



Medical Coverage Policy

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Bariatric Surgery

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Related Coverage Resources

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[Obstructive Sleep Apnea Treatment Services](#)
[Panniculectomy and Abdominoplasty](#)
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Coverage Policy

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

Bariatric surgery for the treatment of morbid obesity using a covered procedure outlined below is considered medically necessary when ALL of the following criteria are met:

- The individual is ≥ 18 years of age **OR** has reached full expected skeletal growth **AND** has evidence of **EITHER** of the following:

- a BMI (Body Mass Index) ≥ 40
- a BMI (Body Mass Index) 35–39.9 with at least one clinically significant obesity-related comorbidity, including but not limited to the following:
 - o mechanical arthropathy in a weight-bearing joint (symptomatic degenerative joint disease in a weight bearing joint)
 - o diabetes mellitus
 - o poorly controlled hypertension (systolic blood pressure at least 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite optimal medical management)
 - o hyperlipidemia
 - o coronary artery disease
 - o lower extremity lymphatic or venous obstruction
 - o obstructive sleep apnea
 - o pulmonary hypertension
 - o evidence of fatty liver disease (i.e., nonalcoholic fatty liver disease [NAFLD] or nonalcoholic steatohepatitis [NASH])
- A statement from a physician/physician's assistant/nurse practitioner/registered dietician (i.e., other than the requesting surgeon) that the individual has failed previous attempts to achieve and maintain weight loss by medical management.
- A thorough multidisciplinary evaluation within the previous six months which includes ALL of the following:
 - a description of the proposed procedure(s)
 - a separate medical evaluation and/or a recommendation for bariatric surgery from a physician/physician's assistant/nurse practitioner other than the requesting surgeon or associated staff
 - unequivocal clearance for bariatric surgery by a mental health provider
 - a nutritional evaluation by a physician or registered dietician

Bariatric Surgery Procedures

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

Procedure	Open CPT® Codes	Laparoscopic CPT® Codes
Roux-en-Y gastric bypass	43846, 43847	43644, 43645
Adjustable silicone gastric banding (e.g., LAP-BAND®, REALIZE™)	43843, 43999	43770
Biliopancreatic Diversion with Duodenal Switch (BPD/DS)	43845	43659, 44799 (single stage) 43775 (first stage, if performed) 43845-52 (second stage)
BPD without DS	43633	43659
Sleeve gastrectomy as a stand-alone or staged procedure	43843 (stand alone or first stage) 43846 or 43999 (second stage)	43775 (stand-alone or first stage) 43644 or 43659 (second stage)
Vertical band gastroplasty	43842	43659

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 surgery procedures for the treatment of morbid obesity, when performed alone or in conjunction with another bariatric surgery 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
Gastroplasty (stomach stapling)	43659, 43843
Intestinal bypass (jejunioileal bypass)	44238, 44799
Intragastric balloon (e.g., Orbera™, ReShape™, Obalon)	43999
Laparoscopic greater curvature plication	43659
Loop gastric bypass	43659, 43843
Mini-gastric bypass	43659, 43843
Natural Orifice Transluminal Endoscopic Surgery (NOTES)/endoscopic oral-assisted bariatric surgery procedures , including but not limited to the following: ➤ restorative obesity surgery, endoluminal (ROSE) ➤ StomaphyX™ ➤ duodenojejunal bypass liner (e.g., Endobarrier™) ➤ transoral gastroplasty (e.g., TOGA®) ➤ endoscopic closure devices (e.g., Apollo OverStitch™)	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
Single-anastomosis DS	43659, 43999, 44799
Stomach aspiration therapy (e.g., AspireAssist®)	43659, 43999
Vagus nerve blocking (e.g., Maestro®)	0312T, 0313T, 0316T, 0317T
Vagus nerve stimulation	61885 and 64568 OR 61885 and 64553

Reoperation and Revisional Bariatric Surgery

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 symptomology (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 primary bariatric surgery procedure (e.g., stricture, obstruction, erosion, gastric prolapse, ulceration, fistula formation, esophageal dilatation):

- surgical repair or reversal (i.e., takedown)

- conversion to a medically necessary bariatric surgery procedure

Revision of a previous bariatric surgical procedure or conversion to another medically necessary procedure due to inadequate weight loss is considered medically necessary when ALL of the following are met:

- The requested procedure includes ANY of the following:

Procedure	Open CPT® Codes	Laparoscopic CPT® Codes
Roux-en-Y gastric bypass	43846, 43847	43644, 43645
Adjustable silicone gastric banding (e.g., LAP-BAND®, REALIZE™)	43843, 43999	43770
Biliopancreatic Diversion with Duodenal Switch (BPD/DS)	43845	43659, 44799 (single stage) 43775 (first stage, if performed) 43845-52 (second stage)
BPD without DS	43633	43659
Sleeve gastrectomy as a stand-alone or staged procedure	43843 (stand alone or first stage) 43846 or 43999 (second stage)	43775 (stand-alone or first stage) 43644 or 43659 (second stage)
Vertical band gastroplasty	43842	43659

- There is evidence of full compliance with the previously prescribed postoperative dietary and exercise program.
- Due to a technical failure[†] of the original bariatric surgical procedure (e.g., pouch dilatation, unsuccessful band adjustments), the individual has failed to achieve adequate weight loss, which is defined as failure to lose at least 50% of excess body weight or failure to achieve body weight to within 30% of ideal body weight at least two years following the original surgery.

