella G, Coccia F, Leonetti F, Basso N. Type 2 diabetes in obese patients with body mass index of 30-35 kg/m2: sleeve gastrectomy versus medical treatment. Surg Obes Relat Dis. 2012 Jan-Feb;8(1):20-4. doi: 10.1016/j.soard.2011.06.015. Epub 2011 Jul 13. PMID: 21924686.

2. Abdelbaki TN, Huang CK, Ramos A, Neto MG, Talebpour M, Saber AA. Gastric plication for morbid obesity: a systematic review. Obes Surg. 2012 Oct;22(10):1633-9. doi: 10.1007/s11695-012-0723-z.

3. Abou Ghazaleh R, Bruzzi M, Bertrand K, M'harzi L, Zinzindohoue F, Douard R, Berger A, Czernichow S, Carette C, Chevallier JM. Is Mini-Gastric Bypass a Rational Approach for Type-2 Diabetes? Curr Atheroscler Rep. 2017 Oct 24;19(12):51.

4. Abu Dayyeh BK, Acosta A, Camilleri M, Mundi MS, Rajan E, Topazian MD, Gostout CJ. Endoscopic Sleeve Gastroplasty Alters Gastric Physiology and Induces Loss of Body Weight in Obese Individuals. Clin Gastroenterol Hepatol. 2017 Jan;15(1):37-43.e1. doi: 10.1016/j.cgh.2015.12.030. Epub 2015 Dec 31. PMID: 26748219.

5. Adams TD, Gress RE, Smith SC, Halverson RC, Simper SC, Rosamond WD, et al. Long-term mortality after gastric bypass surgery. N Engl J Med. 2007 Aug 23;357(8):753-61.

6. Adil MT, Al-Taan O, Rashid F, Munasinghe A, Jain V, Whitelaw D, Jambulingam P, Mahawar K. A Systematic Review and Meta-Analysis of the Effect of Roux-en-Y Gastric Bypass on Barrett's Esophagus. Obes Surg. 2019 Nov;29(11):3712-3721. doi: 10.1007/s11695-019-04083-0. PMID: 31309524.

7. Ahmed HO, Ezzat RF. Quality of life of obese patients after treatment with the insertion of intra-gastric balloon versus Atkins diet in Sulaimani Governorate, Kurdistan Region, Iraq. Ann Med Surg (Lond). 2018 Nov 24;37:42-46.

8. AHRQ. Technology assessment program. Short- and Long-Term Outcomes after Bariatric Surgery in the Medicare Population. Jan 7, 2018, archived. Accessed Jun 15, 2023. Available at URL address: https://archive.ahrq.gov/clinic/techarch.htm

9. Alami RS, Morton JM, Schuster R, Lie J, Sanchez BR, Peters A, et al. Is there a benefit to preoperative weight loss in gastric bypass patients? A prospective randomized trial. Surg Obes Relat Dis. 2007 Mar-Apr;3(2):141-5; discussion 145-6.

10. Ali MR, Moustarah F, Kim JJ; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons. Surg Obes Relat Dis. 2016 Mar-Apr;12(3):462-7. doi: 10.1016/j.soard.2015.12.026. Epub 2015 Dec 22.

11. Ali MR, Baucom-Pro S, Broderick-Villa GA, Campbell JB, Rasmussen JJ, Weston AN, et al. Weight loss before gastric bypass: feasibility and effect on postoperative weight loss and weight loss maintenance. Surg Obes Relat Dis. 2007 Sep-Oct;3(5):515-20.

12. Ali MR, Fuller WD, Choi MP, Wolfe BM. Bariatric surgical outcomes. Surg Clin North Am. 2005 Aug;85(4):835-52, vii.

13. American Association for the Study of Liver Diseases (AASLD). AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. May 2023. Accessed Jun 15, 2023. Available at URL address: https://www.aasld.org/practice-guidelines/clinical-assessment-and-management-nonalcoholic-fatty-liver-disease

14. American College of Cardiology/American Heart Association Task Force on Practice Guidelines—Obesity Expert Panel, Jensen MD, Ryan DH, et al. Executive summary: Guidelines (2013) for the management of overweight and obesity in adults. Obesity (Silver Spring, Md). 2014;22(Suppl 2):S5-S39.

15. American Diabetes Association (ADA). 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: Standards of Care in Diabetes—2023. Accessed Jun 15, 2023. Available at URL address: https://diabetesjournals.org/care/issue/46/Supplement_1

16. American Diabetes Association (ADA). 14. Children and Adolescents: Standards of Medical Care in Diabetes—2023. Accessed Jun 15, 2023. Available at URL address: https://diabetesjournals.org/care/article/46/Supplement_1/S230/148046/14-Children-and-Adolescents-Standards-of-Care-in

17. American Diabetes Association (ADA). Standards of medical care in diabetes - 2023. Accessed Jun 15, 2023. Available at URL address: https://diabetesjournals.org/care/issue/46/Supplement_1

18. American Dietetic Association. Position of the American Dietetic Association: Nutrition intervention in the treatment of anorexia nervosa, bulimia nervosa, and other eating disorders. J Am Diet Assoc. 2006 Dec;106(12):2073-82.

19. American Gastroenterological Association. American Gastroenterological Association medical position statement on Obesity. Gastroenterology. 2002 Sep;123(3):879-81.

20. American Society for Gastrointestinal Endoscopy (ASGE). The role of endoscopy in the bariatric surgery patient. 2015. Accessed Jun 12, 2023. Available at URL address: https://www.asge.org/home/resources/key-resources/guidelines#upper-gi

21. American Society for Metabolic and Bariatric Surgery (ASMBS). American Society for Metabolic and Bariatric Surgery and American Hernia Society consensus guideline on bariatric surgery and hernia surgery. Oct 2018. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resources/american-society-for-metabolic-and-bariatric-

surgery-and-american-hernia-society-consensus-guideline-on-bariatric-surgery-and-hernia-surgery

22. American Society for Metabolic and Bariatric Surgery (ASMBS). ASMBS Position Statement on Preoperative Patient Optimization Before Metabolic and Bariatric Surgery. Oct 2021. Accessed on Jun 15, 2023. Available at URL address: https://asmbs.org/resources/asmbs-position-statement-on-preoperative-patient-optimization-before-metabolic-and-bariatric-surgery

23. American Society for Metabolic and Bariatric Surgery (ASMBS). Emerging Technologies and Clinical Issues Committees of the ASMBS. Position Statement on emerging endosurgical interventions for treatment of obesity. 2009a Jan; Reviewed Nov 2013. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resources/emerging-endosurgical-interventions-for-treatment-of-obesity

24. American Society for Metabolic and Bariatric Surgery (ASMBS). Policy Statement on Gastric Plication. 2011 Oct; Reviewed Oct 2015. Accessed Jun 12, 2023. Available at URL address: https://asmbs.org/resources/policy-statement-on-gastric-plication

25. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position statement on bariatric surgery in class I obesity (BMI 30–35 kg/m^2). Aug 2018. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resources/asmbs-updated-position-statement-on-bariatric-surgery-in-class-i-obesity

26. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position statement on sleeve gastrectomy as a bariatric procedure. Aug 2017. Accessed Jun 12, 2023. Available at URL address: https://asmbs.org/resources/updated-position-statement-on-sleeve-gastrectomy-as-a-bariatric-procedure

27. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position statement on perioperative venous thromboembolism prophylaxis in bariatric surgery. Jan 2022. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resource-categories/position-statements

28. American Society for Metabolic and Bariatric Surgery (ASMBS). Review of the literature on one-anastomosis gastric bypass. Jun 2018. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resources/review-of-the-literature-on-one-anastomosis-gastric-bypass

29. Amirian H, Torquati A, Omotosho P. Racial Disparity in 30-Day Outcomes of Metabolic and Bariatric Surgery. Obes Surg. 2020 Mar;30(3):1011-1020. doi: 10.1007/s11695-019-04282-9. PMID: 31745861; PMCID: PMC7222128.

30. Anderson MA, Gan SI, Fanelli RD, et al. Role of endoscopy in the bariatric surgery patients. Gastrointest Endosc. 2008:68(1):1-10.

31. Angrisani L, Lorenzo M, Borrelli V. Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial. Surg Obes Relat Dis. 2007 Mar-Apr;3(2):127-32; discussion 132-3.

32. Anthone GJ. The duodenal switch operation for morbid obesity. Surg Clin North Am. 2005 Aug;85(4):819-33, viii.

33. Anthone GJ, Lord RV, DeMeester TR, Crookes PF. The duodenal switch operation for the treatment of morbid obesity. Ann Surg. 2003 Oct;238(4):618-27; discussion 627-8.

34. Apovian CM, Shah SN, Wolfe BM, Ikramuddin S, Miller CJ, Tweden KS, Billington CJ, Shikora SA. Two-Year Outcomes of Vagal Nerve Blocking (vBloc) for the Treatment of Obesity in the ReCharge Trial. Obes Surg. 2017 Jan;27(1):169-176.

35. Appel LJ, Clark JM, Yeh HC, Wang NY, Coughlin JW, Daumit G, et al. Comparative effectiveness of weight-loss interventions in clinical practice. N Engl J Med. 2011 Nov 24;365(21):1959-68.

36. Arias E, Martínez PR, Ka Ming Li V, Szomstein S, Rosenthal RJ. Mid-term Follow-up after Sleeve Gastrectomy as a Final Approach for Morbid Obesity. Obes Surg. 2009 Mar 12. [Epub ahead of print]

37. Armstrong SC, Bolling CF, Michalsky MP, et al. AAP SECTION ON OBESITY, SECTION ON SURGERY. Pediatric Metabolic and Bariatric Surgery: Evidence, Barriers, and Best Practices. Pediatrics. 2019;144(6):e20193223

38. ASGE Bariatric Endoscopy Task Force and ASGE Technology Committee, Abu Dayyeh BK, Kumar N, Edmundowicz SA, Jonnalagadda S, Larsen M, Sullivan S, Thompson CC, Banerjee S. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc. ≥2015 Sep;82(3):425-38.e5.

39. ASGE Technology Committee, Banerjee S, Barth BA, Bhat YM, Desilets DJ, Gottlieb KT, et al. Endoscopic closure devices. Gastrointest Endosc. 2012 Aug;76(2):244-51.

40. August GP, Caprio S, Fennoy I, Freemark M, Kaufman FR, Lustig RH, Silverstein JH, Speiser PW, Styne DM, Montori VM. Prevention and treatment of pediatric obesity: an Endocrine Society clinical practice guideline based on expert opinion. J Clin Endocrinol Metab 2008 Dec;93(12):4576-99.

41. Baker S, Barlow S, Cochran W, Fuchs G, Klish W, Krebs N, et al. Overweight children and adolescents: a clinical report of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr. 2005 May;40(5):533-43.

42. Baltasar A, Serra C, Perez N, Bou R, Bengochea M, Ferri L. Laparoscopic sleeve gastrectomy: a multi-purpose bariatric operation. Obes Surg. 2005 Sep;15(8):1124-8.

43. Bazerbachi F, Haffar S, Sawas T, Vargas EJ, Kaur RJ, Wang Z, Prokop LJ, Murad MH, Abu Dayyeh BK. Fluid-Filled Versus Gas-Filled Intragastric Balloons as Obesity Interventions: a Network Meta-analysis of Randomized Trials. Obes Surg. 2018 Apr 16

44. Benotti PN, Still CD, Wood GC, Akmal Y, King H, El Arousy H, et al. Preoperative weight loss before bariatric surgery. Arch Surg. 2009 Dec;144(12):1150-5.

45. Bessler M, Daud A, Kim T, DiGiorgi M. Prospective randomized trial of banded versus nonbanded gastric bypass for the super obese: early results. Surg Obes Relat Dis. 2007 Jul-Aug;3(4):480-4; discussion 484-5.

46. Betzel B, Homan J, Aarts EO, Janssen IMC, de Boer H, Wahab PJ, Groenen MJM, Berends FJ. Weight reduction and improvement in diabetes by the duodenal-jejunal bypass liner: a 198 patient cohort study. Surg Endosc. 2017 Jul;31(7):2881-2891.

