Medical Coverage Policy

Effective Date.. 6/15/2017
Next Review Date...................................... 6/15/2018
Coverage Policy Number 0051

Bariatric Surgery

Table of Contents

Related Coverage Resources

Gastric Pacing/Gastric Electrical Stimulation (GES)
Obstructive Sleep Apnea Treatment Services
Panniculectomy and Abdominoplasty
Sleep Testing Services
Vagus Nerve Stimulation (VNS)

Coverage Policy

Bariatric surgery is specifically excluded under many benefit plans and may be governed by state and/or federal mandates. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Unless excluded from the benefit plan, this service is covered when the following medical necessity criteria are met.

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

- Medical management including evidence of active participation within the last 12 months in a weight-management program that is supervised either by a physician/physician's assistant/nurse practitioner or a registered dietician for a minimum of three consecutive months ((i.e., ≥ 89 days). The weight-management program must include monthly documentation of **ALL** of the following components:
  - weight
  - current dietary program
  - physical activity (e.g., exercise program)

  Programs such as Weight Watchers®, Jenny Craig® and Optifast® are acceptable alternatives if done in conjunction with the supervision of a physician/physician's assistant/nurse practitioner or registered dietician and detailed documentation of participation is available for review. However, physician-supervised programs consisting exclusively of pharmacological management are not sufficient to meet this requirement.

- A thorough multidisciplinary evaluation within the previous six months which includes ALL of the following:
  - an evaluation by a bariatric surgeon recommending surgical treatment, including a description of the proposed procedure(s) and all of the associated Current Procedural Terminology (CPT) codes
  - a separate medical evaluation and/or a recommendation for bariatric surgery from a physician/ physician's assistant/nurse practitioner other than the requesting surgeon
  - 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 (first 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 (jejunoileal bypass)	44238, 44799
Intragastric balloon (e.g., Orbera™, ReShape™)	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 covered 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 covered bariatric surgery procedure if coverage for bariatric surgery is available under the individual's current health benefit plan

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:

- Coverage for bariatric surgery is available under the individual's current health benefit plan.
- The requested procedure is a regularly covered bariatric surgery (see above for specific procedures).
- 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 is considered experimental, investigational or unproven for this indication.

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)
- herniorrhaphy for an asymptomatic hiatal hernia
- routine vena cava filter placement for individuals not at high risk for venous thromboembolism (VTE)

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/m^2 (Brethauer, et al., 2013). The National Heart, Lung and Blood Institute (NHLBI) (1998) recommends 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) defines 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:

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

Clinically severe or morbid obesity is defined as a BMI ≥ 40 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/m^2) and have two or more obesity-related medical conditions or are frankly obese (BMI >30 kg/m^2), a six-month goal of a 10% weight loss can be set (1 to 2 lb/wk) and a program of diet, exercise, and behavioral therapy prescribed. If, after six months, the target weight is not achieved, one can consider adding pharmacologic therapy for those at greatest risk (BMI >27 kg/m^2 plus two or more cardiovascular risk factors, or BMI >30 kg/m^2).
- For markedly obese persons at greatest risk (BMI >35 kg/m^2 with two or more obesity-related medical conditions or BMI >40 kg/m^2), consider a surgical approach if serious and repeated attempts using the foregoing measures have been unsuccessful.

The NHLBI guidelines (1998) 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 recommends 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 greater than or equal to 30 with no concomitant obesity-related risk factors or diseases, or for individuals with a BMI greater than or equal to 27 with concomitant obesity-related risk factors or diseases.

Clinical supervision is an essential component of dietary management. According to the NHLBI, “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 (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 (AACE Diabetes Mellitus Clinical Practice Guidelines Task Force, 2007). During the period of active weight loss, regular visits of at least once per month and preferably more often with a health professional for the purposes of reinforcement, encouragement, and monitoring will facilitate weight reduction” (NHLBI, 1998). Physicians can also provide clinical oversight and monitoring of what are often complex comorbid conditions and can select the optimal and most medically appropriate weight management, nutritional and exercise strategies. Some commercially available diet programs do not consistently provide counselors who are trained and certified as registered dieticians or with other equivalent clinical training. However, diet programs/plans, such as Weight Watchers®, Jenny Craig® or similar plans are acceptable methods of dietary management if there is concurrent documentation of at least monthly clinical encounters with a physician.

Surgical Intervention

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

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

With bariatric surgery procedures, patients lose an average of 50–60% of excess body weight and have a decrease in BMI of about $10kg/m^2$ during the first 12–24 postoperative months. 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 with short-term follow-up. Cohen et al. (2006) reported an excess weight loss (EWL) rate of 81% for patients (n=37) with uncontrolled co-morbidities who underwent laparoscopic Roux-en-Y gastric bypass. The mean preoperative BMI for these patients was 32.5 kg/m^2. The follow-up range was 6–48 months. A case series (n=93) by Parikh et al. (2006) examined the effectiveness of laparoscopic adjustable gastric banding with the LAP-BAND in patients with a BMI of 30-35 kg/m^2. Of the 93 patients, 42 (45%) had co-morbidities, including asthma, diabetes, hypertension, and sleep apnea. At three years of follow-up, the BMI was 18-24 kg/m^2 in 34%, 25-29 kg/m^2 in 51%, and 30-35 kg/m^2 in 10%.

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

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

Preoperative Weight Loss Requirement: 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 state 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. 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 ($p=0.06$).

A prospective RCT by Solomon and colleagues (2008) conducted a prospective randomized 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 was no statistically significant difference between the two groups when patient weight, BMI, amount of excess weight-loss, change in BMI, and resolution of comorbidities were compared.

Harnisch et al (2008) performed a retrospective analysis of 1629 consecutive patients undergoing LRYGB and compared patients with a preoperative weight gain (n=115) to those with a preoperative loss (n=88) of ≥ 10 lbs. No difference was found in the % excess weight loss at 12 months. At 12 and 24 months of follow-up there was no significant difference in the resolution rates of diabetes, hypertension, and continuous positive airway pressure discontinuation. No differences in perioperative complications or conversion rates were detected.
Ali et al. (2007) reported on a series of 351 patients who had undergone LRYGB. Patients were divided into four groups depending on the percentage of body weight loss achieved before surgery: group 1, none or gain; group 2, <5%; group 3, 5-10%; and group 4, >10%. Data were collected regarding the demographics, BMI change, and excess weight loss. The maximum follow-up was 36 months. Of the 351 patients enrolled in the study, follow-up data was available for 302 at six months, 246 at 12 months, 167 at 24 months and 71 at 36 months. Groups 3 and 4 had significantly greater initial excess weight and BMI ($p<0.05$) but these became similar after the preoperative weight loss. Most patients (74%) were able to lose weight before surgery, with 36% losing >5% body weight. Patients who lost weight preoperatively demonstrated more excess weight loss and BMI change from baseline that reached statistical significance at several points during follow-up ($p<0.05$). This study is limited by its retrospective design and loss to follow-up.

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 small sample size and loss 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 (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 this 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.

A 2016 position statement issued by the ASMBS cites the lack of data from RCTs supporting mandated preoperative weight loss. The ASMBS states 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) states 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 (2010) evidence-based guidelines state 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."

According to the guidelines for bariatric surgery from the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (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 state 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).

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.

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 state 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 (Mechanik, 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).

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.

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).

LAP-BAND: The LAP-BAND received premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) in June 2001. The FDA- approval letter states 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, as 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 done either 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.

REALIZE: The REALIZE Adjustable Gastric Band received a PMA from the U.S. FDA in 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.

LASGB 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 and prospective case series. Numerous case series have been published, with several studies including over 500 patients each. A limited number of randomized trials have been published, with few studies comparing adjustable gastric banding with established surgical approaches, such as gastric bypass. Well-designed comparative clinical trials comparing adjustable banding with established bariatric surgical procedures are limited. BMI inclusion criteria for studies have generally been within the guidelines set forth by the NHLBI (i.e., BMI ≥ 40 or 35–39.9 with an obesity related co-morbid condition). While a number of these studies and case series report a substantial weight loss following laparoscopic banding, the percentage of 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 results in a higher percentage of weight loss compared to LAGB.

Jan et al. (2005) studied a consecutive series of patients who underwent either LRYGB or LAGB 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 after LRYGB potentially greater and the reoperation rate greater in the LAGB group. Early weight loss was greater in the bypass group; however, it was noted that the difference appeared to diminish over time (Jan, et al., 2005).

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 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 ($r=0.48$; $p=0.032$).

Data supporting the use of laparoscopic gastric banding comes primarily from a large number of clinical series. There is evidence to suggest that laparoscopic adjustable gastric banding (LAGB) is safe and effective and may be a surgical option for those obese individuals with a BMI of less than 50 who are not candidates for Roux-en-Y gastric bypass (Chapman, et al., 2004). 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 is removed. The small pouch that remains is connected directly to the final segment of the small intestine, diverting bile and pancreatic juice into the distal ileum. Increased malabsorption and greater excess weight loss (EWL) occur, but at the expense of a higher incidence of both surgical and metabolic complications. These complications include: anastomotic ulceration, diarrhea, protein caloric malnutrition, metabolic bone disease and deficiencies in the fat-soluble vitamins, vitamin B_{12}, iron and calcium.