[†]In the absence of a technical failure or major complication, individuals with weight loss failure ≥ two years following a primary bariatric surgery procedure must meet the initial medical necessity criteria for surgery.

NOTE: Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations is not a medically necessary indication for revision or conversion surgery.

Surgical reversal (i.e., takedown), revision of a previous bariatric surgical procedure or conversion to another bariatric surgical procedure for ANY other indication is considered not medically necessary.

[Bariatric Surgery for the Treatment of Diabetes Mellitus](#)

A bariatric surgical procedure performed solely for the treatment of diabetes mellitus with a BMI < 35 is considered experimental, investigational or unproven.

[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 individuals who are 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)

Cigna considers herniorrhaphy performed for the repair of a hiatal hernia at the time of the primary bariatric procedure to be integral to the procedure and not separately reimbursable.

Cigna considers upper gastrointestinal endoscopy performed concurrent with a bariatric surgery procedure to confirm a surgical anastomosis or to establish anatomical landmarks to be an integral part of the more comprehensive surgical procedure and not separately reimbursable.

Overview

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

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/m² (Brethauer, et al., 2013). The National Heart, Lung and Blood Institute (NHLBI) (1998) recommended that the BMI should be used to classify overweight and obesity and to estimate relative risk for disease compared to normal weight. The NHLBI (1998) 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	25–29.9 kg/m ²
Obesity (Class 1)	30–34.9 kg/m ²
Obesity (Class 2)	35–39.9 kg/m ²
Extreme Obesity (Class 3)	≥ 40 kg/m ²

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

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

Clinically severe or morbid obesity is defined as a BMI ≥ 40 or a BMI of 35–39.9 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. 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 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).

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/m²) and have two or more obesity-related medical conditions or are frankly obese (BMI >30 kg/m²), 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/m² plus two or more cardiovascular risk factors, or BMI > 30 kg/m²).
- For markedly obese persons at greatest risk (BMI > 35 kg/m² with two or more obesity-related medical conditions or BMI > 40 kg/m²), consider a surgical approach if serious and repeated attempts using the foregoing measures have been unsuccessful.

The NHLBI guidelines (1998) make 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 [ADA], 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 dietitians 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/m² during the first 12–24 postoperative months. Many 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/m². The follow-up range was 6–48 months. A case series (n=93) by Parikh et al. (2006) examined the effectiveness of laparoscopic adjustable gastric banding with the LAP-BAND in patients with a BMI of 30-35 kg/m². 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/m² in 34%, 25-29 kg/m² in 51%, and 30-35 kg/m² in 10%.

A randomized controlled trial conducted (RCT) by O'Brien et al. (2006) assigned 80 patients with mild to moderate obesity (i.e., BMI 30 kg/m² to 35 kg/m²) 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.

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 (Hayes, 2017; 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.

In a 2017 Directory Report, Hayes conducted a technology assessment on the effectiveness of preoperative supervised weight loss programs defined as those supervised by a physician that included diet, exercise, and counseling components. These programs also included Weight Watchers, Jenny Craig and others. The programs generally lasted 4–6 months. Single-component programs (e.g., diet only) and programs that required weight loss but did not administer a supervised weight loss program were excluded from the review. Four studies met inclusion criteria (one randomized controlled trial, one prospective comparative cohort study, and two retrospective reviews). All studies (n=55–560) administered outpatient preoperative supervised weight loss programs with six-month to two-year follow-ups. Few details regarding the program content were reported. The aim of the assessment was to address whether participation in a preoperative supervised weight loss program improved surgical, perioperative, or postoperative outcomes, including morbidity and mortality. Preoperative weight loss was included when reported by the studies. Three studies reported preoperative weight loss during six-month programs with only modest changes in body weight prior to surgery being reported. There were no statistically significant differences between the groups in comparison studies. Four studies reported postoperative weight changes at three months to two year follow-ups. Weight loss was similar between groups at each follow-up time in each study, and there were no statistically significant differences. Current evidence did not address the impact of preoperative supervised weight loss programs on perioperative outcomes (e.g., surgical time, conversions from laparoscopic to open surgery) or morbidity and mortality. No studies reported on safety outcomes. The overall quality of the studies was rated as low. Hayes concluded that preoperative weight loss programs are not associated with greater weight loss prior to or following bariatric surgery. Hayes also noted that four systematic reviews addressing the impact of preoperative weight loss on bariatric surgery outcomes reported inconsistent findings and whether preoperative supervised weight loss programs lead to substantive preoperative weight loss or better surgical outcomes was unclear.

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 (2008) 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).

A 2011 position document from the American Society for Metabolic and Bariatric Surgery (ASMBS) stated that “the preoperative weight loss recommended by the surgeon and/or the multidisciplinary bariatric treatment team because of an individual patient’s needs might have value for the purposes of improving surgical risk or evaluating patient adherence. However, it is supported only by low-level evidence in the published data at present” (Brethauer, 2011).