47. Beymer C, Kowdley KV, Larson A, Edmonson P, Dellinger EP, Flum DR. Prevalence and predictors of asymptomatic liver disease in patients undergoing gastric bypass surgery. Arch Surg. 2003 Nov; 138(11):1240-4.

48. Biertho L, Steffen R, Ricklin T, Horber FF, Pomp A, Inabnet WB, et al. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding: a comparative study of 1,200 cases. J Am Coll Surg. 2003 Oct;197(4):536-44.

49. Bolling CF, Armstrong SC, Reichard KW, et al. AAP SECTION ON OBESITY, SECTION ON SURGERY. Metabolic and Bariatric Surgery for Pediatric Patients With Severe Obesity. Pediatrics. 2019;144(6):e20193224

50. Bondada S, Jen HC, Deugarte DA. Outcomes of bariatric surgery in adolescents. Curr Opin Pediatr. 2011 Oct;23(5):552-6.

51. Bouldin MJ, Ross LA, Sumrall CD, Loustalot FV, Low AK, Land KK. The effect of obesity surgery on obesity comorbidity. Am J Med Sci. 2006 Apr;331(4):183-93.

52. Boza C, Muñoz R, Salinas J, Gamboa C, Klaassen J, Escalona A, Pérez G, Ibañez L, Guzmán S. Safety and efficacy of Roux-en-Y gastric bypass to treat type 2 diabetes mellitus in non-severely obese patients. Obes Surg. 2011 Sep;21(9):1330-6. doi: 10.1007/s11695-011-0463-5. PMID: 21744283.

53. Boza C, Viscido G, Salinas J, Crovari F, Funke R, Perez G. Laparoscopic sleeve gastrectomy in obese adolescents: results in 51 patients. Surg Obes Relat Dis. 2012 Mar;8(2):133-7. Epub 2012 Jan 13.

54. Brethauer SA, Hummel JP, Schauer PR. Systematic review of sleeve gastrectomy as staging and primary bariatric procedure. Surg Obes Relat Dis. 2009 Jul-Aug;5(4):469-75. Epub 2009 Jun 9.

55. Brethauer SA, Kothari S, Sudan R, Williams B, English WJ, Brengman M, Kurian M, Hutter M, Stegemann L, Kallies K, Nguyen NT, Ponce J, Morton JM. Systematic review on reoperative bariatric surgery: American Society for Metabolic and Bariatric Surgery Revision Task Force. Surg Obes Relat Dis. 2014 Sep-Oct;10(5):952-72. doi: 10.1016/j.soard.2014.02.014. Epub 2014 Feb 22. PMID: 24776071.

56. Brown WA, de Leon Ballesteros GP, Ooi G, Higa K, Himpens J, Torres A, Shikora S, Kow L, Herrera MF; IFSO appointed task force reviewing the literature on SADI-S/OADS. Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement-Update 2020. Obes Surg. 2021 Jan;31(1):3-25. doi: 10.1007/s11695-020-05134-7. Epub 2021 Jan 6. PMID: 33409979.

57. Brown WA, Ooi G, Higa K, Himpens J, Torres A; IFSO-appointed task force reviewing the literature on SADI-S/OADS. Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement. Obes Surg. 2018 May;28(5):1207-1216.

58. Buchwald H, Avidor Y, Braunwald E, Jensen MD, Pories W, Fahrbach K, et al. Bariatric surgery: a systematic review and meta-analysis. JAMA. 2004 Oct 13;292(14):1724-37.

59. Buchwald H; Consensus Conference Panel. Consensus conference statement bariatric surgery for morbid obesity: health implications for patients, health professionals, and third-party payers. Surg Obes Relat Dis. 2005 May-Jun;1(3):371-81.

60. Buchwald H, Estok R, Fahrbach K, Banel D, Jensen MD, Pories WJ, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. Am J Med. 2009 Mar;122(3):248-256.e5.

61. Buchwald, Buchwald JN, McGlennon TW. Systematic review and meta-analysis of medium-term outcomes after banded Roux-en-Y gastric bypass. Obes Surg. 2014 Sep;24(9):1536-51.

62. Camilleri M. Treatment of gastroparesis. In UpToDate, Talley NJ, editor. Aug 31, 2022. UpToDate, Waltham, MA. Accessed Jun 15, 2023.

63. Camilleri M, Toouli J, Herrera MF, Kulseng B, Kow L, Pantoja JP, et al. Intra-abdominal vagal blocking (VBLOC therapy): clinical results with a new implantable medical device. 2008 Jun;143(6):723-31.

64. Carbajo MA, Fong-Hirales A, Luque-de-León E, Molina-Lopez JF, Ortiz-de-Solórzano J. Weight loss and improvement of lipid profiles in morbidly obese patients after laparoscopic one-anastomosis gastric bypass: 2-year follow-up. Surg Endosc. 2017 Jan;31(1):416-421.

65. Carbajo MA, Luque-de-León E, Jiménez JM, Ortiz-de-Solórzano J, Pérez-Miranda M, Castro-Alija MJ. Laparoscopic One-Anastomosis Gastric Bypass: Technique, Results, and Long-Term Follow-Up in 1200 Patients. Obes Surg. 2017 May;27(5):1153-1167.

66. Caruana JA, McCabe MN, Smith AD, Camara DS, Mercer MA, Gillespie JA. Incidence of symptomatic gallstones after gastric bypass: is prophylactic treatment really necessary? Surg Obes Relat Dis. 2005 Nov-Dec;1(6):564-7; discussion 567-8.

67. Cassie S, Menezes C, Birch DW, Shi X, Karmali S. Effect of preoperative weight loss in bariatric surgical patients: a systematic review. Surg Obes Relat Dis. 2011 Nov-Dec;7(6):760-7.

68. Catalano MF, Khan NM, Lajin M et al. Mo2005 Gastric outlet revision using endoscopic suturing (ES) in patients presenting with weight regain following Roux-en-Y Gastric Bypass (RYGB). Gastrointestinal Endoscopy 2016; 83: AB491

69. Centers for Medicare and Medicaid Services (CMS). Coverage Decision Memorandum for Bariatric Surgery for Treatment of Co-morbidities Associated with Morbid Obesity. February 21, 2006. Accessed Jun 12, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&ver=30&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+(1st+Recon)&bc=BEAAAAAAEAAA&&fromdb=true

70. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Jun 15, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/search.aspx

71. Centers for Medicare and Medicaid Services (CMS). National Coverage Determinations (NCDs) alphabetical index. Accessed Jun 15, 2023. Available at URL address: https://www.cms.gov/medicare-coverage-database/search.aspx

72. Chalasani N, Younossi Z, Lavine JE, Diehl AM, Brunt EM, Cusi K, Charlton M, Sanyal AJ; American Association for the Study of Liver Diseases; American College of Gastroenterology; American Gastroenterological Association. The diagnosis and management of non-alcoholic fatty liver disease: Practice guideline by the American Association for the Study of Liver Diseases, American College of Gastroenterology, and the American Gastroenterological Association. Am J Gastroenterol. 2012 Jun;107(6):811-26.

73. Chapman AE, Kiroff G, Game P, Foster B, O'Brien P, Ham J, et al. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. Surgery. 2004 Mar;135(3):326-51.

74. Christou NV, Sampalis JS, Liberman M, Look D, Auger S, McLean AP, MacLean LD. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg. 2004 Sep;240(3):416-23.

75. Coffin B, Maunoury V, Pattou F, Hébuterne X, Schneider S, Coupaye M, Ledoux S, Iglicki F, Mion F, Robert M, Disse E, Escourrou J, Tuyeras G, Le Roux Y, Arvieux C, Pouderoux P, Huten N, Alfaiate T, Hajage D, Msika S. Impact of Intragastric Balloon Before Laparoscopic Gastric Bypass on Patients with Super Obesity: a Randomized Multicenter Study. Obes Surg. 2017 Apr;27(4):902-909.

76. Cohen R, Pinheiro JS, Correa JL, Schiavon CA. Laparoscopic Roux-en-Y gastric bypass for BMI < 35 kg/m(2): a tailored approach. Surg Obes Relat Dis. 2006 May-Jun;2(3):401-4, discussion 404.

77. Collins BJ, Miyashita T, Schweitzer M, Magnuson T, Harmon JW. Gastric bypass: why Roux-en-Y? A review of experimental data. Arch Surg. 2007 Oct;142(10):1000-3; discussion 1004.

78. Colquitt J L, Pickett K, Loveman E, Frampton GK. Surgery for weight loss in adults. Cochrane Database of Systematic Reviews 2014, Issue 8. Art. No.: CD003641. DOI: 10.1002/14651858.CD003641.pub4.

79. Cottam A, Cottam D, Medlin W, Richards C, Cottam S, Zaveri H, Surve A. A matched cohort analysis of single anastomosis loop duodenal switch versus Roux-en-Y gastric bypass with 18-month follow-up. Surg Endosc. 2016 Sep;30(9):3958-64. doi: 10.1007/s00464-015-4707-7. Epub 2015 Dec 22. PMID: 26694182.

80. Cottam D, Qureshi FG, Mattar SG, Sharma S, Holover S, Bonanomi G, et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc. 2006 Jun;20(6):859-63.

81. Courcoulas A, Abu Dayyeh BK, Eaton L, Robinson J, Woodman G, Fusco M, Shayani V, Billy H8, Pambianco D, Gostout C. Intragastric balloon as an adjunct to lifestyle intervention: a randomized controlled trial. Int J Obes (Lond). 2017 Mar;41(3):427-433.

82. Courcoulas AP, Goodpaster BH, Eagleton JK, Belle SH, Kalarchian MA, Lang W, et al. Surgical vs medical treatments for type 2 diabetes mellitus: a randomized clinical trial. JAMA Surg. 2014 Jul;149(7):707-15.

83. Cunneen SA. Review of meta-analytic comparisons of bariatric surgery with a focus on laparoscopic adjustable gastric banding. Surg Obes Relat Dis. 2008 May-Jun;4(3 Suppl):S47-55.

84. Daniels SR, Jacobson MS, McCrindle BW, Eckel RH, Sanner BM. American Heart Association Childhood Obesity Research Summit Report. Circulation. 2009 Apr 21;119(15):e489-517.

85. De Castro ML, Morales MJ, Del Campo V, Pineda JR, Pena E, Sierra JM, et al. Efficacy, safety, and tolerance of two types of intragastric balloons placed in obese subjects: a double-blind comparative study. Obes Surg. 2010 Dec;20(12):1642-6.

86. DeMaria EJ, Sugerman HJ, Kellum JM, Meador JG, Wolfe LG. Results of 281 consecutive total laparoscopic Roux-en-Y gastric bypasses to treat morbid obesity. Ann Surg. 2002 May;235(5):640-5.

87. DeMaria EJ, Sugerman HJ, Meador JG, Doty JM, Kellum JM, Wolfe L, et al. High failure rate after laparoscopic adjustable silicone gastric banding for treatment of morbid obesity. Ann Surg. 2001 Jun;233(6):809-18.

88. Department of Defense, Department of Veterans Affairs, Veterans Health Administration . Va/Dod Clinical Practice Guideline for screening and management of overweight and obesity. April 18, 2014. Accessed Jun 15, 2023. Available at URL address: https://www.healthquality.va.gov/guidelines/CD/obesity/CPGManagementOfOverweightAndObesityFINAL041315.pdf

89. De Peppo F, Caccamo R, Adorisio O, Ceriati E, Marchetti P, Contursi 3, Alterio A, Della Corte C, Manco M, Nobili V. The Obalon swallowable intragastric balloon in pediatric and adolescent morbid obesity. Endosc Int Open. 2017 Jan;5(1):E59-E63.

90. Dhindsa BS, Saghir SM, Naga Y, Dhaliwal A, Ramai D, Cross C, Singh S, Bhat I, Adler DG. Efficacy of transoral outlet reduction in Roux-en-Y gastric bypass patients to promote weight loss: a systematic review and meta-analysis. Endosc Int Open. 2020 Oct;8(10):E1332-E1340. doi: 10.1055/a-1214-5822. Epub 2020 Sep 22. PMID: 33015335; PMCID: PMC7511267.