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

BPD Literature Review: There is limited available evidence in the literature evaluating the safety and effectiveness of BPD without DS, as the procedure has been largely supplanted by BPD/DS. Sethi et al. (2016) published a retrospective cohort study (n=100) of patients who underwent BPD (34%) and BPD/DS (64%) between 1999 and 2011 in a single institution. The mean preoperative BMI was 50 (range 35.4–75.3). The primary outcome was weight loss measured at two, five, and 10 years postoperatively. Secondary outcomes included co-morbidity remission; long-term complications; nutritional deficiencies; and patient satisfaction. Mean follow-up was 8.2 years and ranged from one to 15 years. At 10 years, 72% of patients (56/78 eligible) were available for follow-up. Excess weight loss (EWL) was 65.1% at two years, 63.8% at five years, and 67.9% at 10-15 years postoperatively. BPD/DS was found to be associated with 11% greater EWL across the study period (p<0.0001). A greater %EWL was also reported to occur in those with preoperative BMI < 50 kg/m^2 versus ≥ 50 kg/m^2 (p=0.042). At a mean of 7.7years postoperatively, remission of co-morbidities was 65% for hypertension, 40% for GERD, 58% for diabetes, and 75% for hyperlipidemia. Long-term complications requiring surgery occurred in 37% of patients (incisional hernia [9%], internal hernia [8%], weight loss failure [8%], small bowel obstruction [7%], severe malnutrition [4%], and hiatal hernia [2%]) at an average of 4.4 years postoperatively. Complications were evenly distributed between BPD and BPD/DS with the exception of internal hernias which were only identified in BPD/DS patients. Satisfaction with choice of surgical procedure was reported by 97% of patients. Study limitations include the retrospective design and loss to follow-up. **Level of Evidence: 3**

Gracia et al. (2007) studied two series of BPD patients depending on the length of the common and alimentary limbs in their procedures. A modified BPD (75-225 cm) was performed in 70 patients and 150 patients underwent BPD as described by Scopinaro (50-200 cm). The results were analyzed in terms of weight loss, co-morbidity improvement, and postoperative morbidity using BAROS. The follow-up range was 1-12 years. BMI loss and percentage of excess BMI lost (%EBMIL) were higher in the Scopinaro group than in the modified group, without statistical significance. At four-year follow-up, the EBMIL was 78.9% for patients in the Scopinaro group and 77.2% for those in the modified group. There was more prevalence of malnutrition and of iron deficiency in the Scopinaro group 16% and 60% respectively, than in the modified group 2% and 40% respectively. Early postoperative morbidity was 28.5% in the Scopinaro group and 15.5% in the modified group. The most common complication was wound infection 9% in the Scopinaro group versus 7% in the modified group. More major complications included wound dehiscence (n=2, 2.7%) occurring in the Scopinaro group, anastomotic leaks that required reoperation in both the Scopinaro (n=3, 2%) and the modified (n=1, 1.4%) groups. On long-term follow-up, major complications were: incisional hernia (50%, 42 %) and protein malnutrition that required in-hospital parenteral nutrition (11%, 2.8%) (n=16) respectively for patients in the Scopinaro and modified groups. Total postoperative mortality of BPD was 1.3% (3/220). The causes of death were anastomotic leak, pulmonary thromboembolism, and pneumonia with adult respiratory distress syndrome.

Guedea et al. (2004) evaluated weight loss, morbidity and mortality after BPD in 74 patients who completed five or more years of follow-up. Mean preoperative BMI was 54 +/- 8 kg/m^2. The procedure consisted of a 200-cm alimentary limb and a 50-cm common limb. Initial excess weight loss (EWL) and course of BMI were analyzed between morbidly obese and super-obese patients. EWL at one year follow-up was 67%, at two years 75%, at five years 70% and at seven years 71%. There were significant differences between morbidly obese (BMI <50 kg/m^2 and super-obese (BMI >50 kg/m^2), with better results in the morbidly obese group (p=0.026). There was no mortality in this series. Early postoperative morbidity was 16% with the most frequent complication being wound infection (6.75%). Major complications were: wound dehiscence (n=2, 2.7%) and anastomotic leak (2, 2.7%). The late postoperative rate of incisional hernias was 33.8%, however, 16.2% of patients had had an abdominal hernia prior to bariatric surgery. Glycemia, cholesterolemia, and triglyceridemia became normal in 100% of patients at one year after BPD and remained stable during all follow-up. Blood pressure decreased, so that 82.4% of the patients who were on antihypertensive medications had stopped these by one year after the operation. All patients who had sleep apnea syndrome and overnight continuous positive airway pressure were able to discontinue that treatment at six months.

BPD/DS Literature Review: Evidence evaluating the use of BPD/DS has been includes randomized controlled and comparative trials and case series (Topart, et al., 2011; O'Rourke, et al., 2006, Parikh, et al., 2005; Rabkin, et al., 2003; Anthone, et al., 2003). Sovik et al. (2011) conducted a randomized, parallel-group trial (n=60) comparing the outcomes of weight loss, improvements in cardiovascular risk factors, and adverse events in patients who underwent duodenal switch (n=29) versus gastric bypass (n=31). Participants were eligible for inclusion if they had a BMI of 50-60 kg/m^2, were 20 to 50 years of age, and had not sustained previous weight loss. Exclusion criteria were a history of major abdominal or bariatric surgery, disabling cardiopulmonary diseases, cancer, long-term treatment with oral corticosteroids, and conditions associated with poor adherence. The primary outcome was the change in BMI after two years. Secondary outcomes included anthropometric measures; concentrations of blood lipids and glucose, and adverse events. The study was completed by 58/60 patients. At two-year follow-up, there was a statistically significant difference in BMI and total cholesterol concentration reduction favoring duodenal switch (p<0.001). Reductions in low-density lipoprotein cholesterol concentration, anthropometric measures, and fat mass were also greater after duodenal switch (p≤0.010 for each between-group comparison). Overall, significantly more participants in the duodenal switch group had adverse events occurring from surgery and up until two years: 10/31 (32%) after gastric bypass compared to 18/29 (62%) after duodenal switch (p=0.021). It was noted that "because duodenal switch is often reserved for patients with a BMI greater than 50 kg/m^2, balancing the health benefits and safety of this operation to those of other procedures is important. Study results are limited by the small sample size and relatively short-term follow-up (Sovik, et al., 2011).

Søvik et al. (2010) randomized 60 patients with a BMI of 50-60 kg/m^2 to undergo laparoscopic Roux-en-y gastric bypass (LRYGB) or laparoscopic BPD/DS. BMI, percentage of excess BMI lost, complications and readmissions were compared between groups. The mean BMI at one year decreased from 54.8 to 38.5 kg/m^2 after LRYGB and from 55.2 to 32.5 kg/m^2 after BPD/DS. The percentage of excess BMI lost was greater after BPD/DS (74.8%) than after LRYGB (54.4%), a difference that was statistically significant (p<0.001).

In a comparative series, Prachand et al. (2006) reported on 350 super-obese patients who underwent open duodenal switch (DS) (n=198) or RYGB (n=152). Successful weight loss was defined as achieving at least 50% loss of excess body weight. At 36 months, the follow-up rate was approximately 50% for each group. The percentage excess weight loss (EWL) at this point continued to be greater for DS than RYGB, 68.9% vs. 54.9% respectively (p < 0.05). The 30-day mortality rate was found to be equal (i.e., one of 198 for DS patients, zero of 152 for RYGB patients). The authors concluded that direct comparison of DS to RYGB demonstrates superior weight loss outcomes for DS. Limitations of the study include its nonrandomized design and loss to follow-up.

In a review of their experience with open biliopancreatic diversion with duodenal switch (BPD/DS), Hess et al. (2005) reported 10-year follow-up data on 167 (92%) of a cohort of 182 patients. The mean initial BMI of patients was 50. 9. The average EWL was reported to be 75%. Type 2 diabetics have had a 98% cure rate (i.e., normal plasma glucose a few weeks after surgery). Hypercholesterolemia and other comorbidities were also reportedly improved. There were eight reversals typically due to excessive weight loss and protein malnutrition. A total of 37 revisions were necessary for the same two reasons, in addition to inadequate weight loss and uncontrolled diarrhea. The investigators maintain that BPD/DS has proven to be a safe and effective procedure for the treatment of morbid obesity with low rates of complications and sustained long-term weight loss.

The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) guideline for laparoscopic bariatric surgery states that In BPD, the common channel should be 60–100 cm, and the alimentary limb 200–360 cm. DS diminishes the most severe complications of BPD, including dumping syndrome and peptic ulceration of the anastomosis. BPD is effective in all BMI >35 kg/m^2 subgroups, with durable weight loss and control of comorbidities beyond five years. Laparoscopic BPD provides equivalent weight loss, shorter hospital stay, and fewer complications than the open approach. BPD may result in greater weight loss and resolution of comorbidities than other bariatric surgeries, but with the highest mortality rate (SAGES, 2009).

The available data suggests that BPD or BPD/DS is supported by the available literature as being safe and effective, but technically challenging. The procedures can be accomplished in patients who are considered candidates for bariatric surgery, and can produce significant long-term weight loss. Additional well-designed randomized trials comparing BPD/DS to other procedures are needed to further define the role of open or laparoscopic BPD/DS in the treatment of morbid obesity.

Sleeve Gastrectomy (SG)

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

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

The %EWL for laparoscopic sleeve gastrectomy (LSG) has been reported to vary from 33%–90% and to be sustained 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) have evaluated SG and support safety and efficacy. Shi et al. (2011) performed a systematic review of the literature (n=15 studies; 940 patients) analyzing outcomes of LSG compared to benchmark clinical data from LAGB and LRYGB. The %EWL for LSG varied from 33% to 90% and appeared to be sustained up to three years. The mortality rate was 0%–3.3% and major complications ranged from 0%–29% (average 12.1%). It was summarized that early, non-randomized data suggest that LSG is efficacious in the surgical management of morbid obesity. However, it is not clear if weight loss following LSG is sustainable in the long term.