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

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).

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. 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):

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 Surgery 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 causes 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; Schauer, et al., 2000; DeMaria, et al., 2002; 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 by connection tubing, 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). Currently, adjustable gastric banding devices approved for marketing in the U.S. include the Bioenterics® LAP-BAND® Adjustable Gastric Banding (LAGB®) System (INAMED Health, Santa Barbara, CA), and the REALIZE™ Adjustable Gastric Band (Ethicon Endo-Surgery, Inc., Cincinnati, OH).

US Food and Drug Administration (FDA)

The LAP-BAND 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 $\geq$ 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 B₁₂, 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/m² 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.

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/m²). 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 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/m². The mean baseline BMI was 46.9 kg/m² for the high-risk patients (range 49.1–69.0) and 60.4 kg/m² 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/m² to 37.1 kg/m² 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): ASMBS updated their 2009 position statement on SG. The Society “recognizes that the concept of staged bariatric surgery using lower risk procedures as the initial treatment appears to have value as a risk-reduction strategy for high-risk patients. Much of the published data supporting SG as a bariatric procedure have described favorable outcomes in patients described as high risk, making it an acceptable option for this subgroup.” In addition, a significant number of patients have demonstrated durable weight loss after SG and might not require conversion to another procedure. The ASMBS states that it is therefore justifiable to recommend SG as an ASMBS-approved bariatric procedure (ASMBS, 2012).

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).

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/Jejunioleal Bypass

In a jejunioleal 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 jejunioleal 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 jejunioleal bypass patients, the most serious of which is irreversible hepatic cirrhosis (Morris, et al., 2017; Collins, et al., 2007). Because of these complications, jejunioleal 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. Currently, there are three FDA approved balloons: 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), and the Obalon (Obalon® Therapeutics, Inc.).

US Food and Drug Administration

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 ReShape® Integrated Dual Balloon System (ReShape Medical, Inc. San Clemente, CA) received a premarket approval application (PMA) approval from the U.S. FDA in July 2015. The ReShape is a temporary implant designed to facilitate weight loss by occupying space in the stomach and producing a sensation of satiety. The dual balloon is delivered transorally down the esophagus and placed into the stomach using the ReShape Delivery Catheter. Once positioned, the dual balloon is inflated with a sterile saline and methylene blue solution, sealed with mineral oil, and left in the stomach for a treatment period of up to six months. At the conclusion of treatment, the ReShape Removal Catheter is used to aspirate the dual balloon endoscopically. According to the FDA, the ReShape system is indicated for weight reduction when used in conjunction with diet and exercise, in obese patients with a BMI of 30–40 kg/m² and one or more obesity-related comorbid conditions. It is indicated for use in adult patients who have failed weight reduction with diet and exercise alone.

The Obalon Balloon System (Obalon® Therapeutics, Inc. Carlsbad, 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/m²) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed six months after the first balloon is placed” 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).

Other balloons being investigated include the Transpyloric Shuttle (BAROnova, Goleta, CA), SatiSphere (Endosphere, Columbus, OH), Spatz Adjustable Balloon System (Spatz Medical, NY, USA), Elipse (Allurion Technologies, Wellesley, MA), 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 Intragastrophic Balloon (Phagia Technologies, Inc., Fort Lauderdale, FL). These devices are currently not FDA approved for use in the US (Bazerbach, et al., 2017; Jirapinyo and Thompson, 2017; Kumar, 2016; Kumar, 2015).

Literature Review

Orbera: 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/m² 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).

Reshape: Ponce et al. (2015) conducted a sham-controlled, double-blinded RCT (n=326), the REDUCE Pivotal Trial, to evaluate the safety and effectiveness of the ReShape dual balloon system with diet and exercise (DUO; n=187) compared to sham endoscopy with diet and exercise (DIET; n=139). Subjects were selected who had a baseline BMI of 30-40 kg/m² with at least one obesity-related co-morbidity, were not at risk of pregnancy, and had failed to lose weight within the previous 36 months with a medically supervised weight loss program. Exclusion criteria included a history of ongoing clinically significant conditions of the gastrointestinal tract or medical conditions which prevented use of the dual balloon. At 24 weeks the DUO patients had the dual balloon removed and continued to receive counseling through week 48. DIET patients were offered the balloon at week 24. Those who accepted had the balloon removed at 48 weeks and continued follow-up through 52 weeks. Of the DUO patients, 136 completed 48 weeks of follow-up. DIET patients who were eligible for and accepted balloon treatment (n=77) also completed follow-up through 48 weeks. The primary outcome measure was %EWL. Other outcome measures included changes in measures of co-morbid conditions, quality of life and safety. The EWL at 24 weeks was 25.1% for DUO patients and 11.3% for DIET patients (p=0.0041). Nearly half (48.8%) of IGB patients achieved ≥ 25% EWL, significantly higher than the expected ≥ 35% (P<0.0001). For the completed DUO cases, the mean EWL was 27.9% at 24 weeks, compared with 12.3% for sham-treated patients (p=0.0007). A statistically significant improvement was demonstrated in the majority of comorbid conditions at 24

weeks ($p < 0.05$). The device was removed in 9% of patients prior to 24 weeks due to abdominal accommodative symptoms. Gastric ulceration occurred in 35% of dual balloon patients. The device deflated in 6% of patients. Additional well-designed studies with longer term follow-up are needed to determine overall safety and efficacy.