91. Di Lorenzo N, Antoniou SA, Batterham RL, Busetto L, Godoroja D, Iossa A, Carrano FM, Agresta F, Alarçon I, Azran C, Bouvy N, Balaguè Ponz C, Buza M, Copaescu C, De Luca M, Dicker D, Di Vincenzo A, Felsenreich DM, Francis NK, Fried M, Gonzalo Prats B, Goitein D, Halford JCG, Herlesova J, Kalogridaki M, Ket H, Morales-Conde S, Piatto G, Prager G, Pruijssers S, Pucci A, Rayman S, Romano E, Sanchez-Cordero S, Vilallonga R, Silecchia G. Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP. Surg Endosc. 2020 Jun;34(6):2332-2358. doi: 10.1007/s00464-020-07555-y. Epub 2020 Apr 23. PMID: 32328827; PMCID: PMC7214495.

92. Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, et al. Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA. 2008 Jan 23;299(3):316-23.

93. Dolce CJ, Russo M, Keller JE, Buckingham J, Norton HJ, Heniford BT, et al. Does liver appearance predict histopathologic findings: prospective analysis of routine liver biopsies during bariatric surgery. Surg Obes Relat Dis. 2009 Jan 23. [Epub ahead of print]

94. Doležalova-Kormanova K, Buchwald JN, Skochova D, Pichlerova D, McGlennon TW, Fried M. Five-Year Outcomes: Laparoscopic Greater Curvature Plication for Treatment of Morbid Obesity. Obes Surg. 2017 Nov;27(11):2818-2828.

95. Doldi SB, Micheletto G, Di Prisco F, Zappa MA, Lattuada E, Reitano M. Intragastric balloon in obese patients. Obes Surg. 2000 Dec;10(6):578-81.

96. Duvnjak M, Lerotić I, Barsić N, Tomasić V, Virović Jukić L, Velagić V. Pathogenesis and management issues for non-alcoholic fatty liver disease. World J Gastroenterol. 2007 Sep 14;13(34):4539-50.

97. Eisenberg D, Shikora SA, Aarts E, Aminian A, Angrisani L, Cohen RV, De Luca M, Faria SL, Goodpaster KPS, Haddad A, Himpens JM, Kow L, Kurian M, Loi K, Mahawar K, Nimeri A, O'Kane M, Papasavas PK, Ponce J, Pratt JSA, Rogers AM, Steele KE, Suter M, Kothari SN. 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for Metabolic and Bariatric Surgery. Surg Obes Relat Dis. 2022 Dec;18(12):1345-1356. doi: 10.1016/j.soard.2022.08.013. Epub 2022 Oct 21. PMID: 36280539.

98. Ellsmere J. Bariatric operations: Late complications with subacute presentations. In UpToDate, Chen W, editor. May 2023. UpToDate, Waltham, MA. Accessed Jun 15, 2023.

99. Endocrine Society. Clinical guideline. Pediatric obesity – assessment, treatment, prevention. Jan 2017. Accessed Jun 15, 2023. Available at URL address: https://www.endocrine.org/guidelines-and-clinical-practice/clinical-practice-guidelines/pediatric-obesity

100. Family Practice Notebook. Midparental Height ©2023. Family Practice Notebook, LLC. Accessed Jun 15, 2023. Available at URL address: http://www.fpnotebook.com/endo/exam/MdprntlHght.htm

101. Farina MG, Baratta R, Nigro A, Vinciguerra F, Puglisi C, Schembri R, et al. Intragastric balloon in association with lifestyle and/or pharmacotherapy in the long-term management of obesity. Obes Surg. 2012 Apr;22(4):565-71.

102. Fayad L, Schweitzer M, Raad M, Simsek C, Oleas R, Dunlap MK, Shah T, Doshi J, El Asmar M, Oberbach A, Singh VK, Steele K, Magnussen T, Kalloo AN, Khashab MA, Kumbhari V. A real-world, insurance-based algorithm using the two-fold running suture technique for Transoral Outlet Reduction for weight regain and dumping syndrome after Roux-En-Y Gastric Bypass. Obes Surg. 2019 Jul;29(7):2225-2232. doi: 10.1007/s11695-019-03828-1. PMID: 30937874.

103. Fernandes MAP, Atallah ÁN, Soares B, Saconato H, Guimarães SM, Matos D, Carneiro Monteiro LR, Richter B. Intragastric balloon for obesity. Cochrane Database of Systematic Reviews 2007, Issue 1. Art. No.: CD004931. DOI: 10.1002/14651858.CD004931.pub2. Accessed Jun 12, 2023.

104. Felberbauer FX, Langer F, Shakeri-Manesch S, Schmaldienst E, Kees M, Kriwanek S, et al. Laparoscopic sleeve gastrectomy as an isolated bariatric procedure: intermediate-term results from a large series in three Austrian centers. Obes Surg. 2008 Jul;18(7):814-8.

105. Flegal KM, Carroll MD, Ogden CL, et al. Prevalence and trends in obesity among US adults, 1999–2008. JAMA. 2010 Jan 20;303(3):235-41.

106. Fobi MA, Lee H, Igwe D Jr, Felahy B, James E, Stanczyk M, et al. Gastric bypass in patients with BMI < 40 but > 32 without life-threatening co-morbidities: preliminary report. Obes Surg. 2002 Feb;12(1): 52-6.

107. Fobi MA, Lee H. The surgical technique of the Fobi-Pouch operation for obesity (the transected silastic vertical gastric bypass). Obes Surg. 1998 Jun;8(3):283-8.

108. Forssell H., Norén E., A novel endoscopic weight loss therapy using gastric aspiration: Results after 6 months. Endoscopy 2015; 47(01): 68-71.

109. Frezza EE, Chiriva-Internati M, Wachtel MS. Analysis of the results of sleeve gastrectomy for morbid obesity and the role of ghrelin. Surg Today. 2008;38(6):481-3. Epub 2008 May 31.

110. Frezza EE, Reddy S, Gee LL, Wachtel MS. Complications after sleeve gastrectomy for morbid obesity. Obes Surg. 2009 Jun;19(6):684-7. Epub 2008 Oct 16.

111. Fried M, Dolezalova K, Buchwald JN, McGlennon TW, Sramkova P, Ribaric G. Laparoscopic greater curvature plication (LGCP) for treatment of morbid obesity in a series of 244 patients. Obes Surg. 2012 Aug;22(8):1298-307. doi: 10.1007/s11695-012-0684-2.

112. Fringeli Y, Worreth M, Langer I. Gastrojejunal Anastomosis Complications and Their Management after Laparoscopic Roux-en-Y Gastric Bypass. J Obes. 2015;2015:698425.

113. Fuks D, Verhaeghe P, Brehant O, Sabbagh C, Dumont F, Riboulot M, et al. Results of laparoscopic sleeve gastrectomy: a prospective study in 135 patients with morbid obesity. Surgery. 2009 Jan;145(1):106-13. Epub 2008 Sep 30.

114. Fuller NR, Pearson S, Lau NS, Wlodarczyk J, Halstead MB, Tee HP, et al. An intragastric balloon in the treatment of obese individuals with metabolic syndrome: a randomized controlled study. Obesity (Silver Spring). 2013 Aug;21(8):1561-70.

115. Fuller W, Rasmussen JJ, Ghosh J, Ali MR. Is routine cholecystectomy indicated for asymptomatic cholelithiasis in patients undergoing gastric bypass? Obes Surg. 2007 Jun;17(6):747-51.

116. Gagner M, Matteotti R. Laparoscopic biliopancreatic diversion with duodenal switch. Surg Clin North Am. 2005;85:141-9.

117. Gagner M, Gumbs AA. Gastric banding: conversion to sleeve, bypass, or DS. Surg Endosc. 2007 Nov;21(11):1931-5.

118. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology. Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity: Executive Summary. Complete Guidelines. Endocr Pract. 2016 Jul;22(7):842-84. Accessed June 15, 2023. Available at URL address: https://www.endocrinepractice.org/article/S1530-891X(20)44630-0/fulltext

119. Genco A, Bruni T, Doldi SB, Forestieri P, Marino M, Busetto L, et al. BioEnterics Intragastric Balloon: The Italian Experience with 2,515 Patients. Obes Surg. 2005 Sep;15(8):1161-4.

120. Genco A, Cipriano M, Materia A, Bacci V, Maselli R, Musmeci L, et al. Laparoscopic sleeve gastrectomy versus intragastric balloon: a case-control study. Surg Endosc. 2009 Aug;23(8):1849-53.

121. Genco A, Lorenzo M, Baglio G, Furbetta F, Rossi A, Lucchese M, et al. Does the intragastric balloon have a predictive role in subsequent LAP-BAND(®) surgery? Italian multicenter study results at 5-year follow-up. Surg Obes Relat Dis. 2014 May-Jun;10(3):474-8. Epub 2013 Dec 6.

122. Gentileschi P, Kini S, Catarci M, Gagner M. Evidence-based medicine: open and laparoscopic bariatric surgery. Surg Endosc. 2002 May;16(5):736-44.

123. Gianos M, Abdemur A, Fendrich I, Gari V, Szomstein S, Rosenthal RJ. Outcomes of bariatric surgery in patients with body mass index <35 kg/m2. Surg Obes Relat Dis. 2012 Jan-Feb;8(1):25-30. doi: 10.1016/j.soard.2011.08.012. Epub 2011 Aug 27. PMID: 22019140.

124. Giardiello C, Borrelli A, Silvestri E, Antognozzi V, Iodice G, Lorenzo M. Air-filled vs water-filled intragastric balloon: a prospective randomized study. Obes Surg. 2012 Dec;22(12):1916-9

125. Goroll AH, Mulley Jr AG, editors. Primary Care Medicine: Office Evaluation and Management of the Adult Patient., 6th ed. Philadelphia: Lippincott Williams & Wilkins; 2009.

126. Göttig S, Daskalakis M, Weiner S, Weiner RA. Analysis of safety and efficacy of intragastric balloon in extremely obese patients. Obes Surg. 2009 Jun;19(6):677-83. Epub 2009 Mar 17.

127. Goyal D, Kim S, Dutson E, Chen Y, Pisegna J, Watson, Rabindra R. Endoscopic Trans-Oral Outlet Reduction in combination with gastroplasty (TORe-G) is a novel technique that is highly efficacious and safe for weight loss in patients with failed Roux-en-Y Gastric Bypass (RYGB). American Journal of Gastroenterology: October 2015 - Volume 110 - Issue - p S656-S657

128. Gracia JA, Martinez M, Aguilella V, Elia M, Royo P. Postoperative morbidity of biliopancreatic diversion depending on common limb length. Obes Surg. 2007 Oct;17(10):1306-11.

129. Gracia JA, Martínez M, Elia M, Aguilella V, Royo P, Jiménez A, Bielsa MA, Arribas D. Obesity surgery results depending on technique performed: long-term outcome. Obes Surg. 2009 Apr;19(4):432-8. Epub 2008 Nov 12.

130. Gravante G, Araco A, Araco F, Delogu D, De Lorenzo A, Cervelli V. Laparoscopic adjustable gastric bandings: a prospective randomized study of 400 operations performed with 2 different devices. Arch Surg. 2007 Oct;142(10):958-61.

131. Guedea ME, Arribas del Amo D, Solanas JA, Marco CA, Bernadó AJ, Rodrigo MA, Diago VA, Díez MM. Results of biliopancreatic diversion after five years. Obes Surg. 2004 Jun-Jul;14(6):766-72.

132. Gustavsson S, Westling A. Laparoscopic adjustable gastric banding: complications and side effects responsible for the poor long-term outcome. Semin Laparosc Surg. 2002 Jun;9(2):115-24.

133. Gys B, Plaeke P, Lamme B, Lafullarde T, Komen N, Beunis A, Hubens G. Endoscopic Gastric Plication for Morbid Obesity: a Systematic Review and Meta-analysis of Published Data over Time. Obes Surg. 2019 Sep;29(9):3021-3029. doi: 10.1007/s11695-019-04010-3. PMID: 31230201.

134. Hales CM, Fryar CD, Carroll MD, Freedman DS, Aoki Y, Ogden CL. Differences in Obesity Prevalence by Demographic Characteristics and Urbanization Level Among Adults in the United States, 2013-2016. JAMA. 2018 Jun 19;319(23):2419-2429. doi: 10.1001/jama.2018.7270. PMID: 29922829; PMCID: PMC6583043.