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

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

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

The American Society for Metabolic and Bariatric Surgery (ASMBS) updated their position statement on SG in 2009. The ASMBS "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).

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).

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

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.

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) suggests 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).

Fobi-Pouch

The Fobi-Pouch has been proposed by one investigator as an alternative to traditional bariatric surgery. The limiting proximal gastric pouch 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), both authored by the developers of the technique, along with anecdotal information. 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.

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

Intragastric Balloon (IGB)
Treatment with the IGB has been proposed as a temporary aid for obese patients who have had unsatisfactory results in their clinical treatment for 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.

The BioEnterics® Intragastric Balloon (BIB® System) (INAMED Health, Santa Barbara, CA) was introduced in the mid-1990s. The BIB system consists of a transparent silicone balloon that is inflated via a silicone catheter through a self-sealing radio-opaque valve. The balloon is generally filled with 400 mL to 700 mL of sterile saline and is left in place for up to six months; beyond this, the risk of spontaneous deflation is considered too high. In 2013, the BIB system was rebranded as Orbera™. Other balloons being investigated include the following:

- ReShape Integrated Dual Balloon System
- Heliosphere® (Helioscopie Medical Implants, Vienne, France),
- Silimed Gastric Balloon (Silimed, Rio de Janeiro, Brazil)
- Ullorex® Oral Intragastric Balloon (Phagia Technologies, Inc., Fort Lauderdale, FL).

Of these devices, the Orbera and the ReShape are currently U.S. FDA-approved.

RESHAPE: 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.

ORBERA: 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 400cc-700 cc of saline to best align with the patient's anatomy. The FDA states 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.

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 Technology Brief reviewed the available evidence (n=10 studies) on intragastric balloons for obesity. The review included randomized controlled comparative trials with patient populations ranging from 18-326. Adult patients undergoing treatments for obesity or those with a BMI ≥ 27 kg/m^2 were selected. Comparators included sham or no IGB, restricted diet and exercise alone, and different IGB devices. Outcome measures included EWL, total weight loss, changes in BMI and quality of life (QOL), adverse events or complications. The follow-up timeframe was four to 24 months. The evidence for EWL with IGBs compared to restricted diet and exercise alone was inconsistent. The evidence for changes in BMI was also found to be inconsistent. Consistent evidence demonstrated improved patient-reported QOL. The evidence was also consistent in terms of the adverse effects associated with IGB which included nausea, vomiting, and/or related abdominal issues. The overall of the evidence was reported to be low based on individual study limitations, some inconsistencies between studies in outcomes, and the lack of large, long-term studies. It was summarized that "the available low-quality evidence suggests that IGBs have mixed results with regard to weight loss and reduction in BMI over the short term when used as an adjunct to diet and exercise" (Hayes 2016; 2017).

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 on 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 were 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 balloon removal 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 and 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 of 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. While study results suggest that the dual balloon device is more effective in producing EWL than diet and exercise alone, additional well design studies with longer term follow-up are need to determine overall safety and efficacy.

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 to 128 patients, and mean baseline BMIs ranged from 35.0 to 50.4 kg/m^2. IGBs were compared to behavioral modification, pharmacotherapy, and observation without treatment. Results were calculated with weighted mean differences which favored IGB for weight loss (p<0.01). Statistically significant differences in favor of IGB were also found for EWL 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-up periods in studies. 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 (Zheng et al., 2015).

Fuller et al. (2013) conducted an RCT (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 between 18 and 60 years with a BMI of 30-40 kg/m^2 for at least two years and had failed supervised weight reduction programs. Exclusion criteria included conditions of the gastrointestinal tract, prior gastric surgery or insertion of an IGB, hepatic or renal insufficiency, or psychiatric disorder. The primary outcome was % 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 IGBG versus control group (p=0.007) No significant difference in % metabolic syndrome remission was found. Adverse events related to the gastrointestinal tract were common in the IGB group but predominantly resolved within two weeks

In a case-control study, Genco et al. (2009) compared 40 patients who underwent LSG as a first step in BPD/DS to 80 patients who had IGB therapy and served as controls. At six-month follow-up, mean BMI was 46.2 ± 3.5 and 45.3 ± 5.5 kg/m^2 for the IGB and LSG patients, respectively. After 12 months IGB patients regained BMI, while LSG patients continued to lose weight. There were no significant differences between groups for the comorbidities evaluated.

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

In a Cochrane review of the evidence for IGB, Fernandes et al. (2007) included nine randomized, controlled clinical trials (n=395) spanning the years 1988 to 1999. One study was performed in 2005. In these trials, IGB was compared 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 this procedure.

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-up of 12 months to five years (Kim, et al., 2015; Niazi, et al., 2013; Fried, et al., 2012; Taha, 2012; Talebpour, et al., 2012; Skrekas, et al., 2011; Ramos, et al., 2010). Outcomes of %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.

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 an age of 18–62 years and a BMI of 32–35 kg/m^2 as well as a history of GERD and obesity for more than five years with unsuccessful attempts at conservative weight-loss therapy, as 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, such as bulimia, medical therapy for weight loss within the previous 2 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 % EWL in all studies was found to be approximately 50% at six months, 60–65% in 12 months, and 60–65% in 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. “The initial data suggests that LGCP may be effective for short- and medium-term weight loss. More data is required and randomized control trials must be completed in order to reach safe conclusions” (Kourkoulos, et al., 2012).

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 (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% to 15.3%. It was concluded that “prospective randomized studies with long-term follow-up comparing gastric plication to other well-established bariatric procedures are needed to prove the reliability and metabolic effectiveness of such new procedure” (Abdelbaki, et al., 2012).

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 placation 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).

The National Institute for Clinical Excellence (NICE) 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 (NICE, 2012).

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

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.

There is insufficient evidence in the published, peer-reviewed medical literature demonstrating safety and effectiveness of gastric placation. 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.

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 has been proposed as a bariatric surgery method. The controversial procedure is performed laparoscopically and is similar to the Roux-en-Y technique except that, after the division of the stomach, a jejunal loop is created and anastomosed to the gastric pouch. Complications include biliary reflux and esophagitis. Evidence supporting the use of the mini-gastric bypass is in the form of small case series (Rutledge, 2001) and one small randomized open comparison of the procedure to LRYGB (Lee, et al., 2005). The authors reported similar efficacy in terms of excess weight loss (EWL) at two years. However, longer-term follow-up with regard to the risk of complications is recommended by the investigators.

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).

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. 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 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 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.

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

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

According to the National Institute for Health and Care Excellence (NICE) guidance on the use of duodenal–jejunal bypass sleeves, "current evidence on the safety and efficacy of implantation of a duodenal–jejunal bypass sleeve) for managing obesity is limited in quality and quantity. Therefore, 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" (NICE, 2013).

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 popularly described as a non-invasive weight loss procedure to reduce the size of a patient's stomach without any incisions.

StomaphyX: The StomaphyX was granted marketing approval by the FDA via the 510(k) process on March 9, 2007 because it is considered to be 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 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. According to the FDA, the StomaphyX system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract.

According to the American Society for Metabolic and Bariatric Surgery (ASMBS) there are currently a number of end luminal innovations and novel devices and technologies in different stages of development or application to the treatment of obesity, including provisional interventions. "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. Therefore, the use of novel technologies should be limited to clinical trials done in accordance with the ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention" (ASMBS, 2009a).

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) states 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.

There is insufficient evidence in the published, peer-reviewed scientific literature to support the use of any of the following bariatric procedures in the treatment of clinically severe/morbid obesity, as they have not been proven to achieve equivalent or improved patient outcomes relative to available alternatives:

- Fobi-Pouch
- intragastric balloon (IGB)
- mini-gastric bypass (jejunum is anastomosed to the stomach, as in the Billroth II procedure)
- Natural Orifice Transluminal Endoscopic Surgery™ (NOTES™) (e.g., ROSE, StomaphyX™)/endoscopic oral-assisted procedures

Single-Anastomosis Duodenal Switch

The BPD/DS, while proven to be efficacious for 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 that is faster and easier to perform.

The evidence evaluating single anastomosis duodeno-ileal bypass or SADI-S for morbid obesity consists of few 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.

According to the ASMBS, “single-anastomosis duodenal switch procedures are considered investigational at present. The procedure 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, 2016).

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).

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

- 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 (2016). In this study, patients were randomized to receive treatment with aspiration therapy plus lifestyle counseling (n=137) or lifestyle counseling alone (n=70).Inclusion criteria were age 21–65 years old and a BMI of 35.0–55.0 kg/m^2. Exclusion criteria included previous bariatric surgery, serious cardiovascular disease, use of medications that cause clinically significant weight gain or loss, and a history of an eating disorder. The first co-primary end point was mean % 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 with success defined as at least 50% of the AspireAssist group achieving at least 25% EWL. Secondary end points included change in %TBW 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, and the short-term follow-up period (Thompson, et al., 2017). Study results suggest 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. **Level of Evidence: 1**

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 EWL was 54.4% at 12 months and 61.5% at 24 months. In diabetic patients (n=7), there was a significant reduction in HbA1c level from a median of 47to a median of 42 (p=0.03). The primary adverse effect was moderate to severe pain. Quality of life measured by EQ-5D and VAS was reported to significantly increase during treatment. Study limitations include the non-randomized controlled design, small patient population, and short-term follow-up.

A randomized controlled pilot study (n=18 subjects) by Sullivan et al. (2013) assigned obese subjects in a 2:1 ration to undergo aspiration therapy for one year plus lifestyle therapy (n=11) or lifestyle therapy alone (n=7). Lifestyle intervention comprised a 15- session diet and behavioral education program. Adults with a BMI between 40.0 and 50.0 kg/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 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. Additional well-designed, long-term studies are needed to support this treatment for Class II and III obesity.