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).

Multiple Intra gastric 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.

A Hayes Directory Report evaluated the safety and efficacy of intragastric balloons (IGBs). Thirteen randomized controlled trials ($n=18-326$) met inclusion criteria. Eleven studies included Orbera, two studies evaluated the ReShape Duo and three studies included the Heliosphere which is not FDA approved for use in the United States. Ten studies evaluated IGB and lifestyle interventions, with or without sham comparators, two studies compared gas-filled and saline-filled devices, and one study compared IGBs with hyaluronic acid injections. Follow-ups ranged from 4–24 months. The IGBs did not consistently promote weight loss to a significantly greater degree compared with restricted diet and exercise alone. Excess or total weight loss amounts among IGB patients were reported to be higher than lifestyle intervention alone in five studies but not significantly different in three studies. Five studies reported greater reductions in BMI with IGBs compared with restricted diet and exercise alone. One study found no significant reduction in BMI following IGB. Two studies reported no difference in satiety between IGB and restricted diet alone. Quality of life (QOL) measures improved in three studies and none in one study. IGB use was associated with considerable rates of nausea, vomiting, and other related abdominal issues in ten studies. Nine of the studies also reported serious events that required medical management or early retrieval of the device in 4.6%–18.8% of patients. The devices were consistently associated with high rates of gastrointestinal adverse events that were of mild-to-moderate severity, and infrequently associated with more serious events. No treatment-related deaths were reported in the reviewed studies. The evidence is insufficient to determine definitive patient selection criteria for IGBs. Hayes concluded that based on the low-quality evidence there are mixed results regarding the outcomes of IGBs with regard to weight loss over the short term when used as an adjunct to diet and exercise. IGBs may improve patient reported QOL but did not appear to have any effect on satiety compared with restricted diet and exercise. All of the studies lacked long-term follow-up, so that the durability of the effects of IGBs on maintaining weight loss and any safety concerns after their removal is unclear.

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/m². 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/m², 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/m², 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 technology assessment of the IGB from the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) concluded that moderate weight loss may be achieved with IGB placement if patients are compliant with a weight-reduction program. Weight gain has been found to recur when the balloon is removed after six months. More data are needed before the IGB can be compared to other short-term interventions such as low-calorie diets (CCOHTA, 2006).

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).

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; I, 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.

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/m², 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 pliation 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).

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.

Loop Gastric Bypass

The loop gastric bypass involves the creation of a gastric pouch in the shape of a tube by dividing the stomach at the junction of the body and the antrum, parallel to the lesser curve. A loop of jejunum is then anastomosed to the gastric pouch. 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.

Mini-Gastric Bypass

The mini-gastric bypass, also called the Omega loop gastric bypass and single- or one-anastomosis gastric bypass, 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 continue 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).

Literature Review

Evidence supporting the use of the mini-gastric bypass is primarily in the form of retrospective reviews (n=1200–1520) (Carbajo, et al., May 2017; Taha, et al., 2017) and small case series (Carbajo, et al., Jan 2017). 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/m² 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.

There is insufficient evidence in the published, peer-reviewed scientific literature to support the safety and efficacy of the mini-gastric bypass.

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, 2018). NOSCAR stated that research on the safety and efficacy of NOTES has generally been confined to animal studies.

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 StomaphyX 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 DJBL 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 compared 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.

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.

Single-Anastomosis 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.

Literature Review

The evidence evaluating single anastomosis duodeno-ileal bypass or SADI-S for morbid obesity consists primarily of a limited number of case series (Lee, et al., 2013; Sánchez-Pernaute, et al., 2012). There is insufficient evidence in the peer reviewed literature demonstrating the safety and efficacy of modified DS procedures including single anastomosis duodeno-ileal bypass with or without sleeve gastrectomy for the treatment of morbid obesity.

A 2018 Hayes technology brief on single-anastomosis duodenal switch (SADS) for weight loss included five studies (n=106-182) that met inclusion criteria. The evidence was primarily in the form of retrospective reviews. No randomized controlled trials were identified. Four of the studies were from one bariatric center and utilized the same pool of SADS patients in retrospective matched cohort analyses. The mean BMI was > 40 kg/m² in four studies and 38 kg/m² in the remaining study. The mean age ranged from 42–52 years. The primary outcome measure was weight loss. The evidence suggested that SADS promotes significant weight loss in patients with morbid or extreme obesity. Weight loss appeared to cease by 15 months and may be durable for up to two years following surgery. SADS was more effective at promoting weight loss than Roux-en-Y gastric bypass (RYGB) or vertical sleeve gastrectomy. Comparisons with biliopancreatic diversion with duodenal switch (BPD-DS) yielded mixed results. Reported complications were generally minor and occurred at similar or lower incidences than the comparative bariatric surgeries. The need for reoperation was rare. Hayes concluded that because of the small number of poor- or very-poor-quality studies investigating the use of SADS substantial uncertainty exists regarding the durability of effect, safety, and comparative efficacy with other treatments for obesity.