135. Halmi D, Kolesnikov E. Preoperative placement of retrievable inferior vena cava filters in bariatric surgery. Surg Obes Relat Dis. 2007 Nov-Dec;3(6):602-5. Epub 2007 Jun 4.

136. Hamad GG, Ikramuddin S, Gourash WF, Schauer PR. Elective cholecystectomy during laparoscopic Roux-en-Y gastric bypass: is it worth the wait? Obes Surg. 2003 Feb;13(1):76-81.

137. Hamad GG, Bergqvist D. Venous thromboembolism in bariatric surgery patients: an update of risk and prevention. Surg Obes Relat Dis. 2007 Jan-Feb;3(1):97-102. Epub 2006 Dec 27.

138. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics. 2023;151(2):e2022060640

139. Hamoui N, Anthone GJ, Kaufman HS, Crookes PF. Sleeve gastrectomy in the high-risk patient. Obes Surg. 2006 Nov;16(11):1445-9.

140. Hamoui N, Chock B, Anthone GJ, Crookes PF. Revision of the duodenal switch: indications, technique, and outcomes. J Am Coll Surg. 2007 Apr;204(4):603-8.

141. Harnisch MC, Portenier DD, Pryor AD, Prince-Petersen R, Grant JP, DeMaria EJ. Preoperative weight gain does not predict failure of weight loss or co-morbidity resolution of laparoscopic Roux-en-Y gastric bypass for morbid obesity. Surg Obes Relat Dis. 2008 May-Jun;4(3):445-50.

142. Healthy People 2030. Overweight and obesity. Accessed on Jun 9, 2023. Available at URL address: https://health.gov/healthypeople/objectives-and-data/browse-objectives/overweight-and-obesity/reduce-proportion-adults-obesity-nws-03

143. Healthy People 2020. Nutrition and Weight Status. U.S. Department of Health and Human Services. 2022. Accessed on Jun 9, 2023. Available at URL address: https://wayback.archive-it.org/5774/20220413181722/https://www.healthypeople.gov/2020/topics-objectives/topic/nutrition-and-weight-status#twenty

144. Hedberg J, Sundbom M. Superior weight loss and lower HbA1c 3 years after duodenal switch compared with Roux-en-Y gastric bypass--a randomized controlled trial. Surg Obes Relat Dis. 2012 May-Jun;8(3):338-43.

145. Hedjoudje A, Abu Dayyeh BK, Cheskin LJ, Adam A, Neto MG, Badurdeen D, Morales JG, Sartoretto A, Nava GL, Vargas E, Sui Z, Fayad L, Farha J, Khashab MA, Kalloo AN, Alqahtani AR, Thompson CC, Kumbhari V. Efficacy and Safety of Endoscopic Sleeve Gastroplasty: A Systematic Review and Meta-Analysis. Clin Gastroenterol Hepatol. 2020 May;18(5):1043-1053.e4. doi: 10.1016/j.cgh.2019.08.022. Epub 2019 Aug 20. PMID: 31442601.

146. Hess DS, Hess DW. Biliopancreatic diversion with a duodenal switch. Obes Surg. 1998 Jun;8(3):267-82.

147. Hess DS, Hess DW, Oakley RS. The biliopancreatic diversion with the duodenal switch: results beyond 10 years. Obes Surg. 2005 Mar;15(3):408-16.

148. Himpens J, Cadière GB, Bazi M, Vouche M, Cadière B, Dapri G. Long-term Outcomes of Laparoscopic Adjustable Gastric Banding. Arch Surg. 2011 Mar 21. [Epub ahead of print]

149. Himpens J, Dapri G, Cadiere GB. A prospective randomized study between laparoscopic gastric banding and laparoscopic isolated sleeve gastrectomy: results after 1 and 3 years. Obes Surg. 2006 Nov;16(11):1450-6.

150. Holeczy P, Novak P, Kralova A. 30% complications with adjustable gastric banding: what did we do wrong? Obes Surg. 2001 Dec;11(6):748-51.

151. Huang CK. Effectiveness and safety of laparoscopic Roux-en-Y Gastric bypass in treating type 2 diabetes mellitus in non-morbidly obese patients. Zhongguo Yi Xue Ke Xue Yuan Xue Bao. 2011 Jun;33(3):272-6. doi: 10.3881/j.issn.1000-503X.2011.03.013. PMID: 21718609.

152. Ibele AR, Mattar SG. Adolescent bariatric surgery. Surg Clin North Am. 2011 Dec;91(6):1339-51, x.

153. Ikramuddin S, Korner J, Lee WJ, Connett JE, Inabnet WB, Billington CJ, et al. Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: the Diabetes Surgery Study randomized clinical trial. JAMA. 2013 Jun 5;309(21):2240-9. doi: 10.1001/jama.2013.5835.

154. Ikramuddin S, Blackstone RP, Brancatisano A, Toouli J, Shah SN, Wolfe BM, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. JAMA. 2014 Sep 3;312(9):915-22. doi: 10.1001/jama.2014.10540.

155. Imaz I, Martínez-Cervell C, García-Alvarez EE, Sendra-Gutiérrez JM, González-Enríquez J. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg. 2008 Jul;18(7):841-6. Epub 2008 May 6.

156. Inge TH. Surgical management of severe obesity in adolescents. Hoppin AG (ed). Apr 11, 2023. UpToDate. Waltham, MA. Accessed Jun 15, 2023.

157. Inge TH, Courcoulas AP, Jenkins TM, Michalsky MP, Brandt ML, Xanthakos SA, Dixon JB, Harmon CM, Chen MK, Xie C, Evans ME, Helmrath MA; Teen–LABS Consortium. Five-Year Outcomes of Gastric Bypass in Adolescents as Compared with Adults. N Engl J Med. 2019 May 30;380(22):2136-2145.

158. Inge TH, Jenkins TM, Xanthakos SA, Dixon JB, Daniels SR, Zeller MH, Helmrath MA. Long-term outcomes of bariatric surgery in adolescents with severe obesity (FABS-5+): a prospective follow-up analysis. Lancet Diabetes Endocrinol. 2017 Mar;5(3):165-173.

159. Inge TH, Krebs NF, Garcia VF, Skelton JA, Guice KS, Strauss RS, et al. Bariatric surgery for severely overweight adolescents: concerns and recommendations. Pediatrics. 2004 Jul;114(1):217-23.

160. International Diabetes Federation. IDF clinical practice recommendations for managing type 2 diabetes in primary care. 2017. Accessed Jun 15, 2023. Available at URL address: https://www.idf.org/e-library/guidelines.html

161. Jamal MK, DeMaria EJ, Johnson JM, Carmody BJ, Wolfe LG, Kellum JM, et al. Insurance-mandated preoperative dietary counseling does not improve outcome and increases dropout rates in patients considering gastric bypass surgery for morbid obesity. Surg Obes Relat Dis. 2006 Mar-Apr;2(2):122-7.

162. Jan JC, Hong D, Periera N, Patterson EJ. Laparoscopic adjustable gastric banding versus laparoscopic gastric bypass for morbid obesity: a single-institution comparison study of early results. J Gastrointest Surg. 2005 Jan;9(1):30-9.

163. Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ; American College of Cardiology/American Heart Association Task Force on Practice Guidelines; Obesity Society. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2985-3023. doi: 10.1016/j.jacc.2013.11.004. Epub 2013 Nov 12. Erratum in: J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):3029-3030. PMID: 24239920.

164. Jirapinyo P, Kumar N, AlSamman MA, Thompson CC. Five-year outcomes of transoral outlet reduction for the treatment of weight regain after Roux-en-Y gastric bypass. Gastrointest Endosc. 2020 May;91(5):1067-1073. doi: 10.1016/j.gie.2019.11.044. Epub 2019 Dec 7. PMID: 31816315; PMCID: PMC7183415.

165. Jirapinyo P, Thompson CC. Endoscopic Bariatric and Metabolic Therapies: Surgical Analogues and Mechanisms of Action. Clin Gastroenterol Hepatol. 2017 May;15(5):619-630.

166. Kahrilas PJ. Hiatus Hernia. In: UpToDate, Talley NJ (Ed). Mar 6, 2023. UpToDate, Waltham, MA. Accessed Jun 15, 2023.

167. Kahrilas PJ. Clinical manifestations and diagnosis of gastroesophageal reflux in adults. In: UpToDate, Talley NJ (Ed). Jul 15, 2022. UpToDate, Waltham, MA. Accessed on Jun 15, 2023.

168. Kahrilas PJ. Medical management of gastroesophageal reflux disease in adults. In: UpToDate, Talley NJ (Ed). Sep 19, 2022. UpToDate, Waltham, MA. Accessed on June 1, 2022.

169. Kahrilas PJ, Kim HC, Pandolfino JE. Approaches to the diagnosis and grading of hiatal hernia. Best Pract Res Clin Gastroenterol. 2008;22(4):601-16.

170. Kallies K, Rogers AM; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery updated statement on single-anastomosis duodenal switch. Surg Obes Relat Dis. 2020 Jul;16(7):825-830. doi: 10.1016/j.soard.2020.03.020. Epub 2020 Mar 30. PMID: 32371036.

171. Karamanakos SN, Vagenas K, Kalfarentzos F, Alexandrides TK. Weight loss, appetite suppression, and changes in fasting and postprandial ghrelin and peptide-YY levels after Roux-en-Y gastric bypass and sleeve gastrectomy: a prospective, double blind study. Ann Surg. 2008 Mar;247(3):401-7.

172. Karcz WK, Karcz-Socha I, Marjanovic G, Kuesters S, Goos M, Hopt UT, et al. To band or not to band--early results of banded sleeve gastrectomy. Obes Surg. 2014 Apr;24(4):660-5.

173. Kashyap SR, Bhatt DL, Wolski K, Watanabe RM, Abdul-Ghani M, Abood B, et al. Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care. 2013 Aug;36(8):2175-82.

174. Kelly AS, Barlow SE, Rao G, Inge TH, Hayman LL, Steinberger J, Urbina EM, Ewing LJ, Daniels SR; American Heart Association Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young, Council on Nutrition, Physical Activity and Metabolism, and Council on Clinical Cardiology. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart Association. Circulation. 2013 Oct 8;128(15):1689-712.

175. Khan Z, Khan MA, Hajifathalian K, Shah S, Abdul M, Saumoy M, Aronne L, Lee W, Sharaiha RZ. Efficacy of Endoscopic Interventions for the Management of Obesity: a Meta-analysis to Compare Endoscopic Sleeve Gastroplasty, AspireAssist, and Primary Obesity Surgery Endolumenal. Obes Surg. 2019 Jul;29(7):2287-2298. doi: 10.1007/s11695-019-03865-w. PMID: 30982170.

176. Kim SB, Kim KK, Chung JW, Kim SM. Initial Experiences of Laparoscopic Gastric Greater Curvature Plication in Korea-A Review of 64 Cases. J Laparoendosc Adv Surg Tech A. 2015 Oct;25(10):793-9. doi: 10.1089/lap.2015.0164. Epub 2015 Sep 21.

177. Kim JJ, Rogers AM, Ballem N, Schirmer B; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. ASMBS updated position statement on insurance mandated preoperative weight loss requirements. Surg Obes Relat Dis. 2016 Jun;12(5):955-9. Accessed Jun 9, 2023. Available at URL address: https://asmbs.org/resource-categories/position-statements

178. Koehestanie P, de Jonge C, Berends FJ, Janssen IM, Bouvy ND, Greve JW. The effect of the endoscopic duodenal-jejunal bypass liner on obesity and type 2 diabetes mellitus, a multicenter randomized controlled trial. Ann Surg. 2014 Dec;260(6):984-92. doi: 10.1097/SLA.0000000000000794.

179. Kourkoulos M, Giorgakis E, Kokkinos C, Mavromatis T, Griniatsos J, Nikiteas N, et al. Laparoscopic gastric plication for the treatment of morbid obesity: a review. Minim Invasive Surg. 2012;2012:696348.

180. Kumar N. Endoscopic therapy for weight loss: Gastroplasty, duodenal sleeves, intragastric balloons, and aspiration. World J Gastrointest Endosc. 2015 Jul 25;7(9):847-59.

181. Kumar N. Weight loss endoscopy: Development, applications, and current status. World J Gastroenterol. 2016 Aug 21; 22(31): 7069–7079.