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

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 VNB for severe obesity consists of RCTs and case series. Morton et al. (2016) conducted an RCT (n=84 patients) to evaluate the safety and efficacy of vBloc in patients with moderate obesity and comorbidities. This sub-group from the 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% EWL of 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. These results indicate that vBloc is superior to sham intervention for moderate obesity patients with comorbidities. The study is limited by the use of data from a subpopulation and the short term follow-up period.

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 RCTs (=2 studies; ReCharge and EMPOWER studies described below), and one case series. Limitations of studies included small sample sizes, short 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 (Hayes, 2016; 2017).

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 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 endpoint was % EWL at 12 months and the percentage of patients achieving ≥ 20% EWL and ≥ 25% EWL. At 12 months, 52% of patients in the vagal nerve block group achieved 20% or more excess weight loss and 38% achieved 25% or more excess weight loss. In the sham group 32% of subjects achieved 20% or more loss and 23% achieved 25% or more loss. Efficacy endpoints were not met. A total of eight patients in the active therapy group required a revision procedure. Therapy-related serious adverse event rate in the vagal nerve block group was 3.7%, and included mild to moderate heartburn, dyspepsia, and abdominal pain. Acknowledged limitations include homogeneity of the patient population and a low rate of common metabolic comorbidities such diabetes. Study results indicate no significant difference in % EWL between active vagal nerve block therapy and treatment with a sham device.

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 described include compliance issues related to wearing an external device versus a completely implantable system, and the study inclusion of dietary counseling, behavior modification, and exercise training, which may have contributed to the % EWL.

Camilleri et al. (2009) conducted an open-label multicenter study (n=31) to assess the effects of a vagal blocking device on EWL, safety, dietary intake, and vagal function. Electrodes were implanted laparoscopically near the esophagogastric junction to provide intermittent vagal blocking in patients with a BMI range of 35-50 kg/m^2. The mean EWL at six months follow-up was 14.2% (p<0 .001). Calorie intake decreased by >30% at six months (p ≤ 0.01), 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.

The ASMBS position statement on VNB for obesity states 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

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= .13). There were no perioperative adverse events. However, surgical revision was required in seven patients for either 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 LAGB (n=8 studies; 352 patients), 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). 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 between the ages of 13 and 17 who underwent LABG. The mean preoperative BMI was 48. The %EWL at six-, 12- and 24-month follow-up was 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%.

A 2015 position statement from the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) 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 NAFLD is not an indication for bariatric surgery. RYGB and 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).

The ASMBS Pediatric Committee published best practice guidelines in 2012. According to these guidelines, “although current evidence is not sufficiently robust to allow a precise discrimination or recommendations among specific bariatric procedures, an increasing body of data demonstrating evidence of safety and efficacy exists for two of the more commonly performed bariatric procedures for this age group (i.e., Roux-en-Y gastric bypass [RYGB] and adjustable gastric band [AGB])” (Michalsky, et al., 2012). The ASMBS outlines the following as being strong indications for bariatric surgery in morbidly obese adolescents:

- type 2 diabetes
- moderate or severe obstructive sleep apnea (e.g., apnea-hypopnea index >15)
- nonalcoholic steatohepatitis
- pseudotumor cerebri

Similar to adults, selection criteria for adolescents being considered for a bariatric procedure should include a BMI of 35 kg/m2 with major co-morbidities or a BMI of 40 kg/m2 with other co-morbidities (e.g., hypertension, dyslipidemia) (Michalsky, et al., 2012).

Guidelines issued by the Endocrine Society Task Force recommend that bariatric surgery be considered only under the following conditions:

1. The child has attained Tanner 4 or 5 pubertal development and final or near-final adult height.
2. The child has a BMI greater than 50 kg/m^2 or has BMI above 40 kg/m^2 and significant, severe comorbidities.
3. Severe obesity and co-morbidities persist despite a formal program of lifestyle modification, with or without a trial of pharmacotherapy.
4. Psychological evaluation confirms the stability and competence of the family unit.
5. There is access to an experienced surgeon in a medical center employing a team capable of long term follow-up of the metabolic and psychosocial needs of the patient and family, and the institution is either participating in a study of the outcome of bariatric surgery or sharing data.
6. The patient demonstrates the ability to adhere to the principles of healthy dietary and activity habits.

The Task Force recommends against bariatric surgery for preadolescent children, for pregnant or breastfeeding adolescents, and for those planning to become pregnant within two years of surgery; for any patient who has not mastered the principles of healthy dietary and activity habits; for any patient with an unresolved eating disorder, untreated psychiatric disorder, or Prader-Willi syndrome (August, et al., 2008).

Recommendations from the American Academy of Pediatrics (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 ≥ 50 kg/m^2 or ≥ 40 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" (Spears, et al., 2007).

Similarly, the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition states 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).

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.

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 RYGB and sleeve gastrectomy, with both procedures having better outcomes than adjustable gastric banding. For people with very high BMI, 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. Sleeve gastrectomy led to better weight-loss outcomes than adjustable gastric banding after three years follow-up; this was based on one trial only. 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 (Colquitt, et al., 2014).

A systematic review by Colquitt et al. (2009) included RCTs (n=3) and three prospective cohort studies (n=3) 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 just one trial. The limited evidence suggests 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 LAGB (n=18), BPD with and without DS (n=7), and RYGBP (n=18). Of the LABG reports, 12 provided data on the LAP-BAND, five on the Obtech® band (Ethicon Endo-Surgery, Inc., Cincinnati, OH), and one study included both devices. Pooled data for all procedures showed a mean EWL 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 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 ≥ 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 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 $\geq$ 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.
- RYGB, 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 (Sjöstrom, et al., 2004).
- Diet therapy alone in the absence of surgery is relatively ineffective in treating obesity over the long term (Buchwald, et al., 2004).
- Severely obese patients who undergo bariatric surgery achieve greater short-, intermediate- and long-term (i.e., 10 years) weight loss, more physical activity and lower energy intake than severely obese patients treated with conventional medical interventions, such as very low-calorie diets and pharmacotherapy (Sjöstrom, et al., 2004; Buchwald, et al., 2004).
- Intermediate- and long-term (i.e., 10 years) incidence rates of recovery from risk factors such as diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, hyperlipidemia and hyperuricemia are more favorable in surgically-treated patients than in nonsurgical, severely obese patients (Sjöstrom, et al., 2004; Buchwald, et al., 2004).
- Bariatric surgery reverses, eliminates or significantly improves risk factors of diabetes, hyperlipidemia, hypertension and obstructive sleep apnea (Buchwald, et al., 2004).
- Severely obese diabetic individuals treated with bariatric surgery have shown an 80% reduction in mortality (Sjöstrom, et al., 2004).
- Weight-loss surgery has been reported to reduce the relative risk of death by 89% with an absolute mortality reduction of 5.49% (Christou, et al., 2004).
- Gastric bypass has been reported to result in more favorable overall health outcomes (i.e., weight loss, risk factor recovery/reduction) relative to other surgical interventions, such as banding procedures (Buchwald, et al., 2004).

Buchwald et al. (2009) performed a meta-analysis of 19 studies with 43 treatment arms and 11,175 patients to determine the impact of bariatric surgery on T2DM in association with the procedure performed and the weight reduction achieved. The included studies reported both weight loss and diabetes resolution separately for the 4070 diabetic patients. At baseline, the mean age was 40.2 years with a mean BMI of 47.9 kg/m^2, and 10.5% had previous bariatric procedures. Meta-analysis of weight loss was 38.5 kg or 55.9% excess weight loss (EWL). Overall, 78.1% of diabetic patients had complete resolution, and diabetes was improved or resolved in 86.6% of patients. Weight loss and diabetes resolution were greatest for patients undergoing biliopancreatic diversion with duodenal switch (BPD/DS), followed by gastric bypass, and least for banding procedures. In the studies reporting only diabetic patients, 82% of patients had resolution of the clinical and laboratory manifestations of diabetes in the first two years after surgery, and 62% remained free of diabetes more than two years after surgery (80% and 75% for the total group) (Buchwald, et al., 2009).

Gracia et al. (2009) conducted a retrospective cohort study of different procedures for morbid obesity: open vertical banded gastroplasty (VBG) (n=125), open Scopinaro biliopancreatic diversion (BPD) (n=150), open modified BPD (i.e., common limb 75 cm; alimentary limb 225 cm) (n=100), and laparoscopic Roux-en-Y gastric bypass (LRYGB) (n=115). Mean follow-up was: VBG 12 years, BPD seven years, and LRYGB 4 years. An excellent initial weight loss was observed at the end of the second year of follow-up in all techniques, followed by regain of weight observed in the VBG and LRYGB groups. Patients in the BPD groups maintained weight loss results. Mortality was: VBG 1.6%, BPD 1.2%, and LRYGB 0%. Early postoperative complications were: VBG 25%, BPD 20.4%, and LRYGB 20%. Late postoperative morbidity was: protein malnutrition 11% in Scopinaro BPD, 3% in modified BPD group, and no cases reported either in VBG group or LRYGB group; iron deficiency 20% VBG, 62% Scopinaro BPD, 40% modified BPD, and 30.5% LRYGBP. Conversion to gastric bypass or to BPD was needed for 14.5% of VBG group due to 100% weight regain or vomiting. For those in the Scopinaro BPD group, revision surgery was needed to lengthen the common limb to 100 cm in 3.2% of cases due to severe protein malnutrition. Revision surgery to distal LRYGBP (common limb 75 cm) was required for 0.8% of LRYGBP patients due to 100% weight regain. It was noted that the more complex bariatric procedures increase effectiveness but also increase morbidity and mortality. In the opinion of these investigators, “LRYGB is safe and effective for the treatment of morbid obesity. Modified BPD (75-225 cm) can be considered for the treatment of superobesity (BMI > 50 kg/m^2), and restrictive procedures such as VBG should only be performed in well-selected patients due to high rates of failure in long-term follow-up” (Gracia, et al., 2009).