Professional Societies/Organizations

American Society for Metabolic and Bariatric Surgery (ASMBS): According to the ASMBS, single-anastomosis duodenal switch procedures are considered investigational at present and should be performed under a study protocol with third-party oversight to ensure continuous evaluation of patient safety and to review adverse events and outcomes (Kim, 2016a).

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

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/m² 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/m². 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/m² 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) (n=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/m² 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 47 to 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 ratio 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/m² or between 35.0 and 39.9 kg/m² 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 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/m² 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.

A Hayes Technology Brief reviewed the available evidence (n=3 studies/28-294 patients) on the Maestro Rechargeable System (EnteroMedics Inc.) for Vagal Blocking for Obesity Control. The review included two randomized controlled trials (ReCharge and EMPOWER studies described below) and one case series. Limitations of the studies included small sample sizes, short-term follow-up periods, and loss to follow-up. The overall body of evidence was found to be insufficient to draw conclusions about the efficacy of the Maestro device. The RCTs failed to reach co-primary weight loss endpoints. Different definitions for primary outcome measures (e.g., EWL, QOL) and slightly different treatment protocols were used in each study limiting comparison and synthesis of results. It was concluded that well-designed studies with larger patient populations comparing the device to proven obesity treatments are needed. A 2018 review revealed three new studies which reported up to two years of follow-up on small patient populations. The studies did not change Hayes original conclusion that additional studies are needed to support the safety and efficacy of this procedure (Hayes, 2016; 2018).

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 $\geq 20\%$ EWL and $\geq 25\%$ 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 $\geq 5\%$ TWL; and 34% had $\geq 10\%$ 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/m² or 35-39.9 kg/m² 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/m². The mean EWL at six months follow-up was 14.2% (p<0.001). Calorie intake decreased by > 30% at six months (p< 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 Children and Adolescents

Concerns have been raised about the appropriateness of bariatric surgery for children and adolescents. The impact of bariatric surgery on physical growth and sexual maturation has not been adequately explored and it is generally agreed upon that those under 18 years of age should only be considered for bariatric surgery if they have reached skeletal maturity (i.e., attained Tanner 4 or 5 pubertal development and final or near-final adult height). Physical development may be determined using hand and wrist radiographs to estimate bone age. Estimated adult height may also be determined using the mid-parental height calculation:

Boy

In: (Father's Height + Mother's Height + 5) / 2

Cm: (Father's Height + Mother's Height + 13) / 2

Girl

In: (Father's Height - 5 + Mother's Height) / 2

Cm: (Father's Height - 13 + Mother's Height) / 2

Several unique concerns have been raised about bariatric surgery in pediatric populations, including questions about timing of intervention, risk-taking behaviors after successful weight loss, compliance, and durability of weight loss. These questions highlight the importance of well-designed, prospective research efforts to better inform important decisions (Daniels, et al., 2009).

The safety and efficacy of bariatric surgery have not yet been established in this population. There is insufficient evidence to support surgical intervention for morbid obesity in this subset of individuals under 18 years of age who have not reached full skeletal maturity.

Literature Review

Bariatric surgery in patients under 18 years of age or in those who have not reached full expected skeletal growth has not been well-studied. 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 LAGB. 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

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/m² with severe comorbidities:
 - type 2 diabetes mellitus
 - moderate-to-severe sleep apnea
 - pseudotumor cerebri
 - NASH with advanced fibrosis

- BMI > 50 kg/m² 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 2018 guidelines included the following changes:

- 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/m² or 120% of the 95th percentile with a co-morbidity or b) BMI > 40kg/m² 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/m²) 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, ABMS 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:

1. The patient has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
2. The patient has a BMI $> 40 \text{ kg/m}^2$ and significant, severe comorbidities.
3. Extreme obesity and co-morbidities persist despite compliance with a formal program of lifestyle modification, with or without pharmacotherapy.
4. 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).
5. 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.
6. 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): Recommendations from the AAP for the treatment of overweight and obesity were issued by an expert panel of pediatricians and pediatric surgeons. According to this Panel, minors being considered for bariatric surgery should “be physically mature, have a BMI of $\geq 50 \text{ kg/m}^2$ or $\geq 40 \text{ kg/m}^2$ with significant comorbidities, have experienced failure of a formal, six-month weight loss program, and be capable of adhering to the long-term lifestyle changes required after surgery. In addition, centers should offer this procedure only if surgeons are experienced in bariatric surgery and a team of specialists is capable of long-term follow-up care of the metabolic and psychosocial needs of the patient and family” (Spear, et al., 2007).

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN):

NASPGHAN stated that until more data are available in children, gastric bypass surgery should be considered only for well-informed and motivated adolescents who meet the following criteria:

- severe obesity (BMI ≥ 40)
- failure of ≥ 6 months of organized attempts at weight loss
- near-complete skeletal maturity
- significant comorbidities that would be responsive to sustained weight loss

Extensive counseling, education, and support are required both before and after gastric bypass. Only a surgeon with extensive experience with bariatric surgery should perform gastric bypass surgery. Finally, adolescents undergoing gastric bypass require lifelong medical and nutritional surveillance, especially during pregnancy (Baker, et al., 2005).