182. Kumar N, Abu Dayyeh BK, Lopez-Nava Breviere G, Galvao Neto MP, Sahdala NP, Shaikh SN, Hawes RH, Gostout CJ, Goenka MK, Orillac JR, Alvarado A, Jirapinyo P, Zundel N, Thompson CC. Endoscopic sutured gastroplasty: procedure evolution from first-in-man cases through current technique. Surg Endosc. 2018 Apr;32(4):2159-2164. doi: 10.1007/s00464-017-5869-2. Epub 2017 Oct 26. PMID: 29075966; PMCID: PMC5845469.

183. Kumar N, Bazerbachi F, Rustagi T, McCarty TR, Thompson CC, Galvao Neto MP, Zundel N, Wilson EB, Gostout CJ, Abu Dayyeh BK. The Influence of the Orbera Intragastric Balloon Filling Volumes on Weight Loss, Tolerability, and Adverse Events: a Systematic Review and Meta-Analysis. Obes Surg. 2017 Sep;27(9):2272-2278.

184. Laterza L, Boskoski I, Landi R et al. Transoral Outlet Reduction for therapy of weight regain after gastric bypass: 770. American Journal of Gastroenterology 2017; 112: S430–S431

185. Lee CM, Cirangle PT, Jossart GH. Vertical gastrectomy for morbid obesity in 216 patients: report of two-year results. Surg Endosc. 2007 Oct;21(10):1810-6. Epub 2007 Mar 14.

186. Lee WJ, Huang MT, Yu PJ, Wang W, Chen TC. Laparoscopic vertical banded gastroplasty and laparoscopic gastric bypass: a comparison. Obes Surg. 2004 May;14(5):626-34.

187. Lee WJ, Chong K, Ser KH, Lee YC, Chen SC, Chen JC, et al. Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: a randomized controlled trial. Arch Surg. 2011 Feb;146(2):143-8.

188. Lee WJ, Lee KT, Kasama K, Seiki Y, Ser KH, Chun SC, et al. Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG): short-term result and comparison with gastric bypass. Obes Surg. 2014 Jan;24(1):109-13.

189. Lee WJ, Lee KT, Kasama K, Seiki Y, Ser KH, Chun SC, et al. Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG): short-term result and comparison with gastric bypass. Obes Surg. 2014 Jan;24(1):109-13.

190. Lee WJ, Yu PJ, Wang W, Chen TC, Wei PL, Huang MT. Laparoscopic Roux-en-Y versus mini-gastric bypass for the treatment of morbid obesity: a prospective randomized controlled clinical trial. Ann Surg. 2005 Jul;242(1):20-8.

191. Leyva-Alvizo A, Arredondo-Saldaña G, Leal-Isla-Flores V, Romanelli J, Sudan R, Gibbs KE, Petrick A, Soriano IS; ASMBS Foregut Committee. Systematic review of management of gallbladder disease in patients undergoing minimally invasive bariatric surgery. Surg Obes Relat Dis. 2020 Jan;16(1):158-164. doi: 10.1016/j.soard.2019.10.016. Epub 2019 Oct 31. PMID: 31839526.

192. Lim R, Beekley A, Johnson DC, Davis KA. Early and late complications of bariatric operation. Trauma Surg Acute Care Open. 2018 Oct 9;3(1):e000219. doi: 10.1136/tsaco-2018-000219. PMID: 30402562; PMCID: PMC6203132.

193. Longitudinal Assessment of Bariatric Surgery (LABS) Consortium, Flum DR, Belle SH, King WC, Wahed AS, Berk P, Chapman W, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. N Engl J Med. 2009 Jul 30;361(5):445-54.

194. Maglione MA, Gibbons MM, Livhits M, Ewing B, Hu J, Ruelaz Maher A, et al. Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m^2 [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Jun. Report No.: 12(13)-EHC139-EF.AHRQ Comparative Effectiveness Reviews.

195. Mahawar KK, Carr WR, Jennings N, Balupuri S, Small PK. Simultaneous sleeve gastrectomy and hiatus hernia repair: a systematic review. Obes Surg. 2015 Jan;25(1):159-66.

196. Malik A, Mellinger JD, Hazey JW, Dunkin BJ, MacFadyen BV Jr. Endoluminal and transluminal surgery: current status and future possibilities. Surg Endosc. 2006 Aug;20(8):1179-92. Epub 2006 Jul 24.

197. Marincola G, Gallo C, Hassan C, Raffaelli M, Costamagna G, Bove V, Pontecorvi V, Orlandini B, Boškoski I. Laparoscopic sleeve gastrectomy versus endoscopic sleeve gastroplasty: a systematic review and meta-analysis. Endosc Int Open. 2021 Jan;9(1):E87-E95. doi: 10.1055/a-1300-1085. Epub 2021 Jan 1. Erratum in: Endosc Int Open. 2021 Jan;9(1):C1. PMID: 33403240; PMCID: PMC7775813.

198. Marinos G, Eliades C, Raman Muthusamy V, Greenway F. Weight loss and improved quality of life with a nonsurgical endoscopic treatment for obesity: clinical results from a 3- and 6-month study. Surg Obes Relat Dis. 2014 Sep-Oct;10(5):929-34. doi: 10.1016/j.soard.2014.03.005. Epub 2014 Mar 12. PMID: 25066439.

199. Martinez-Brocca MA, Belda O, Parejo J, Jimenez L, del Valle A, Pereira JL, et al. Intragastric balloon-induced satiety is not mediated by modification in fasting or postprandial plasma ghrelin levels in morbid obesity. Obes Surg. 2007 May;17(5):649-57.

200. Mechanick JI, Apovian C, Brethauer S, Timothy Garvey W, Joffe AM, Kim J, Kushner RF, Lindquist R, Pessah-Pollack R, Seger J, Urman RD, Adams S, Cleek JB, Correa R, Figaro MK, Flanders K, Grams J, Hurley DL, Kothari S, Seger MV, Still CD. Clinical Practice Guidelines for the Perioperative Nutrition, Metabolic, and Nonsurgical Support of Patients Undergoing Bariatric Procedures - 2019 Update: Cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic and Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. Obesity (Silver Spring). 2020 Apr;28(4):O1-O58. doi: 10.1002/oby.22719. PMID: 32202076. Accessed Jun 9, 2023. Available at URL address: https://asmbs.org/app/uploads/2020/04/Mechanick-2020-AACE-TOS-ASMBS-Guidelines.pdf

201. Mechanick JI, Kushner RF, Sugerman HJ, Gonzalez-Campoy JM, Collazo-Clavell ML, Guven S, et al. American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery Medical guidelines for clinical practice for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient. Endocr Pract. 2008 Jul-Aug;14 Suppl 1:1-83.

202. Mechanick JI, Youdim A, Jones DB, Garvey WT, Hurley DL, McMahon MM, et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient--2013 update: cosponsored by American Association of Clinical

Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery. Obesity (Silver Spring). 2013 Mar;21 Suppl 1:S1-27. Accessed Jun 9, 2023. Available at URL address: https://asmbs.org/resources/clinical-practice-guidelines-for-the-perioperative-nutritional-metabolic-and-nonsurgical-support-of-the-bariatric-surgery-patient

203. Michalsky M, Reichard K, Inge T, Pratt J, Lenders C; American Society for Metabolic and Bariatric Surgery. ASMBS pediatric committee best practice guidelines. Surg Obes Relat Dis. 2012 Jan-Feb;8(1):1-7.

204. Miller K, Pump A, Hell E. Vertical banded gastroplasty versus adjustable gastric banding: prospective long-term follow-up study. Surg Obes Relat Dis. 2007 Jan-Feb;3(1):84-90. Epub 2006 Nov 20.

205. Mitzman B, Cottam D, Goriparthi R, Cottam S, Zaveri H, Surve A, Roslin MS. Stomach Intestinal Pylorus Sparing (SIPS) Surgery for Morbid Obesity: Retrospective Analyses of Our Preliminary Experience. Obes Surg. 2016 Sep;26(9):2098-2104. doi: 10.1007/s11695-016-2077-4. PMID: 26932811.

206. Mion F, Ibrahim M, Marjoux S, Ponchon T, Dugardeyn S, Roman S, Deviere J. Swallowable Obalon® gastric balloons as an aid for weight loss: a pilot feasibility study. Obes Surg. 2013 May;23(5):730-3.

207. Mingrone G, Panunzi S, De Gaetano A, Guidone C, Iaconelli A, Leccesi L, et al. Bariatric Surgery versus Conventional Medical Therapy for Type 2 Diabetes. N Engl J Med. 2012 Mar 26. [Epub ahead of print]

208. Mocanu V, Dang JT, Switzer N, Madsen K, Birch DW, Karmali S. Sex and Race Predict Adverse Outcomes Following Bariatric Surgery: an MBSAQIP Analysis. Obes Surg. 2020 Mar;30(3):1093-1101. doi: 10.1007/s11695-020-04395-6. PMID: 31916134.

209. Moon RC, Kirkpatrick V, Gaskins L, Teixeira AF, Jawad MA. Safety and effectiveness of single- versus double-anastomosis duodenal switch at a single institution. Surg Obes Relat Dis. 2019 Feb;15(2):245-252. doi: 10.1016/j.soard.2018.11.004. Epub 2018 Nov 14. PMID: 30606470.

210. Morino M, Toppino M, Bonnet G, del Genio G. Laparoscopic adjustable silicone gastric banding versus vertical banded gastroplasty in morbidly obese patients: a prospective randomized controlled clinical trial. Ann Surg. 2003 Dec;238(6):835-41.

211. Morris L, Beketaev I, Barrios R, Reardon P. Colon adenocarcinoma after jejunoileal bypass for morbid obesity. J Surg Case Rep. 2017 Nov; 2017(11): rjx214.

212. Morton JM, Shah SN, Wolfe BM, Apovian CM, Miller CJ, Tweden KS, et al. Effect of Vagal Nerve Blockade on Moderate Obesity with an Obesity-Related Comorbid Condition: the ReCharge Study. Obes Surg. 2016 May;26(5):983-9. doi: 10.1007/s11695-016-2143-y.

213. Musella M, Susa A, Manno E, De Luca M, Greco F, Raffaelli M, Cristiano S, Milone M, Bianco P8, Vilardi A, Damiano I, Segato G, Pedretti L, Giustacchini P, Fico D, Veroux G, Piazza L. Complications Following the Mini/One Anastomosis Gastric Bypass (MGB/OAGB): a Multi-institutional Survey on 2678 Patients with a Mid-term (5 Years) Follow-up. Obes Surg. 2017 Nov;27(11):2956-2967.

214. Nadler EP, Youn HA, Ren CJ, Fielding GA. An update on 73 US obese pediatric patients treated with laparoscopic adjustable gastric banding: comorbidity resolution and compliance data. J Pediatr Surg. 2008 Jan;43(1):141-6.

215. National Center for Health Statistics. Percentage of obesity for adults aged 18 and over, United States, 2019-2021. National Health Interview Survey. Generated interactively: Jun 9, 2023 from https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html

216. National Heart, Lung, and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The Evidence Report. NIH Pub. No. 98-4083. 1998 Sep. Accessed Jun 9, 2023. Available at URL address: https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf

217. National Heart, Lung, and Blood Institute (NHLBI). The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. 2000 Oct. Accessed Jun 15, 2023. Available at URL address: http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf

218. National Institute for Health and Care Excellence (NICE). Interventional procedure guidance 569. Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Nov 2016. Accessed Jun 12, 2023. Available at URL address: https://www.nice.org.uk/guidance/ipg569

219. National Institute for Health and Care Excellence (NICE). Obesity: identification, assessment and management [CG189]. Nov 2014, updated Sep 2022. Accessed Jun 15, 2023. Available at URL address: https://www.nice.org.uk/guidance/cg189

220. National Institute for Health and Care Excellence (NICE). Interventional procedure guidance 471. Implantation of a duodenal–jejunal bypass sleeve for managing obesity. Nov 2013. Accessed Jun 15, 2023. Available at URL address: https://www.nice.org.uk/guidance/ipg471

221. National Institute for Health and Care Excellence (NICE). IPG432 Laparoscopic gastric plication for the treatment of severe obesity. Nov 2012. Accessed Jun 12, 2023. Available at URL address: https://www.nice.org.uk/guidance/ipg432

222. National Institutes of Diabetes and Digestion and Kidney Disease (NIDDK). Longitudinal Assessment of Bariatric Surgery (LABS). May 2022. Accessed Jun 15, 2023. Available at URL address: https://www.niddk.nih.gov/about-niddk/research-areas/obesity/longitudinal-assessment-bariatric-surgery

223. Natural Orifice Surgery Consortium for Assessment and Research™ (NOSCAR®). About NOSCAR. FAQ. 2021. Accessed Jun 15, 2023. Available at URL address: http://www.noscar.org/faq/

224. Neichoy BT, Schniederjan B, Cottam DR, Surve AK, Zaveri HM, Cottam A, Cottam S. Stomach Intestinal Pylorus-Sparing Surgery for Morbid Obesity. JSLS. 2018 Jan-Mar;22(1):e2017.00063. doi: 10.4293/JSLS.2017.00063. PMID: 29398898; PMCID: PMC5779797.