Adams et al. (2007) conducted a retrospective cohort study to compare long-term rates of death from any cause and from specific causes in subjects who had undergone gastric bypass surgery compared to a group of severely obese controls. A total of 7925 surgical patients and 7925 severely obese control subjects were matched for age, sex, and BMI. The mean BMI differed significantly between the surgery group and the control group (p<0.001). During a mean follow-up of 7.1 years, adjusted long-term mortality from any cause in the surgery group decreased by 40%, as compared to the control group (p<0.001). Cause-specific mortality in the surgery group decreased by 56% for coronary artery disease (p=0.006), by 92% for diabetes (p=0.005), and by 60% for cancer (p<0.001). The estimated number of lives saved after a mean follow-up of 7.1 years was 136 per 10,000 gastric bypass surgeries. Rates of death not caused by disease (e.g., accidents, suicide), were reported to be 58% higher in the surgery group than in the control group (p=0.04). Acknowledged limitations to the study include the unknown baseline health status of patients seeking bypass surgery compared to that of control subjects. Also, the risk of death according to the amount of weight lost could not be analyzed as data on weight at time of death was unavailable (Adams, et al., 2007).

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. Cr 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 indicate 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 (Hayes, 2014; 2016). 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 metabolic complications of jejunoileal bypass, obstruction, alkaline or acid reflux esophagitis, band erosion, stricture, anastomatic ulcer, or gastric pouch dilatation (may occur following gastric restrictive procedures).

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 continues with return of comorbid conditions after initial success, requiring re-evaluation for additional surgical intervention. Such failure may be the result of a leak in the band, a large stomach pouch, or a gastrogastric fistula that can be corrected with a reoperation. Although noncompliance with diet and exercise regimens plays a role, weight gain and recurrence of comorbid conditions may occur despite patient compliance due to individual biology. In these cases, a more aggressive bariatric procedure may be indicated to provide effective therapy (Sudan, et al., 2014).

There are three main categories of RBS (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 RBS procedure performed is determined by factors such as type of primary procedure, patient anatomy and medical history and indications for RBS. Weight loss and comorbidity outcomes of LAGB patients converted to RYGB, SG, and 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 (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 either 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. Fewer studies have investigated the safety and efficacy of bariatric surgery, also referred to as metabolic surgery, in patients with a BMI less than 35 (class I obesity). Although bariatric surgery has also been proposed as a potential treatment for type 1 DM (T1DM), the published peer-reviewed medical literature contains limited evidence regarding this indication.

Literature Review: A Hayes Directory Report reviewed the available evidence (n=18 studies) on Roux-en-Y Gastric Bypass for Diabetes in Obese or Severely Obese Patients. The review included RCTs (n=7 studies) and cohort and nonrandomized controlled trials (n=11 studies) with sample sizes ranging from 34-201 patients. Follow-up in studies was 12 months to five years. Adult patients with T2DM and moderate or mild obesity (BMI < 35 kg/m^2) were included in seven studies. The overall quality of the evidence was found to be moderate. Consistent evidence demonstrated that RYGB is superior to conventional medical treatment for T2DM for patients with severe obesity. Hayes reported very limited but positive evidence for improvement in health status (e.g., glycated hemoglobin [HbA1c], , T2DM remission, EWL, BMI) after RYGB in the subpopulation of patients with T2DM and moderate or mild obesity. It was summarized that additional studies are needed to establish the safety and effectiveness of RYGB in this population (Hayes, 2014; 2016).

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 indicate 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 include an inadequate sample size and duration to detect differences in the incidence of diabetes complications, such as myocardial infarction, stroke, or death. The study protocol specifies further follow-up at years for all patients, which should allow additional assessment of even longer-term efficacy (Schauer, et al., 2014). Schauer et al. (2017) published five-year outcomes for the STAMPEDE trial. At five years, the criterion for the primary end point was met by 2/38 patients (5%) who received medical therapy alone versus 14/49 patients (29%) who underwent gastric bypass (p=0.01), and 11/47 patients (23%) who underwent sleeve gastrectomy (p= 0.03). Patients who underwent surgical procedures had a greater mean percentage reduction from baseline in glycated hemoglobin level than did patients who received medical therapy alone (p=0.003). A single major late surgical complication (i.e., reoperation) was reported.

Maglione et al. (2013) performed an Agency for Healthcare Research and Quality (AHRQ) review of the evidence (n=24 studies) on efficacy, safety, and comparative effectiveness of various types of bariatric surgery for treating adult patients with a body mass index (BMI) of 30.0 to 34.9 kg/m^2 and diabetes or impaired glucose tolerance (IGT). The review compared effectiveness of surgery versus nonsurgical interventions in this population and included primarily observational studies (n=19 studies), in addition to trials comparing different procedures (n=2 studies), and surgical versus nonsurgical interventions (n=3 studies). Studies for the analysis had to report on LAGB, RYGB, 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/m^2 in the short term was found. At one-year follow-up, surgery patients show 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—three randomized controlled trials (RCTs) directly compared surgical with nonsurgical interventions, and two came from the same group of researchers. 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 (Maglione, et al., 2013).

Ikramuddin et al. (2013) conducted a multicenter unblinded randomized trial (n=120) to compare Roux-en-Y gastric bypass with lifestyle and intensive medical management (n=60) with intensive management alone (n=60). Subjects with a hemoglobin A1c (HbA1c) level of ≥ 8.0%, BMI between 30.0 and 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 relatively small patient population and short-term follow-up.

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

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

Dixon et al. (2008) conducted an unblinded RCT to determine if surgically induced weight loss results 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 suggest 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 (Dixon, et al., 2008).

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 and short-term follow-up (Gianos, et al., 2012; Abbatini, et al., 2012; Huang, et al., 2011; Boza, et al., 2011; Serrot, et al., 2011).

According to guidelines from the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS), "The beneficial effect of bariatric surgery on T2DM is one of the most important outcomes observed. Control rates for most procedures currently performed vary from 40% to 100%. Gastric bypass and malabsorptive procedures offer the highest rates of remission of T2DM. Improvements in fasting blood glucose levels occur before significant weight loss. Insulin-treated patients experience substantial decreases in insulin requirements, with the majority of patients with T2DM able to discontinue insulin therapy by six weeks after bariatric surgery. Euglycemia has been maintained up to 14 years after RYGB, a superior outcome when compared with solely gastric restrictive procedures. BPD and BPD/DS may be even more effective at improvement of the metabolic abnormalities of T2DM, leading to discontinuation of glucose-lowering therapy in most patients. The LAGB procedure has also been shown to improve T2DM, although at a slower rate (64% to 71% remission rates within the first year) than RYGB, BPD, or BPD/DS" (Mechanik, et al., 2008).

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.

In 2013, the ASMBS in conjunction with the American Association of Clinical Endocrinologists (AACE), and the Obesity Society (TOS) 2013 updated their joint bariatric surgery guidelines. This guidance states that patients with BMI of 30-34.9 kg/m^2 with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit. There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria (Mechanick, et al., 2013). Clinical practice guidelines issued by the AACE and ACE in 2016 reaffirm these findings (Garvey, et al., 2016).

Recommendations from a 2016 joint position statement by international diabetes organizations include the following (Rubino, et al., 2016):

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

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

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

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

Cholecystectomy at the Time of Bariatric Surgery
It has been shown that there is a moderate correlation between obesity and the development of gallstones, with the risk of cholelithiasis rising as BMI increases. Furthermore, evidence in the scientific literature suggests that the rapid weight loss which occurs following certain bariatric surgical procedures increases cholesterol load, thereby increasing the risk for gallstone formation. For these reasons, some surgeons advocate the routine removal of asymptomatic normal gallbladders at the time of bariatric surgery (specifically gastric bypass procedures). It has been suggested that patients undergoing gastric bypass are at a greater risk than with other procedures, such as gastric banding, due to the malabsorption and early and rapid postoperative weight loss associated with this procedure. The issue of performing routine prophylactic cholecystectomy concurrently with bariatric surgery continues to be debated, however. 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 only 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.

Fuller et al. (2007) reported on 144 consecutive patients undergoing RYGB who were routinely screened for cholelithiasis by ultrasound. The mean age was 43 years and the mean BMI was 46 kg/m^2. A total of 29 patients had a history of prior cholecystectomy. Cholelithiasis was diagnosed preoperatively in 22 of the remaining 115 patients. Of those 22 patients, nine (41%) were symptomatic and underwent concurrent cholecystectomy and RYGB. The remaining 13 patients (59%) had asymptomatic cholelithiasis preoperatively but did not undergo cholecystectomy at the time of surgery. Patients who did not have cholecystectomy were managed with ursodiol for 6 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 (Fuller, et al., 2007).

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.

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).

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 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.

Joint practice guidelines issued in 2012 by the American Association for the Study of Liver Diseases (AASLD), American College of Gastroenterology (ACG), and the American Gastroenterological Association (AGA) state 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 include 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
A hiatal hernia occurs when part of the stomach pushes upward through the diaphragm. Hiatal hernias may be either sliding, in which the gastroesophageal junction itself slides through the defect into the chest, or non-sliding (paraesophageal), in which case the junction remains fixed while another part of the stomach moves up through the defect. Non-sliding or paraesophageal hernias can be dangerous as they may allow the stomach to rotate and obstruct.