Systematic Reviews on Bariatric Surgery

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 non-surgical 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.

A systematic review by Colquitt et al. (2009) included three randomized controlled trials (RCTs) and three prospective cohort studies comparing surgery to non-surgical management, and 20 RCTs comparing different bariatric procedures. A meta-analysis was not appropriate. It was found that surgery results in greater weight loss than conventional treatment in moderate (BMI > 30) as well as severe obesity. Reductions in comorbidities, such as diabetes and hypertension, also occur. Bariatric procedures were assessed, but some comparisons were assessed by one trial. The limited evidence suggested that weight loss following gastric bypass is greater than vertical banded gastroplasty or adjustable gastric banding, but similar to isolated sleeve gastrectomy (SG) and banded gastric bypass. Isolated SG appears to result in greater weight loss than adjustable gastric banding. Evidence comparing vertical banded gastroplasty with adjustable gastric banding was found to be inconclusive.

O'Brien and Colleagues: O'Brien et al. (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 LAGB 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., 2006).

Centers for Medicare and Medicaid Services (CMS): In February 2006, CMS issued an updated coverage decision for bariatric surgery. Based on their analysis of the medical literature, it was determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) are reasonable and necessary for Medicare beneficiaries who have a BMI $\geq$ 35, have at least one comorbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. According to CMS, medical treatment which includes dietary manipulation, behavior modification and medication, should be routinely attempted either individually or in combination and shown to be unsuccessful prior to considering a patient for bariatric surgery. There are no consistent standards in the literature regarding the optimal length of a medical treatment trial; however, 6–12 months is believed to be a reasonable time frame.

Reanalysis of the data on surgical volume identified surgical experience as a significant factor in safety for bariatric surgery at both facility and surgeon levels. Based on this finding, CMS modified their proposed decision to now provide coverage for patients age 65 and older as long as the bariatric procedures are performed in facilities that are most likely to achieve better outcomes. CMS has determined that covered bariatric surgery

procedures are reasonable and necessary only when performed at facilities that are certified by the American College of Surgeons (ACS) or by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE).

Agency for Healthcare Research and Quality (AHRQ) Evidence Report: In October 2004, the Agency for Healthcare Research and Quality of the U.S. Department of Health and Human Services released an evidence report on the surgical and pharmacological treatment of obesity. The detailed report drew the following conclusions regarding surgery:

- Bariatric surgical treatment results in greater sustained weight loss than nonsurgical treatments in very obese individuals (BMI ≥ 40), resulting in improved health outcomes (reduction in diabetes and sleep apnea, improved quality of life). While not conclusive, the data suggest greater sustained weight loss for bariatric surgical treatment than for nonsurgical treatment in patients with BMI between 35 and 40.
- Roux-en-Y Gastric bypass (RYGB), vertical banded gastroplasty (VBG) and adjustable banding procedures all result in substantial weight loss.
- RYGB results in greater weight loss than VBG in severely obese individuals.
- Postoperative mortality rates of less than one percent have been achieved by a number of surgeons and bariatric surgical centers. The postoperative mortality rate in other settings may be higher.
- Few clinical trials have compared outcomes among different bariatric surgical procedures. The existing data suggest the possibility of clinically important differences in the proportion of patients reporting various complications and adverse events among those treated with RYGB, VBG, and adjustable banding procedures.
- Laparoscopic procedures result in fewer wound complications or incisional hernias than open procedures.
- The actual proportions of patients who experience some complications of bariatric surgery may be quite substantial, greater than 20 percent (although most are minor in severity)" (Shekelle, et al., 2004).

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 (Sjöström, 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 (Sjöström, 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 (Sjöström, 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 (Sjöström, 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/m², 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, 2010).

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 jejunioileal bypass, obstruction, alkaline or acid reflux esophagitis, band erosion, stricture, anastomatic ulcer, or gastric pouch dilatation following gastric restrictive procedures (Hayes, 2014; updated 2017).

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 gastrogastic 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., 2014).

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 Diabetes Mellitus (DM)

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

In a Directory Report, Hayes (2017) evaluated the safety and efficacy of Roux-en-Y gastric bypass (RYGB) for the treatment of type II diabetes (T2DM). The Report included: 1) one systematic review and two cohort studies with long-term follow-up for patients with a BMI ≥ 35 kg/m²; 2) one systematic review and three cohort studies with intermediate-term follow-up in patients with a presurgical BMI < 35 kg/m²; and 3) one systematic review and three randomized controlled trials comparing outcomes of patients treated with RYGB vs. medical treatment programs. Evidence reported that “substantive proportions” of patients with a presurgical BMI ≥ 35 kg/m² achieved diabetes remission or improvement 5–8 years following RYGB and for up to three years for patients with a presurgical BMI < 35 kg/m². Comparative evidence reported that significantly greater proportions of