225. Neligan PJ, Williams N. Nonsurgical and surgical treatment of obesity. Anesthesiol Clin North America. 2005 Sep;23(3):501-23, vii.

226. Niazi M, Maleki AR, Talebpour M. Short-Term Outcomes of Laparoscopic Gastric Plication in Morbidly Obese Patients: Importance of Postoperative Follow-up. Obes Surg. 2013 Jan;23(1):87-92. doi: 10.1007/s11695-012-0777-y.

227. Nobili V, Corte CD, Liccardo D, Mosca A, Caccamo R, Morino GS, Alterio A, De Peppo F. Obalon intragastric balloon in the treatment of paediatric obesity: a pilot study. Pediatr Obes. 2015 Oct;10(5):e1-4.

228. Nobili V, Vajro P, Dezsofi A, Fischler B, Hadzic N, Jahnel J, et al. Indications and Limitations of Bariatric Intervention in Severely Obese Children and Adolescents With and Without Nonalcoholic Steatohepatitis: ESPGHAN Hepatology Committee Position Statement. J Pediatr Gastroenterol Nutr. 2015 Apr;60(4):550-61. Accessed Jun 15, 2023. Available at URL address: https://journals.lww.com/jpgn/pages/collectiondetails.aspx?TopicalCollectionId=10

229. Nocca D, Krawczykowsky D, Bomans B, Noël P, Picot MC, Blanc PM, et al. A prospective multicenter study of 163 sleeve gastrectomies: results at 1 and 2 years. Obes Surg. 2008 May;18(5):560-5.

230. Norén E, Forssell H. Aspiration therapy for obesity; a safe and effective treatment. BMC Obes. 2016 Dec 28;3:56. doi: 10.1186/s40608-016-0134-0. eCollection 2016.

231. Ntuk UE, Gill JM, Mackay DF, Sattar N, Pell JP. Ethnic-specific obesity cutoffs for diabetes risk: cross-sectional study of 490,288 UK biobank participants. Diabetes Care. 2014 Sep;37(9):2500-7. doi: 10.2337/dc13-2966. Epub 2014 Jun 29. PMID: 24974975.

232. Nyström M, Machytka E, Norén E, Testoni PA, Janssen I, Turró Homedes J, Espinos Perez JC, Turro Arau R. Aspiration Therapy As a Tool to Treat Obesity: 1- to 4-Year Results in a 201-Patient Multi-Center Post-Market European Registry Study. Obes Surg. 2018 Feb 1.

233. Obeid FN, Bowling WM, Fike JS, Durant JA. Efficacy of prophylactic inferior vena cava filter placement in bariatric surgery. Surg Obes Relat Dis. 2007 Nov-Dec;3(6):606-8; discussion 609-10. Epub 2007 Oct 23.

234. O'Brien PE, Dixon JB. A rational approach to cholelithiasis in bariatric surgery: its application to the laparoscopically placed gastric band. Arch Surg. 2003 Aug;138(8):908-12.

235. O'Brien PE, McPhail T, Chaston TB, Dixon JB. Systematic review of medium-term weight loss after bariatric operations. Obes Surg. 2006 Aug;16(8):1032-40.

236. O'Brien PE, Dixon JB, Laurie C, Skinner S, Proietto J, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. Ann Intern Med. 2006 May 2;144(9):625-33.

237. O'Brien PE, Sawyer SM, Laurie C, Brown WA, Skinner S, Veit F, et al. Laparoscopic adjustable gastric banding in severely obese adolescents: a randomized trial. JAMA. 2010 Feb 10;303(6):519-26.

238. Ogden CL, Carroll MD, Curtin LR, et al. Prevalence of high body mass index in US children and adolescents, 2007–2008. JAMA. 2010 Jan 20;303(3):242-9.

239. Ogden CL, Carroll MD, Fryar CD, Flegal KM. Prevalence of Obesity Among Adults and Youth: United States, 2011-2014. NCHS Data Brief. 2015 Nov;(219):1-8. PMID: 26633046.

240. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. JAMA. 2014 Feb 26;311(8):806-14. doi: 10.1001/jama.2014.732. PMID: 24570244; PMCID: PMC4770258.

241. Ogden CL Flegal KM. Changes in terminology for childhood overweight and obesity. June 2010. Accessed Jun 9, 2023. Available at URL address: http://www.cdc.gov/nchs/data/nhsr/nhsr025.pdf

242. Ogden CL, Fryar CD, Hales CM, Carroll MD, Aoki Y, Freedman DS. Differences in Obesity Prevalence by Demographics and Urbanization in US Children and Adolescents, 2013-2016. JAMA. 2018 Jun 19;319(23):2410-2418. doi: 10.1001/jama.2018.5158. PMID: 29922826; PMCID: PMC6393914.

243. Olbers T, Fagevik-Olsén M, Maleckas A, Lönroth H. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic vertical banded gastroplasty for obesity. Br J Surg. 2005 May;92(5):557-62.

244. O'Rourke RW, Andrus J, Diggs BS, Scholz M, McConnell DB, Deveney CW. Perioperative morbidity associated with bariatric surgery: an academic center experience. Arch Surg. 2006 Mar;141(3):262-8.

245. Papasavas P, El Chaar M, Kothari SN; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity. Surg Obes Relat Dis. 2015 Dec 7. Accessed Jun 15, 2023. Available at URL address: https://asmbs.org/resources/vagal-blocking-therapy-for-obesity

246. Parikh M, Chung M, Sheth S, McMacken M, Zahra T, Saunders JK, Ude-Welcome A, et al. Randomized pilot trial of bariatric surgery versus intensive medical weight management on diabetes remission in type 2 diabetic patients who do NOT meet NIH criteria for surgery and the role of soluble RAGE as a novel biomarker of success. Ann Surg. 2014 Oct;260(4):617-22; discussion 622-4.

247. Parikh M, Duncombe J, Fielding GA. Laparoscopic adjustable gastric banding for patients with body mass index of <or=35 kg/m^2. Surg Obes Relat Dis. 2006 Sep-Oct;2(5):518-22.

248. Parikh MS, Laker S, Weiner H, Hajiseyedjavadi O, Ren CJ. Objective comparison of complications resulting from laparoscopic bariatric procedures. Am Coll Surg. 2006 Feb;202(2):252-61. Epub 2005 Dec 19.

249. Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ. Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. Obes Surg. 2005 Jun-Jul;15(6):858-63.

250. Pauli EM, Delaney CP, Champagne B, Stein S, Marks JM. Safety and effectiveness of an endoscopic suturing device in a human colonic treat-and-resect model. Surg Innov. 2013 Dec;20(6):594-9. doi: 10.1177/1553350613479204. Epub 2013 Feb 26. PMID: 23445712.

251. Paulus GF, de Vaan LE, Verdam FJ, Bouvy ND, Ambergen TA, van Heurn LW. Bariatric Surgery in Morbidly Obese Adolescents: a Systematic Review and Meta-analysis. Obes Surg. 2015 May;25(5):860-78.

252. Perez NP, Westfal ML, Stapleton SM, Stanford FC, Griggs CL, Pratt JS, Chang DC, Kelleher CM. Beyond insurance: race-based disparities in the use of metabolic and bariatric surgery for the management of severe pediatric obesity. Surg Obes Relat Dis. 2020 Mar;16(3):414-419. doi: 10.1016/j.soard.2019.11.020. Epub 2019 Dec 4. PMID: 31917198; PMCID: PMC7058484.

253. Peterli R, Wölnerhanssen B, Peters T, Devaux N, Kern B, Christoffel-Courtin C, et al. Improvement in glucose metabolism after bariatric surgery: comparison of laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy: a prospective randomized trial. Ann Surg. 2009 Aug;250(2):234-41.

254. Phillips E, Ponce J, Cunneen SA, Bhoyrul S, Gomez E, Ikramuddin S, et al. Safety and effectiveness of Realize adjustable gastric band: 3-year prospective study in the United States. Surg Obes Relat Dis. 2009 Jan 18. [Epub ahead of print]

255. Picot J, Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess. 2009 Sep;13(41):1-190, 215-357, iii-iv.

256. Ponce J, Quebbemann BB, Patterson EJ. Prospective, randomized, multicenter study evaluating safety and efficacy of intragastric dual-balloon in obesity. Surg Obes Relat Dis. 2013 Mar-Apr;9(2):290-5.

257. Ponce J, Woodman G, Swain J, Wilson E, English W, Ikramuddin S, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis. 2015 Jul-Aug;11(4):874-81. Epub 2014 Dec 16.

258. Prachand VN, Davee RT, Alverdy JC. Duodenal switch provides superior weight loss in the super-obese (BMI > or =50 kg/m^2) compared with gastric bypass. Ann Surg. 2006 Oct;244(4):611-9.

259. Pratt JSA, Browne A, Browne NT, Bruzoni M, Cohen M, Desai A, Inge T, Linden BC, Mattar SG, Michalsky M, Podkameni D, Reichard KW, Stanford FC, Zeller MH & Zitsman J. ASMBS Pediatric Metabolic and Bariatric Surgery Guidelines, 2018. Surg Obes Relat Dis: 2018 Mar 23.

260. Pratt JS, Lenders CM, Dionne EA, Hoppin AG, Hsu GL, Inge TH, et al. Best practice updates for pediatric/adolescent weight loss surgery. Obesity (Silver Spring). 2009 May;17(5):901-10.

261. Rabkin RA, Rabkin JM, Metcalf B, Lazo M, Rossi M, Lehman-Becker LB. Laparoscopic technique for performing duodenal switch with gastric reduction. Obes Surg. 2003 Apr;13(2):263-8.

262. Rajjo T, Mohammed K, Alsawas M, et al. Treatment of pediatric obesity: an umbrella systematic review. J Clin Endocrinol Metab. 2017 Mar 1;102(3):763-775.

263. Ramos A, Galvao Neto M, Galvao M, Evangelista LF, Campos JM, Ferraz A. Laparoscopic greater curvature plication: initial results of an alternative restrictive bariatric procedure. Obes Surg. 2010 Jul;20(7):913-8.

264. Razak F, Anand SS, Shannon H, Vuksan V, Davis B, Jacobs R, Teo KK, McQueen M, Yusuf S. Defining obesity cut points in a multiethnic population. Circulation. 2007 Apr 24;115(16):2111-8. doi: 10.1161/CIRCULATIONAHA.106.635011. Epub 2007 Apr 9. PMID: 17420343.

265. Robert M, Espalieu P, Pelascini E, Caiazzo R, Sterkers A, Khamphommala L, Poghosyan T, Chevallier JM, Malherbe V, Chouillard E, Reche F, Torcivia A0, Maucort-Boulch D, Bin-Dorel S, Langlois-Jacques C, Delaunay D, Pattou F, Disse E. Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass for obesity (YOMEGA): a multicentre, randomised, open-label, non-inferiority trial. Lancet. 2019 Mar 30;393(10178):1299-1309.

266. Rohde U, Hedbäck N, Gluud LL, Vilsbøll T, Knop FK. Effect of the EndoBarrier Gastrointestinal Liner on obesity and type 2 diabetes: a systematic review and meta-analysis. Diabetes Obes Metab. 2016 Mar;18(3):300-5.