Hiatal hernia is associated with obesity and gastroesophageal reflux disease (GERD) and its complications. Medical therapy for GERD includes medications that neutralize or reduce stomach acid. Surgery is generally reserved for emergency situations and for those who are not responsive to medications. Hiatal hernia repair surgery 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.

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). Operable symptomatic patients with a paraesophageal hernia should undergo repair. 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 (Schieman, et al., 2009).

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 considered generally to be at moderate risk for lower extremity deep vein thrombosis (DVT) and 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)

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/m^2 (range 47-105). IVC filters were inserted at the time of bariatric surgery according to the patient's risk factors, including immobility, previous DVT/PE, venous stasis, and pulmonary compromise. No instances of PE were documented, and no immediate or late complications related to filter placement occurred. DVT occurred in one patient, and one patient, with a BMI 105 kg/m^2, died secondary to rhabdomyolysis. Study limitations include the lack of randomization and small sample size. The authors noted that additional studies are needed to confirm the efficacy of IVC filter placement for PE risk reduction and related mortality in the super morbidly obese.

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

The AACE/ TOS/ ASMBS guidelines for the bariatric surgery patient state that “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 these 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).

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 state 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 (Mechanik, et al., 2008).

In 2008, the 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.

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
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 state 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, (LAGB), RYGB, and biliopancreatic diversion with duodenal switch (Mechanick, et al., 2013; 2008).

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

- Weight (adults): BMI ≥40 kg/m^2 with no comorbidities, BMI ≥35 kg/m^2 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

According to the Society of American Gastrointestinal Endoscopic Surgeons (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 (SAGES, 2009).

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

- the person has a BMI of 40 kg/m^2 or more, or between 35 kg/m^2 and 40 kg/m^2 and other significant disease (e.g., type 2 diabetes or high blood pressure) that could be improved if they lost weight
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss 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/m^2 in whom surgical intervention is considered appropriate (NICE, 2014).

The European Association for Endoscopic Surgery (EAES) issued evidence-based guidelines for obesity surgery in 2004. 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).

Use Outside of the US
Please see previous sections for relevant information from international organizations.

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 band over bypass, band over sleeve, gastroplasty, loop gastric bypass, mini-gastric bypass

Silicone Gastric Banding Adjustment

Considered medically necessary when criteria in the applicable policy statements listed above are met:

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

	aspiration of saline

Considered Experimental/Investigational/Unproven when used to report any procedure listed as Experimental/Investigational/Unproven for bariatric surgery:

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 Repeat 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

<u>Bariatric Surgery for Diabetes Mellitus</u>

Considered Experimental/Investigational/Unproven when performed solely for the treatment of diabetes mellitus:

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

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

Prophylactic Vena Cava Placement

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

Other Procedures Performed in Conjunction with Bariatric Surgery

Considered not medically necessary when performed in conjunction with a bariatric surgery in the absence of signs or symptoms of disease:

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
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;

References

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

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

3. Alami RS, Morton JM, Schuster R, Lie J, Sanchez BR, Peters A, et al. Is there a benefit to preoperative weight loss in gastric bypass patients? A prospective randomized trial. Surg Obes Relat Dis. 2007 Mar-Apr;3(2):141-5; discussion 145-6. Epub 2007 Feb 27.

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

5. Ali MR, Baucom-Pro S, Broderick-Villa GA, Campbell JB, Rasmussen JJ, Weston AN, et al. Weight loss before gastric bypass: feasibility and effect on postoperative weight loss and weight loss maintenance. Surg Obes Relat Dis. 2007 Sep-Oct;3(5):515-20. Epub 2007 Aug 8.

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

7. American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE). Position statement on the 2014 advanced framework for a new diagnosis of obesity as a chronic disease. 2014. Accessed Apr 14, 2016. Available at URL address: https://www.aace.com/publications/position-statements

8. American College of Surgeons Bariatric Surgery Center Network (ACS BSCN). Bariatric Accreditation Program Manual. Version V4.03-01-11. Accessed Apr 24, 2017. Available at URL address: http://www.mbsaqip.org/docs/Program%20Manual%20v4%2004-10-12.pdf

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

10. American Society for Metabolic and Bariatric Surgery. Guidelines for granting privileges in bariatric surgery. 2006. Accessed Apr 24, 2017. Available at URL address: https://asmbs.org/resources/granting-privileges-in-bariatric-surgery

11. American Society for Metabolic and Bariatric Surgery (ASMBS). Updated position Statement on Prophylactic Measures to Reduce the Risk of Venous Thromboembolism in Bariatric Patients. Jul 2013. Accessed Apr 24, 2017. Available at URL address: https://asmbs.org/resource-categories/position-statements

12. American Society for Metabolic and Bariatric Surgery (ASMBS). Emerging Technologies and Clinical Issues Committees of the ASMBS. Position Statement on emerging endosurgical interventions for treatment of obesity. 2009a Jan; Reviewed Nov 2013. Accessed Apr 24, 2017. Available at URL address: https://asmbs.org/resources/emerging-endosurgical-interventions-for-treatment-of-obesity

13. American Society for Metabolic and Bariatric Surgery (ASMBS). Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery. Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure. 2012 May. Accessed Apr 24, 2017. Available at URL address: https://asmbs.org/resources/sleeve-gastrectomy-as-a-bariatric-procedure

14. American Society for Metabolic and Bariatric Surgery (ASMBS). Policy Statement on Gastric Plication. 2011 Oct; Reviewed Oct 2015. Accessed Apr 24, 2017. Available at URL address: https://asmbs.org/resources/policy-statement-on-gastric-plication

15. Angrisani L, Lorenzo M, Borrelli V. Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial. Surg Obes Relat Dis. 2007 Mar-Apr;3(2):127-32; discussion 132-3. Epub 2007 Feb 27.

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

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

18. Appel LJ, Clark JM, Yeh HC, Wang NY, Coughlin JW, Daumit G, et al. Comparative effectiveness of weight-loss interventions in clinical practice. N Engl J Med. 2011 Nov 24;365(21):1959-68. Epub 2011 Nov 15.

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

20. ASGE Technology Committee, Banerjee S, Barth BA, Bhat YM, Desilets DJ, Gottlieb KT, et al. Endoscopic closure devices. Gastrointest Endosc. 2012 Aug;76(2):244-51. doi: 10.1016/j.gie.2012.02.028. Epub 2012 Jun 2.

21. ASMBS Clinical Issues Committee. Bariatric surgery in class I obesity (body mass index 30-35 kg/m^2). Surg Obes Relat Dis. 2013 Jan-Feb;9(1):e1-10. doi: 10.1016/j.soard.2012.09.002. Epub 2012 Sep 18.

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

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

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

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

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

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

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

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

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

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

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

33. Brethauer S, Kashyap S, Schauer P. Cleveland Clinic: Obesity. March 2013. Accessed Apr 24, 2017. Available at URL address: http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/endocrinology/obesity/

34. Brethauer S. ASMBS Position Statement on Preoperative Supervised Weight Loss Requirements. Surg Obes Relat Dis. 2011 May-Jun;7(3):257-60. Epub 2011 Mar 16.

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

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

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

38. Buchwald H1, Buchwald JN, McGlennon TW. Systematic review and meta-analysis of medium-term outcomes after banded Roux-en-Y gastric bypass. Obes Surg. 2014 Sep;24(9):1536-51. doi: 10.1007/s11695-014-1311-1.

39. Camilleri M, Toouli J, Herrera MF, Kulseng B, Kow L, Pantoja JP, et al. Intra-abdominal vagal blocking (VBLOC therapy): clinical results with a new implantable medical device. 2008 Jun;143(6):723-31. Epub 2008 May 9.

40. Canadian Coordinating Office for Health Technology Assessment (CCOHTA). Issues in Emerging Health Technologies. Issue 79. January 2006. Intragastric Balloons: A Temporary Treatment for Obesity. Accessed Apr 24, 2017. Available at URL address: http://www.cadth.ca/media/pdf/401_balloons_cetap_e.pdf

41. Centers for Medicare and Medicaid Services (CMS). Coverage Decision Memorandum for Bariatric Surgery for Treatment of Co-morbidities Associated with Morbid Obesity. February 21, 2006. Accessed Apr 14, 2016. Available at URL address: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2841CP.pdf

42. Chalasani N, Younossi Z, Lavine JE, Diehl AM, Brunt EM, Cusi K, Charlton M, Sanyal AJ; American Association for the Study of Liver Diseases; American College of Gastroenterology; American Gastroenterological Association. The diagnosis and management of non-alcoholic fatty liver disease: Practice guideline by the American Association for the Study of Liver Diseases, American College of

Gastroenterology, and the American Gastroenterological Association. Am J Gastroenterol. 2012 Jun;107(6):811-26. doi: 10.1038/ajg.2012.128.

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

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

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

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

47. Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD003641.

48. Colquitt JL, Pickett K, Loveman E, Frampton GK. Cochrane Database Syst Rev. 2014 Aug 8;8:CD003641. doi: 10.1002/14651858.CD003641.pub4. Surgery for weight loss in adults.

49. Cottam D, Qureshi FG, Mattar SG, Sharma S, Holover S, Bonanomi G, et al. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. Surg Endosc. 2006 Jun;20(6):859-63. Epub 2006 Apr 22.

50. Courcoulas AP, Goodpaster BH, Eagleton JK, Belle SH, Kalarchian MA, Lang W, et al. Surgical vs medical treatments for type 2 diabetes mellitus: a randomized clinical trial. JAMA Surg. 2014 Jul;149(7):707-15. doi: 10.1001/jamasurg.2014.467.