patients achieved diabetes remission after RYGB compared with medical treatment programs for up to five years. There were too few studies reporting changes in HbA1C or diabetes medications to address these two outcomes. According to Hayes, the overall quality of evidence was rated as moderate and most long-term (>10 years) evidence had quality flaws (e.g., incomplete reporting and substantive loss to follow-up). Hayes concluded that there is sufficient evidence to support the use of RYGB for treatment of T2DM in patients with a BMI ≥ 35 kg/m² with no known contraindications. There is moderate-quality of evidence that RYGB is effective with intermediate-term glycemic control in patients with a BMI of 30–35 kg/m². However, to date, there are less data published on patients with a BMI of 30 to 35 kg/m² than ≥ 35 kg/m², including less data directly comparing RYGB with medical treatment programs. In addition, evidence on long-term effectiveness and prevention of diabetes-related complications is lacking in this subset of patients. Finally, due to the limited number of studies, small patient populations and short-term follow-ups, Hayes concluded that there is insufficient data to support the use of RYGB in adults with a presurgical BMI < 30 kg/m² nor has definitive patient selection criteria been established for these nonobese individuals.

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/m² 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/m² but less than 35 kg/m² 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/m² 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/m² and less than 35 kg/m² 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 $\geq 8.0\%$, 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 $9.2 \pm 1.5\%$. The primary end point was the proportion of patients with a glycated hemoglobin level of $\leq 6.0\%$ 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/m² 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/m² (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).

Professional Societies/Organizations

American Diabetes Association: The 2018 American Diabetes Association Standards of Medical Care in Diabetes discusses metabolic surgery for the treatment of diabetes. The ADA recommendations include the following:

- Metabolic surgery should be recommended as an option to treat type 2 diabetes in appropriate surgical candidates with BMI ≥ 40 kg/m² (BMI ≥ 37.5 kg/m² in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in adults with BMI 35.0–39.9 kg/m² (32.5–37.4 kg/m² in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy
- Metabolic surgery should be considered as an option for adults with type 2 diabetes with a BMI 30.0–34.9 kg/m² (27.5–32.4 kg/m² in Asian Americans) if hyperglycemia is inadequately controlled despite optimal medical control by either oral or injectable medications (including insulin).

Regarding type 2 diabetics with a BMI as low as 30 kg/m², ADA refers the reader to the Joint Statement below by the International Diabetes Organizations (Rubino, et al., 2016). 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.

Regarding teenagers, 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.

American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS): The 2013 update 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/m² 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/m² and one or more severe obesity-related co-morbidities, including type 2 diabetes (T2DM), 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), pseudotumor cerebri, gastroesophageal reflux disease (GERD), asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, may also be offered a bariatric procedure.
- Patients with BMI of 30–34.9 kg/m² 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 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/m²).
- 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).

American Society for Metabolic and Bariatric Surgery (ASMBS): The ASMBS Clinical Issues Committee (2012) published guidelines on class I obesity (e.g., BMI 30-35 kg/m²) in 2013. Based on the evidence from four RCTs (Schauer, et al., 2012; Lee, et al., 2011; Dixon, et al., 2008; O'Brien, et al., 2005) and 16 observational studies, the ASMBS determined that “for patients with BMI 30–35 who do not achieve substantial and durable weight and co-morbidity improvement with nonsurgical methods, bariatric surgery should be an available option for suitable individuals.” However the selection criteria in some of the evaluated studies included patients with severe obesity, making it difficult to generalize results solely to class I obesity.

American Association of Clinical Endocrinologists (AACE)/The Obesity Society (TOS)/American Association of Clinical Endocrinologists (AACE): The Societies updated their joint bariatric surgery guidelines. This guidance stated that patients with BMI of 30-34.9 kg/m² 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).

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/m²), 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/m²) 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/m².
- 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/m²) 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 nondiseased, 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 nonsymptomatic 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/m². 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): In a Choosing Wisely statement, the 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 (Choosing Wisely, 2015).

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, 2017):

- demonstration of hepatic steatosis by imaging or biopsy
- exclusion of significant alcohol consumption or other causes of hepatic steatosis

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), American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA): Joint practice guidelines issued in 2012 by AASLD/ACG/AGA stated that both excessive body mass index (BMI) and visceral obesity are recognized risk factors for NAFLD. According to the guidelines, in patients with severe obesity undergoing bariatric surgery, the prevalence of NAFLD can exceed 90% and up to 5% of patients may have unsuspected cirrhosis. There is also a very high prevalence of NAFLD in individuals with T2DM. AASLD /ACG/AGA recommendations included the following (Chalasani, et al., 2012):

- Liver biopsy should be considered in patients with NAFLD who are at increased risk of having steatohepatitis and advanced fibrosis.
- The presence of metabolic syndrome and the NAFLD Fibrosis Score 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 coexisting chronic liver diseases cannot be excluded without a liver biopsy.
- Foregut bariatric surgery is not contraindicated in otherwise eligible obese individuals with NAFLD or NASH (but without established cirrhosis).
- The type, safety, and efficacy of foregut bariatric surgery in otherwise eligible obese individuals with established cirrhosis due to NAFLD are not established.
- It is premature to consider foregut bariatric surgery as an established option to specifically treat NASH.

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, 2018; 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, 2018; 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).