267. Rubino F, Nathan DM, Eckel RH, Schauer PR, Alberti KG, Zimmet PZ, et al. Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. Diabetes Care. 2016 Jun;39(6):861-77.

268. Rutledge R. The mini-gastric bypass: experience with the first 1,274 cases. Obes Surg. 2001 Jun;11(3):276-80.

269. Salameh JR. Bariatric surgery; past and present. Am J Med Sci. 2006 Apr;331(4):194-200.

270. Sánchez-Pernaute A, Rubio MÁ, Cabrerizo L, Ramos-Levi A, Pérez-Aguirre E, Torres A. Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) for obese diabetic patients. Surg Obes Relat Dis. 2015 Sep-Oct;11(5):1092-8. doi: 10.1016/j.soard.2015.01.024. Epub 2015 Feb 7. PMID: 26048517.

271. Sánchez-Pernaute A, Rubio MÁ, Pérez Aguirre E, Barabash A, Cabrerizo L, Torres A. Single-anastomosis duodenoileal bypass with sleeve gastrectomy: metabolic improvement and weight loss in first 100 patients. Surg Obes Relat Dis. 2013 Sep-Oct;9(5):731-5. Epub 2012 Aug 7.

272. Sarr MG, Billington CJ, Brancatisano R, Brancatisano A, Toouli J, Kow L, et al. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. Obes Surg. 2012 Nov;22(11):1771-82.

273. Sauerland S, Angrisani L, Belachew M, Chevallier J, Favretti F, Finer N, et al. Obesity surgery: evidence-based guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc. 2005 Feb;19(2):200-21. Accessed Jun 15, 2023. Available at URL address: https://eaes.eu/wp-content/uploads/2016/11/2004-Sauerland-Obesity-Surgery-guidelines-EAES-Surg-Endosc-2005-pdf.pdf

274. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Aminian A, Brethauer SA, Navaneethan SD, Singh RP, Pothier CE, Nissen SE, Kashyap SR; STAMPEDE Investigators. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. N Engl J Med. 2017 Feb 16;376(7):641-651.

275. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Brethauer SA, Navaneethan SD, Aminian A, Pothier CE, Kim ES, Nissen SE, Kashyap SR; the STAMPEDE Investigators. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 3-Year Outcomes. N Engl J Med. 2014 Mar 31. [Epub ahead of print]

276. Schauer PR, Kashyap SR, Wolski K, Brethauer SA, Kirwan JP, Pothier CE, et al. Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes. N Engl J Med. 2012 Mar 26. [Epub ahead of print]

277. Schauer P, Chand B, Brethauer S. New applications for endoscopy: the emerging field of endoluminal and transgastric bariatric surgery. Surg Endosc. 2007 Mar;21(3):347-56. Epub 2006 Dec 16.

278. Schauer PR, Burguera B, Ikramuddin S, Cottam D, Gourash W, Hamad W, et al. Effect of laparoscopic Roux-en-Y gastric bypass on type 2 diabetes mellitus. Ann Surg. 2003 Oct;238(4):467-85.

279. Schauer PR, Ikramuddin S, Gourash W, Ramanathan R, Luketich J. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. Ann Surg. 2000 Oct;232(4):515-29.

280. Schieman C, Grondin SC. Paraesophageal hernia: clinical presentation, evaluation, and management controversies. Thorac Surg Clin. 2009 Nov;19(4):473-84.

281. Schouten R, Rijs CS, Bouvy ND, Hameeteman W, Koek GH, Janssen IM, et al. A multicenter, randomized efficacy study of the EndoBarrier Gastrointestinal Liner for presurgical weight loss prior to bariatric surgery. Ann Surg. 2010 Feb;251(2):236-43.

282. Schwaitzberg SD. Surgical management of gastroesophageal reflux in adults. In: UpToDate, Louie BE and Talley NJ (ed.). Oct 5, 2021. UpToDate, Waltham, MA. Accessed Jun 15, 2023.

283. Seki Y, Kasama K, Haruta H, Watanabe A, Yokoyama R, Porciuncula JP, Umezawa A, Kurokawa Y. Five-Year-Results of Laparoscopic Sleeve Gastrectomy with Duodenojejunal Bypass for Weight Loss and Type 2 Diabetes Mellitus. Obes Surg. 2017 Mar;27(3):795-801.

284. Serrot FJ, Dorman RB, Miller CJ, Slusarek B, Sampson B, Sick BT, Leslie DB, Buchwald H, Ikramuddin S. Comparative effectiveness of bariatric surgery and nonsurgical therapy in adults with type 2 diabetes mellitus and body mass index <35 kg/m2. Surgery. 2011 Oct;150(4):684-91. doi: 10.1016/j.surg.2011.07.069. PMID: 22000180.

285. Sethi M, Chau E, Youn A, Jiang Y, Fielding G, Ren-Fielding C. Long-term outcomes after biliopancreatic diversion with and without duodenal switch: 2-, 5-, and 10-year data. Surg Obes Relat Dis. 2016 Nov;12(9):1697-1705.

286. Shalhub S, Parsee A, Gallagher SF, Haines KL, Willkomm C, Brantley S, et al. The importance of routine liver biopsy in diagnosing nonalcoholic steatohepatitis in bariatric patients. Obes Surg. 2004 Jan;14(1):54-9.

287. Sharples AJ, Charalampakis V, Daskalakis M, Tahrani AA, Singhal R. Systematic Review and Meta-Analysis of Outcomes After Revisional Bariatric Surgery Following a Failed Adjustable Gastric Band. Obes Surg. 2017 Oct;27(10):2522-2536.

288. Sheka AC, Kizy S, Wirth K, Grams J, Leslie D, Ikramuddin S. Racial disparities in perioperative outcomes after bariatric surgery. Surg Obes Relat Dis. 2019 May;15(5):786-793. doi: 10.1016/j.soard.2018.12.021. Epub 2018 Dec 22. PMID: 30772252.

289. Sheth SG, Chopra S. Epidemiology, clinical features, and diagnosis of nonalcoholic fatty liver disease in adults. Nov 7, 2022. In: UpToDate, Lindor KD, Robson KM (Eds). UpToDate, Waltham, MA. Accessed on Jun 15, 2023.

290. Shi X, Karmali S, Sharma AM, Birch DW. A Review of Laparoscopic Sleeve Gastrectomy for Morbid Obesity. Obes Surg. 2010 Apr 9. [Epub ahead of print]

291. Shikora SA, Wolfe BM, Apovian CM, Anvari M, Sarwer DB, Gibbons RD, et al. Sustained Weight Loss with Vagal Nerve Blockade but Not with Sham: 18-Month Results of the ReCharge Trial. J Obes. 2015;2015:365604.

292. Silecchia G, Boru C, Pecchia A, Rizzello M, Casella G, et al. Effectiveness of laparoscopic sleeve gastrectomy (first stage of biliopancreatic diversion with duodenal switch) on co-morbidities in super-obese high-risk patients. Obes Surg. 2006 Sep;16(9):1138-44.

293. Singhal R, Bryant C, Kitchen M, Khan KS, Deeks J, Guo B, Super P. Band slippage and erosion after laparoscopic gastric banding: a meta-analysis. Surg Endosc. 2010 Dec;24(12):2980-6.

294. Sjöstrom L, Lindroos AK, Peltonen M, Torgerson J, Bouchard C, Carlsson B, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. N Engl J Med. 2004 Dec 23;351(26):2683-93.

295. Sjöström L, Narbro K, Sjöström CD, Karason K, Larsson B, Wedel H, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med. 2007 Aug 23;357(8):741-52.

296. Skrekas G, Antiochos K, Stafyla VK. Laparoscopic gastric greater curvature plication: results and complications in a series of 135 patients. Obes Surg. 2011 Nov;21(11):1657-63. doi: 10.1007/s11695-011-0499-6.

297. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for clinical application of laparoscopic bariatric surgery. Jun 2008. Accessed Jun 12, 2023. Available at URL address: https://www.sages.org/publications/guidelines/

298. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Guidelines for the management of hiatal hernia. Apr 2013. Accessed Jun 15, 2023. Available at URL address: https://www.sages.org/publications/guidelines/guidelines-for-the-management-of-hiatal-hernia/

299. Solomon H, Liu GY, Alami R, Morton J, Curet MJ. Benefits to patients choosing preoperative weight loss in gastric bypass surgery: new results of a randomized trial. J Am Coll Surg. 2009 Feb;208(2):241-5. Epub 2008 Dec 4.

300. Søvik TT, Taha O, Aasheim ET, Engström M, Kristinsson J, Björkman S, et al. Randomized clinical trial of laparoscopic gastric bypass versus laparoscopic duodenal switch for superobesity. Br J Surg. 2010 Feb;97(2):160-6.

301. Søvik TT, Aasheim ET, Taha O, Engström M, Fagerland MW, Björkman S, et al. Weight loss, cardiovascular risk factors, and quality of life after gastric bypass and duodenal switch: a randomized trial. Ann Intern Med. 2011 Sep 6;155(5):281-91.

302. Spinos D, Skarentzos K, Esagian SM, Seymour KA, Economopoulos KP. The Effectiveness of Single-Anastomosis Duodenoileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS): an Updated Systematic Review. Obes Surg. 2021 Apr;31(4):1790-1800. doi: 10.1007/s11695-020-05188-7. Epub 2021 Jan 16. PMID: 33452998.

303. Spyropoulos C, Katsakoulis E, Mead N, Vagenas K, Kalfarentzos F. Intragastric balloon for high-risk super-obese patients: a prospective analysis of efficacy. Surg Obes Relat Dis. 2007 Jan-Feb;3(1):78-83.

304. Sreenarasimhaiah J. Prevention or surgical treatment of gallstones in patients undergoing gastric bypass surgery for obesity. Curr Treat Options Gastroenterol. 2004 Apr;7(2):99-104.

305. Still CD, Benotti P, Wood GC, Gerhard GS, Petrick A, Reed M, et al. Outcomes of preoperative weight loss in high-risk patients undergoing gastric bypass surgery. Arch Surg. 2007 Oct;142(10):994-8; discussion 999.

306. Stimac D, Klobučar Majanović S, Turk T, Kezele B, Licul V, Crnčević Orlić Z. Intragastric balloon treatment for obesity: results of a large single center prospective study. Obes Surg. 2011 May;21(5):551-5.

307. Strain GW, Gagner M, Pomp A, Dakin G, Inabnet WB, Hsieh J, Heacock L, Christos P. Comparison of weight loss and body composition changes with four surgical procedures. Surg Obes Relat Dis. 2009 Sep-Oct;5(5):582-7. doi: 10.1016/j.soard.2009.04.001. Epub 2009 Apr 14.

308. Sudan R, Nguyen NT, Hutter MM, Brethauer SA, Ponce J, Morton JM. Morbidity, mortality, and weight loss outcomes after reoperative bariatric surgery in the USA. J Gastrointest Surg. 2015 Jan;19(1):171-8; discussion 178-9. doi: 10.1007/s11605-014-2639-5. Epub 2014 Sep 4. PMID: 25186073.

309. Sullivan S, Stein R, Jonnalagadda S, Mullady D, Edmundowicz S. Aspiration therapy leads to weight loss in obese subjects: a pilot study. Gastroenterology. 2013 Dec;145(6):1245-52.e1-5.

310. Sullivan S, Swain J, Woodman G, Edmundowicz S, Hassanein T, Shayani V, Fang JC, Noar M, Eid G, English WJ, Tariq N, Larsen M, Jonnalagadda SS, Riff DS, Ponce J, Early D, Volckmann E, Ibele AR, Spann MD, Krishnan K, Bucobo JC, Pryor A. Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss. Surg Obes Relat Dis. 2018 Dec;14(12):1876-1889.

311. Surve A, Cottam D, Sanchez-Pernaute A, Torres A, Roller J, Kwon Y, Mourot J, Schniederjan B, Neichoy B, Enochs P, Tyner M, Bruce J, Bovard S, Roslin M, Jawad M, Teixeira A, Srikanth M, Free J, Zaveri H, Pilati D, Bull J, Belnap L, Richards C, Medlin W,

Moon R, Cottam A, Sabrudin S, Cottam S, Dhorepatil A. The incidence of complications associated with loop duodeno-ileostomy after single-anastomosis duodenal switch procedures among 1328 patients: a multicenter experience. Surg Obes Relat Dis. 2018 May;14(5):594-601. doi: 10.1016/j.soard.2018.01.020. Epub 2018 Feb 2. PMID: 29530597.