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

52. Daniels SR, Jacobson MS, McCrindle BW, Eckel RH, Sanner BM. American Heart Association Childhood Obesity Research Summit Report. Circulation. 2009 Apr 21;119(15):e489-517. Epub 2009 Mar 30.

53. De Castro ML1, Morales MJ, Del Campo V, Pineda JR, Pena E, Sierra JM, et al. Efficacy, safety, and tolerance of two types of intragastric balloons placed in obese subjects: a double-blind comparative study. Obes Surg. 2010 Dec;20(12):1642-6. doi: 10.1007/s11695-010-0128-9.

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

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

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

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

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

59. Family Practice Notebook. Midparental Height ©2016, Family Practice Notebook, LLC. Accessed April 24, 2017. Available at URL address: http://www.fpnotebook.com/endo/exam/MdprntlHght.htm

60. Farina MG, Baratta R, Nigro A, Vinciguerra F, Puglisi C, Schembri R, et al. Intragastric balloon in association with lifestyle and/or pharmacotherapy in the long-term management of obesity. Obes Surg. 2012 Apr;22(4):565-71. doi: 10.1007/s11695-011-0514-y.

61. Fernandes M, Atallah AN, Soares BG, Humberto S, Guimaraes S, Matos D, et al. Intragastric balloon for obesity. Cochrane Database Syst Rev. 2007 Jan 24;(1):CD004931.

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

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

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

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

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

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

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

69. Fuller NR, Pearson S, Lau NS, Wlodarczyk J, Halstead MB, Tee HP, et al. An intragastric balloon in the treatment of obese individuals with metabolic syndrome: a randomized controlled study. Obesity (Silver Spring). 2013 Aug;21(8):1561-70. doi: 10.1002/oby.20414. Epub 2013 Jun 11.

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

71. Gagner M, Gumbs AA. Gastric banding: conversion to sleeve, bypass, or DS. Surg Endosc. 2007 Nov;21(11):1931-5. Epub 2007 Aug 20.

72. Garvey WT, Mechanick JI, Brett EM, Garber AJ, Hurley DL, Jastreboff AM, et al. American Association of clinical Endocrinologists and American College of Endocrinology. Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity: Executive Summary. Complete Guidelines available at https://www.aace.com/publications/guidelines. Endocr Pract. 2016 Jul;22(7):842-84. doi: 10.4158/EP161356.ESGL.

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

74. Genco A, Cipriano M, Materia A, Bacci V, Maselli R, Musmeci L, et al. Laparoscopic sleeve gastrectomy versus intragastric balloon: a case-control study. Surg Endosc. 2009 Aug;23(8):1849-53. Epub 2009 Jan 24.

75. Genco A, Lorenzo M, Baglio G, Furbetta F, Rossi A, Lucchese M, et al. Does the intragastric balloon have a predictive role in subsequent LAP-BAND(®) surgery? Italian multicenter study results at 5-year follow-up. Surg Obes Relat Dis. 2014 May-Jun;10(3):474-8. doi: 10.1016/j.soard.2013.10.021. Epub 2013 Dec 6.

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

77. Giardiello C, Borrelli A, Silvestri E, Antognozzi V, Iodice G, Lorenzo M. Air-filled vs water-filled intragastric balloon: a prospective randomized study. Obes Surg. 2012 Dec;22(12):1916-9. doi: 10.1007/s11695-012-0786-x.

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

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

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

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

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

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

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

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

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

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

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

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

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

91. Hayes Inc. Hayes Medical Technology Brief. Intragastric Balloons for the Treatment of Obesity. Lansdale, PA: HAYES, Inc., ©2016 Winifred S. Hayes, Inc. March 2017.

92. Hayes Inc. Hayes Medical Technology Brief. Maestro Rechargeable System (EnteroMedics Inc.) for Vagal Blocking for Obesity Control. Lansdale, PA: HAYES, Inc., ©2016 Winifred S. Hayes, Inc. February 2016. Updated January 2017.

93. Hayes Inc. Hayes Medical Technology Directory Report. Revisional Surgery for Treatment of Complications After Bariatric Surgery. Lansdale, PA: HAYES, Inc., ©2015 Winifred S. Hayes, Inc. July 2014. Updated July 2016.

94. Hayes Inc. Hayes Medical Technology Directory Report. Roux-en-Y Gastric Bypass for Diabetes in Obese or Severely Obese Patients. Lansdale, PA: HAYES, Inc., ©2015 Winifred S. Hayes, Inc. August 2014. Updated August 2016.

95. Hedberg J, Sundbom M. Superior weight loss and lower HbA1c 3 years after duodenal switch compared with Roux-en-Y gastric bypass--a randomized controlled trial. Surg Obes Relat Dis. 2012 May-Jun;8(3):338-43. doi: 10.1016/j.soard.2012.01.014. Epub 2012 Feb 1.

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

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

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

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

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

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

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

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

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

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

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

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

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

109. Karcz WK, Karcz-Socha I, Marjanovic G, Kuesters S, Goos M, Hopt UT, et al. To band or not to band--early results of banded sleeve gastrectomy. Obes Surg. 2014 Apr;24(4):660-5. doi: 10.1007/s11695-014-1189-y.

110. Kashyap SR, Bhatt DL, Wolski K, Watanabe RM, Abdul-Ghani M, Abood B, et al. Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: analysis of a randomized control trial comparing surgery with intensive medical treatment. Diabetes Care. 2013 Aug;36(8):2175-82. doi: 10.2337/dc12-1596. Epub 2013 Feb 25.

111. Kelly AS, Barlow SE, Rao G, Inge TH, Hayman LL, Steinberger J, Urbina EM, Ewing LJ, Daniels SR; American Heart Association Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young, Council on Nutrition, Physical Activity and Metabolism, and Council on Clinical Cardiology. Severe obesity in children and adolescents: identification, associated health risks, and treatment approaches: a scientific statement from the American Heart Association. Circulation. 2013 Oct 8;128(15):1689-712. doi: 10.1161/CIR.0b013e3182a5cfb3. Epub 2013 Sep 9.

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

113. Kim J; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery statement on single-anastomosis duodenal switch. Surg Obes Relat Dis. 2016 Jun;12(5):944-5. doi: 10.1016/j.soard.2016.05.006. Epub 2016 May 7.

114. Kim JJ, Rogers AM, Ballem N, Schirmer B; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. ASMBS updated position statement on insurance mandated preoperative weight loss requirements. Surg Obes Relat Dis. 2016 Jun;12(5):955-9. doi: 10.1016/j.soard.2016.04.019. Epub 2016 Apr 22.

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

116. Kourkoulos M, Giorgakis E, Kokkinos C, Mavromatis T, Griniatsos J, Nikiteas N, et al. Laparoscopic gastric plication for the treatment of morbid obesity: a review. Minim Invasive Surg. 2012;2012:696348. doi: 10.1155/2012/696348. Epub 2012 Jul 3.

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

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

119. Lee WJ, Chong K, Ser KH, Lee YC, Chen SC, Chen JC, et al. Gastric bypass vs sleeve gastrectomy for type 2 diabetes mellitus: a randomized controlled trial. Arch Surg. 2011 Feb;146(2):143-8. doi: 10.1001/archsurg.2010.326.

120. Lee WJ, Lee KT, Kasama K, Seiki Y, Ser KH, Chun SC, et al. Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG): short-term result and comparison with gastric bypass. Obes Surg. 2014 Jan;24(1):109-13. doi: 10.1007/s11695-013-1067-z.

121. Lee WJ, Lee KT, Kasama K, Seiki Y, Ser KH, Chun SC, et al. Laparoscopic single-anastomosis duodenal-jejunal bypass with sleeve gastrectomy (SADJB-SG): short-term result and comparison with gastric bypass. Obes Surg. 2014 Jan;24(1):109-13. doi: 10.1007/s11695-013-1067-z.

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

123. Maglione MA, Gibbons MM, Livhits M, Ewing B, Hu J, Ruelaz Maher A, et al. Bariatric Surgery and Nonsurgical Therapy in Adults With Metabolic Conditions and a Body Mass Index of 30.0 to 34.9 kg/m2 [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Jun. Report No.: 12(13)-EHC139-EF.AHRQ Comparative Effectiveness Reviews.

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

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

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

127. Mechanick JI, Youdim A, Jones DB, Garvey WT, Hurley DL, McMahon MM, et al. Clinical practice guidelines for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient--2013 update: cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery. Obesity (Silver Spring). 2013 Mar;21 Suppl 1:S1-27. doi: 10.1002/oby.20461.

128. Michalsky M, Reichard K, Inge T, Pratt J, Lenders C; American Society for Metabolic and Bariatric Surgery. ASMBS pediatric committee best practice guidelines. Surg Obes Relat Dis. 2012 Jan-Feb;8(1):1-7. doi: 10.1016/j.soard.2011.09.009. Epub 2011 Sep 23.