Vena Cava Filter Placement at the Time of Bariatric Surgery

Obesity and general surgery are risk factors for venous thromboembolism. Patients undergoing bariatric surgery are generally considered to be at moderate risk for lower extremity deep vein thrombosis (DVT). Pulmonary embolus (PE) may be the first manifestation of venous thromboembolism (VTE) and is the leading cause of mortality in experienced bariatric surgery centers. 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 which should be routinely administered to bariatric surgery patients. The possible role of inferior vena cava (IVC) filters remains controversial and recommendations regarding this issues have not been established (ASMBS, 2007). 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 (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. 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/m² (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/m², 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.

Obeid et al. (2007) conducted a retrospective study to evaluate whether prophylactic placement of an IVC filter in bariatric patients determined to be at high risk is effective in reducing their risk of PE. A total of 1851 patients were identified as low risk and did not receive an IVC filter. Among these patients, 12 DVTs, 11 PEs, and four deaths occurred. Of the 248 high-risk patients who received IVC filters, three DVTs, two PEs, and two deaths occurred. The difference in the rates of PE was not significant (p=0.69). According to the authors, study results suggested that the use of prophylactic IVC filters reduces the risk of PE in high-risk patients to a rate comparable to the baseline risk of a low-risk group. The study is limited by its retrospective, nonrandomized design.

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/m² (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/m², 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 caval 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 caval 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).

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).

Upper Endoscopy at the Time of Bariatric Surgery

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], 2008).

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).

In 2008, the Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) issued a guideline on the use of endoscopy in the bariatric surgery patient. Recommendations include the following:

- An upper endoscopy should be performed in all patients with upper-gastrointestinal-tract symptoms who are undergoing bariatric surgery.
- Upper endoscopy should be considered in all patients undergoing Roux-en-Y gastric bypass (RYGB), regardless of the presence of symptoms.
- In asymptomatic patients who are undergoing gastric banding, a preoperative upper endoscopy should be considered to exclude large hernias that may change the surgical approach.
- An endoscopic evaluation is useful for diagnosis and management of postoperative bariatric surgical symptoms and complications.

The guideline does not discuss any indications for upper endoscopy performed during bariatric surgery (Anderson, et al., 2008).

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 for Bariatric Surgery

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 bariatric surgery (Mechanick, et al., 2013; 2008) stated that the best choice for any bariatric procedure (type of procedure and type of approach) depends on the available local-regional expertise (surgeon and institution), patient

preferences, risk stratification, and other factors, with which the referring physician(s) must become familiar. Within the guidelines, the following bariatric procedures are categorized as investigational:

- gastric bypass with laparoscopic adjustable gastric banding (LAGB)
- robotic procedures
- endoscopic (oral)-assisted techniques
- gastric balloon
- gastric pacer
- vagus nerve pacing
- vagus nerve block
- sleeve gastrectomy

It is further stated that at this time there is insufficient conclusive evidence to recommend specific bariatric surgical procedures for the general severely obese population. If there is appropriate surgical and institutional expertise available, laparoscopic procedures should be selected over open procedures because of decreased postoperative complications. This approach applies for vertical banded gastroplasty, laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB) and biliopancreatic diversion with duodenal switch.

The following are recommended AACE/TOS/ASMBS selection criteria for bariatric surgery:

- Weight (adults): BMI ≥ 40 kg/m² with no comorbidities, BMI ≥ 35 kg/m² with obesity-associated comorbidity
- Weight loss history: failure of previous nonsurgical attempts at weight reduction, including nonprofessional programs (e.g., Weight Watchers, Inc.)
- Commitment: expectation that patient will adhere to postoperative care; follow-up visits with physician(s) and team members; recommended medical management, including the use of dietary supplements; instructions regarding any recommended procedures or tests
- Exclusions: reversible endocrine or other disorders that can cause obesity; current drug or alcohol abuse; uncontrolled, severe psychiatric illness; lack of comprehension of risks, benefits, expected outcomes, alternatives, and lifestyle changes required with bariatric surgery

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 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/m² or more, or between 35 kg/m² and 40 kg/m² 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 for at least six months
- 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/m² in whom surgical intervention is considered appropriate (NICE, 2014).

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).

Coding/Billing Information

Note: 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.

Initial Bariatric Surgery

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
44799 [†]	Unlisted procedure, small intestine

[†]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

HCPCS Codes	Description
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S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
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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
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43999	Unlisted procedure, stomach
44238	Unlisted laparoscopy procedure, intestine (except rectum)
44799	Unlisted procedure, small intestine
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	Incision for 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
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
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed

Reoperation and Revisional Bariatric Surgery

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

CPT®** Codes	Description
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
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43850	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy
43855	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy

43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	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

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)
43850	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy
43855	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	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

HCPSC Codes	Description
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

Not Covered when used to report herniorrhaphy or upper gastrointestinal endoscopy performed at the time of the primary bariatric procedure as each is considered integral to the primary procedure and not separately reimbursable:

CPT® Codes	Description
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
43332	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis
43333	Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis
43334	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis
43335	Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis
43336	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis
43337	Repair, paraesophageal hiatal hernia, (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis

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

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)
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
47610	Cholecystectomy with exploration of common duct;

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