312. Surve A, Zaveri H, Cottam D, Belnap L, Cottam A, Cottam S. A retrospective comparison of biliopancreatic diversion with duodenal switch with single anastomosis duodenal switch (SIPS-stomach intestinal pylorus sparing surgery) at a single institution with two year follow-up. Surg Obes Relat Dis. 2017 Mar;13(3):415-422. doi: 10.1016/j.soard.2016.11.020. Epub 2016 Dec 2. PMID: 28089438.

313. Taha O. Efficacy of laparoscopic greater curvature plication for weight loss and type 2 diabetes: 1-year follow-up. Obes Surg. 2012 Oct;22(10):1629-32. doi: 10.1007/s11695-012-0724-y.

314. Taha O, Abdelaal M, Abozeid M, Askalany A, Alaa M. Outcomes of Omega Loop Gastric Bypass, 6-Years Experience of 1520 Cases. Obes Surg. 2017 Aug;27(8):1952-1960. doi: 10.1007/s11695-017-2623-8.

315. Talebpour M, Motamedi SM, Talebpour A, Vahidi H. Twelve year experience of laparoscopic gastric plication in morbid obesity: development of the technique and patient outcomes. Ann Surg Innov Res. 2012 Aug 22;6(1):7. doi: 10.1186/1750-1164-6.

316. Talebpour M, Sadid D, Talebpour A, Sharifi A, Davari FV. Comparison of Short-Term Effectiveness and Postoperative Complications: Laparoscopic Gastric Plication vs Laparoscopic Sleeve Gastrectomy. Obes Surg. 2018 Apr;28(4):996-1001.

317. Tang Y, Tang S, Hu S. Comparative Efficacy and Safety of Laparoscopic Greater Curvature Plication and Laparoscopic Sleeve Gastrectomy: A Meta-analysis. Obes Surg. 2015 Nov;25(11):2169-75.

318. Tate CM, Geliebter A. Intragastric Balloon Treatment for Obesity: Review of Recent Studies. Adv Ther. 2017 Aug;34(8):1859-1875.

319. Thompson CC, Abu Dayyeh BK, Kushner R, et. al. Percutaneous Gastrostomy Device for the Treatment of Class II and Class III Obesity: Results of a Randomized Controlled Trial. Am J Gastroenterol. 2017 Mar; 112(3): 447–457.

320. Topart P, Becouarn G, Salle A. Five-year follow-up after biliopancreatic diversion with duodenal switch. Surg Obes Relat Dis. 2011 Mar-Apr;7(2):199-205.

321. Treadwell JR, Sun F, Schoelles K. Systematic review and meta-analysis of bariatric surgery for pediatric obesity. Ann Surg. 2008 Nov;248(5):763-76.

322. Trigilio-Black CM, Ringley CD, McBride CL, Sorensen VJ, Thompson JS, Longo GM, et al. Inferior vena cava filter placement for pulmonary embolism risk reduction in super morbidly obese undergoing bariatric surgery. Surg Obes Relat Dis. 2007 Jul-Aug;3(4):461-4. Epub 2007 Jun 4.

323. Tsui ST, Yang J, Zhang X, Tatarian T, Docimo S, Spaniolas K, Pryor AD. Health disparity in access to bariatric surgery. Surg Obes Relat Dis. 2021 Feb;17(2):249-255. doi: 10.1016/j.soard.2020.10.015. Epub 2020 Oct 16. PMID: 33249086.

324. Tucker ON, Szomstein S, Rosenthal RJ. Indications for sleeve gastrectomy as a primary procedure for weight loss in the morbidly obese. J Gastrointest Surg. 2008 Apr;12(4):662-7.

325. U. S. Census Bureau. The Asian population 2010. Accessed Jun 9, 2023. Available at URL address: https://www.census.gov/library/publications/2012/dec/c2010br-11.html

326. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. AspireAssist - P150024. June 14, 2016. Accessed Jun 15, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150024b.pdf

327. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. ORBERA™ Intragastric Balloon System - P140008. August 5, 2015. Accessed Jun 12, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

328. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. ReShape Integrated Dual Balloon System - P140012. July 28, 2015. Accessed Jun 15, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

329. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). TransPyloric Shuttle – P180024. April 23, 2019. Accessed Jun 12, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

330. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. 510(k) Summary. Apollo Endosurgery OverStitch Endoscopic Suture System - K081853. August 18, 2008. Accessed Jun 15, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081853.pdf

331. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). LAP-BAND® Adjustable Gastric Banding (LAGB®) System - P000008. June 5, 2001. Accessed Jun 9, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

332. U. S. Food and Drug Administration (FDA). Lap-Band. PMA P000008 S017: Feb. 16, 2011. FDA expands use of banding system for weight loss. Accessed Jun 15, 2023. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf/P000008S017B.pdf

333. U. S. Food and Drug Administration (FDA). Obalon Balloon System. P160001. Sept 8, 2016. Accessed Jun 12, 2023. Available at URL address: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

334. U. S. Food and Drug Administration (FDA). Weight-loss and weight-management devices. Oct 26, 2022. Accessed Jun 12, 2023. Available at URL address: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/obesitydevices/default.htm

335. U. S. Food and Drug Administration (FDA). Summary of Safety and Effectiveness Data. MAESTRO® Rechargeable System - P130019. January 14, 2015. Accessed Jun 15, 2023.

Available at URL address: https://wayback.archive-it.org/7993/20170404011510/https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm430696.htm

336. U. S. Food and Drug Administration (FDA). Premarket Approval (PMA). REALIZE™ Adjustable Gastric Band. - P070009. September 28, 2007. Accessed Jun 9, 2023. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

337. U. S. Food and Drug Administration (FDA). UPDATE: Potential risks with liquid-filled intragastric balloons – letter to health care providers. Jun 4, 2018, update Apr 27, 2020. Accessed Jun 12, 2023. Available at URL address: https://web.archive.org/web/20220421014945/https://www.fda.gov/medical-devices/letters-health-care-providers/update-potential-risks-liquid-filled-intragastric-balloons-letter-health-care-providers-0

338. U. S. Preventive Services Task Force, Curry SJ, Krist AH, Owens DK, Barry MJ, Caughey AB, Davidson KW, Doubeni CA, Epling JW Jr, Grossman DC, Kemper AR, Kubik M, Landefeld CS, Mangione CM, Phipps MG, Silverstein M, Simon MA, Tseng CW, Wong JB. Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2018 Sep 18;320(11):1163-1171. doi: 10.1001/jama.2018.13022. PMID: 30326502.

339. Victorzon M, Tolonen P. Bariatric Analysis and Reporting Outcome System (BAROS) following laparoscopic adjustable gastric banding in Finland. Obes Surg. 2001 Dec;11(6):740-3.

340. Victorzon M, Tolonen P. Intermediate results following laparoscopic adjustable gastric banding for morbid obesity. Dig Surg. 2002;19(5):354-7.

341. Vidal J, Ibarzabal A, Romero F, Delgado S, Momblán D, Flores L, Lacy A. Type 2 diabetes mellitus and the metabolic syndrome following sleeve gastrectomy in severely obese subjects. Obes Surg. 2008 Sep;18(9):1077-82. Epub 2008 Jun 3.

342. Vijgen GH1, Schouten R, Bouvy ND, Greve JW. Salvage banding for failed Roux-en-Y gastric bypass. Surg Obes Relat Dis. 2012 Nov-Dec;8(6):803-8. doi: 10.1016/j.soard.2012.07.019. Epub 2012 Aug 29.

343. Villegas L, Schneider B, Provost D, Chang C, Scott D, Sims T, et al. Is routine cholecystectomy required during laparoscopic gastric bypass? Obes Surg. 2004 Jan;14(1):60-6.

344. Vos MB, Abrams SH, Barlow SE, Caprio S, Daniels SR, Kohli R, Mouzaki M, Sathya P, Schwimmer JB, Sundaram SS, Xanthakos SA. NASPGHAN Clinical Practice Guideline for the Diagnosis and Treatment of Nonalcoholic Fatty Liver Disease in Children: Recommendations from the Expert Committee on NAFLD (ECON) and the North American Society of Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). J Pediatr Gastroenterol Nutr. 2017 Feb;64(2):319-334. doi: 10.1097/MPG.0000000000001482. PMID: 28107283; PMCID: PMC5413933.

345. Wadden TA, Volger S, Sarwer DB, Vetter ML, Tsai AG, Berkowitz RI, et al. A two-year randomized trial of obesity treatment in primary care practice. N Engl J Med. 2011 Nov 24;365(21):1969-79. Epub 2011 Nov 14.

346. Wang FG, Yu ZP, Yan WM, Yan M, Song MM. Comparison of safety and effectiveness between laparoscopic mini-gastric bypass and laparoscopic sleeve gastrectomy: A meta-analysis and systematic review. Medicine (Baltimore). 2017 Dec;96(50):e8924.

347. Wang FG, Yan WM, Yan M, Song MM. Outcomes of mini vs Roux-en-Y gastric bypass: a meta-analysis and systematic review. Int J Surg. 2018;56:7-14.

348. Washington State Health Care Authority. Health Technology Assessment Program (HTA): Bariatric Surgery, Final Evidence Report. April 10, 2015. Accessed Jun 15, 2023. Available at URL address: https://www.hca.wa.gov/assets/program/bariatric_final_rpt_040315[1].pdf

349. Weber M, Muller MK, Bucher T, Wildi S, Dindo D, Horber F, et al. Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. Ann Surg. 2004 Dec;240(6):975-82.

350. Wittgrove AC, Clark GW. Laparoscopic gastric bypass, Roux-en-Y-500 patients: technique and results, with 3-60 month follow-up. Obes Surg. 2000 Jun;10(3):233-9.

351. World Health Organization. Regional Office for the Western Pacific. (2000). The Asia-Pacific perspective: redefining obesity and its treatment. Sydney : Health Communications Australia. Accessed on Jun 9, 2023. Available at URL address: https://apps.who.int/iris/handle/10665/206936

352. Yan Y, Sha Y, Yao G, Wang S, Kong F, Liu H, et al. Roux-en-Y Gastric Bypass Versus Medical Treatment for Type 2 Diabetes Mellitus in Obese Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Medicine (Baltimore). 2016 Apr;95(17):e3462.

353. Yashkov Y, Bordan N, Torres A, Malykhina A, Bekuzarov D. SADI-S 250 vs Roux-en-Y Duodenal Switch (RY-DS): Results of 5-Year Observational Study. Obes Surg. 2021 Feb;31(2):570-579. doi: 10.1007/s11695-020-05031-z. Epub 2020 Oct 12. PMID: 33047290.

354. Ye Q, Chen Y, Zhan X, Wang Y, Zhu J. Comparison of Laparoscopic Sleeve Gastrectomy and Laparoscopic Greater Curvature Plication Regarding Efficacy and Safety: a Meta-Analysis. Obes Surg. 2017 May;27(5):1358-1364.

355. Zaveri H, Surve A, Cottam D, Ng PC, Enochs P, Billy H, Medlin W, Richards C, Belnap L, Sharp LS, Bermudez DM, Fairley R, Burns TA, Herrell K, Bull J, Menozzi SE, Student JA. A Multi-institutional Study on the Mid-Term Outcomes of Single Anastomosis Duodeno-Ileal Bypass as a Surgical Revision Option After Sleeve Gastrectomy. Obes Surg. 2019 Oct;29(10):3165-3173. doi: 10.1007/s11695-019-03917-1. PMID: 31388962.

356. Zheng Y, Wang M, He S, Ji G. Short-term effects of intragastric balloon in association with conservative therapy on weight loss: a meta-analysis. J Transl Med. 2015 Jul 29;13:246. doi: 10.1186/s12967-015-0607-9.

357. Zhou BF; Cooperative Meta-Analysis Group of the Working Group on Obesity in China. Predictive values of body mass index and waist circumference for risk factors of certain related diseases in Chinese adults--study on optimal cut-off points of body mass index and waist circumference in Chinese adults. Biomed Environ Sci. 2002 Mar;15(1):83-96. PMID: 12046553.