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

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

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

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

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

134. National Heart, Lung, and Blood Institute (NHLBI). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The Evidence Report. NIH Pub. No. 98-4083. 1998 Sep. Accessed Apr 24, 2017. Available at URL address: http://www.nhlbi.nih.gov/health-pro/guidelines/archive

135. National Heart, Lung, and Blood Institute (NHLBI). The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. 2000 Oct. Accessed Apr 24, 2017. Available at URL address: http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf

136. National Institute for Health and Care Excellence (NICE). Interventional procedure guidance 569. Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Nov 2016. Accessed Apr 24, 2017. Available at URL address: https://www.nice.org.uk/guidance/ipg569

137. National Institute for Health and Care Excellence (NICE). Obesity: identification, assessment and management [CG189]. Nov 2014. Accessed Apr 24, 2017. Available at URL address: https://www.nice.org.uk/guidance/cg189/chapter/1-Recommendations#bariatric-surgery-for-people-with-recent-onset-type-2-diabetes

138. National Institute for Health and Care Excellence (NICE). Interventional procedure guidance 471. Implantation of a duodenal–jejunal bypass sleeve for managing obesity. Nov 2013. Accessed Apr 24, 2017. Available at URL address: https://www.nice.org.uk/guidance/ipg471

139. National Institute for Health and Care Excellence (NICE). IPG432 Laparoscopic gastric plication for the treatment of severe obesity. Nov 2012. Accessed Apr 24, 2017. Available at URL address: https://www.nice.org.uk/guidance/ipg432

140. National Institutes of Diabetes and Digestion and Kidney Disease (NIDDK). Longitudinal Assessment of Bariatric Surgery (LABS). January, 2010. Accessed Apr 24, 2017. Available at URL address: http://win.niddk.nih.gov/publications/labs.htm

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

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

143. Nobili V, Vajro P, Dezsofi A, Fischler B, Hadzic N, Jahnel J, et al. Indications and Limitations of Bariatric Intervention in Severely Obese Children and Adolescents With and Without Nonalcoholic Steatohepatitis: ESPGHAN Hepatology Committee Position Statement. J Pediatr Gastroenterol Nutr. 2015 Apr;60(4):550-61. doi: 10.1097/MPG.0000000000000715.

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

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

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

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

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

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

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

151. Ogden CL Flegal KM. Changes in terminology for childhood overweight and obesity. June 2010. Accessed April 24, 2017. Available at URL address: http://www.cdc.gov/nchs/data/nhsr/nhsr025.pdf

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

153. Papasavas P, El Chaar M, Kothari SN; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity. Surg Obes Relat Dis. 2015 Dec 7. pii: S1550-7289(15)01094-1. doi: 10.1016/j.soard.2015.12.004. [Epub ahead of print]

154. Parikh M, Chung M, Sheth S, McMacken M, Zahra T, Saunders JK, Ude-Welcome A, et al. Randomized pilot trial of bariatric surgery versus intensive medical weight management on diabetes remission in type 2 diabetic patients who do NOT meet NIH criteria for surgery and the role of soluble RAGE as a novel biomarker of success. Ann Surg. 2014 Oct;260(4):617-22; discussion 622-4. doi: 10.1097/SLA.0000000000000919.

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

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

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

158. Paulus GF, de Vaan LE, Verdam FJ, Bouvy ND, Ambergen TA, van Heurn LW. Bariatric Surgery in Morbidly Obese Adolescents: a Systematic Review and Meta-analysis. Obes Surg. 2015 May;25(5):860-78. doi: 10.1007/s11695-015-1581-2.

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

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

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

162. Ponce J, Quebbemann BB, Patterson EJ. Prospective, randomized, multicenter study evaluating safety and efficacy of intragastric dual-balloon in obesity. Surg Obes Relat Dis. 2013 Mar-Apr;9(2):290-5. doi: 10.1016/j.soard.2012.07.007. Epub 2012 Jul 31.

163. Ponce J, Woodman G, Swain J, Wilson E, English W, Ikramuddin S, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis. 2015 Jul-Aug;11(4):874-81. doi: 10.1016/j.soard.2014.12.006. Epub 2014 Dec 16.

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

165. Pratt JS, Lenders CM, Dionne EA, Hoppin AG, Hsu GL, Inge TH, et al. Best practice updates for pediatric/adolescent weight loss surgery. Obesity (Silver Spring). 2009 May;17(5):901-10. Epub 2009 Feb 19.

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

167. Ramos A, Galvao Neto M, Galvao M, Evangelista LF, Campos JM, Ferraz A. Laparoscopic greater curvature plication: initial results of an alternative restrictive bariatric procedure. Obes Surg. 2010 Jul;20(7):913-8. doi: 10.1007/s11695-010-0132-0.

168. Rohde U, Hedbäck N, Gluud LL, Vilsbøll T, Knop FK. Effect of the EndoBarrier Gastrointestinal Liner on obesity and type 2 diabetes: a systematic review and meta-analysis. Diabetes Obes Metab. 2016 Mar;18(3):300-5. doi: 10.1111/dom.12603. Epub 2016 Jan 15.

169. Rubino F, Nathan DM, Eckel RH, Schauer PR, Alberti KG, Zimmet PZ, et al. Metabolic Surgery in the Treatment Algorithm for Type 2 Diabetes: A Joint Statement by International Diabetes Organizations. Diabetes Care. 2016 Jun;39(6):861-77. doi: 10.2337/dc16-0236.

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

171. SAGES Guidelines Committee. SAGES guideline for clinical application of laparoscopic bariatric surgery. Surg Obes Relat Dis. 2009 May-Jun;5(3):387-405. doi: 10.1016/j.soard.2009.01.010. Epub 2009 Feb 23.

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

173. Sánchez-Pernaute A, Rubio MÁ, Pérez Aguirre E, Barabash A, Cabrerizo L, Torres A. Single-anastomosis duodenoileal bypass with sleeve gastrectomy: metabolic improvement and weight loss in first 100 patients. Surg Obes Relat Dis. 2013 Sep-Oct;9(5):731-5. doi: 10.1016/j.soard.2012.07.018. Epub 2012 Aug 7.

174. Sarr MG, Billington CJ, Brancatisano R, Brancatisano A, Toouli J, Kow L, et al. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. Obes Surg. 2012 Nov;22(11):1771-82. doi: 10.1007/s11695-012-0751-8.

175. Sauerland S, Angrisani L, Belachew M, Chevallier J, Favretti F, Finer N, et al. Obesity surgery: evidence-based guidelines of the European Association for Endoscopic Surgery (EAES). Surg Endosc. 2005 Feb;19(2):200-21. Epub 2004 Dec 2.

176. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Aminian A, Brethauer SA, Navaneethan SD, Singh RP, Pothier CE, Nissen SE, Kashyap SR; STAMPEDE Investigators. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. N Engl J Med. 2017 Feb 16;376(7):641-651. doi: 10.1056/NEJMoa1600869.

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

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

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

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

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

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

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

184. Sethi M, Chau E, Youn A, Jiang Y, Fielding G, Ren-Fielding C. Long-term outcomes after biliopancreatic diversion with and without duodenal switch: 2-, 5-, and 10-year data. Surg Obes Relat Dis. 2016 Nov;12(9):1697-1705. doi: 10.1016/j.soard.2016.03.006. Epub 2016 Mar 9.

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

186. Shekelle PG, Morton SC, Maglione MA, Suttorp M, Tu W, Li Z, et al. Pharmacological and surgical treatment of obesity. Evid Rep Technol Assess (Summ). 2004 Jul;(103):1-6.

187. Sheth SG, Chopra S. Epidemiology, clinical features, and diagnosis of nonalcoholic fatty liver disease in adults. Last updated Jan 26, 2017. In: UpToDate, Lindor KD, Robson KM (Eds), UpToDate, Waltham, MA. Accessed on May 16, 2017. Available at URL address: https://www.uptodate.com/contents/epidemiology-clinical-features-and-diagnosis-of-nonalcoholic-fatty-liver-disease-in-adults?source=search_result&search=fattly%20liver%20disease&selectedTitle=1~150

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

189. Shikora SA, Wolfe BM, Apovian CM, Anvari M, Sarwer DB, Gibbons RD, et al. Sustained Weight Loss with Vagal Nerve Blockade but Not with Sham: 18-Month Results of the ReCharge Trial. J Obes. 2015;2015:365604. doi: 10.1155/2015/365604. Epub 2015 Jul 12.

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

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

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

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

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

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

196. Søvik TT, Aasheim ET, Taha O, Engström M, Fagerland MW, Björkman S, et al. Weight loss, cardiovascular risk factors, and quality of life after gastric bypass and duodenal switch: a randomized trial. Ann Intern Med. 2011 Sep 6;155(5):281-91. doi: 10.1059/0003-4819-155-5-201109060-00005.

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

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

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

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

201. Sullivan S, Stein R, Jonnalagadda S, Mullady D, Edmundowicz S. Aspiration therapy leads to weight loss in obese subjects: a pilot study. Gastroenterology. 2013 Dec;145(6):1245-52.e1-5. doi: 10.1053/j.gastro.2013.08.056. Epub 2013 Sep 6.

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

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

204. Tang Y, Tang S, Hu S. Comparative Efficacy and Safety of Laparoscopic Greater Curvature Plication and Laparoscopic Sleeve Gastrectomy: A Meta-analysis. Obes Surg. 2015 Nov;25(11):2169-75. doi: 10.1007/s11695-015-1842-0.

205. Topart P, Becouarn G, Salle A. Five-year follow-up after biliopancreatic diversion with duodenal switch. Surg Obes Relat Dis. 2011 Mar-Apr;7(2):199-205. Epub 2010 Nov 13.

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

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

208. Tucker ON, Szomstein S, Rosenthal RJ. Indications for sleeve gastrectomy as a primary procedure for weight loss in the morbidly obese. J Gastrointest Surg. 2008 Apr;12(4):662-7. Epub 2008 Feb 9.

209. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. AspireAssist - P150024. June 14, 2016. Accessed Apr 24, 2017. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf15/p150024b.pdf

210. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. ORBERA™ Intragastric Balloon System - P140008. August 5, 2015. Accessed Apr 14, 2016. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P140008

211. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. ReShape Integrated Dual Balloon System - P140012. July 28, 2015. Accessed Apr 14, 2016. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P140012

212. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. 510(k) Summary. Apollo Endosurgery OverStitch Endoscopic Suture System - K081853. August 18, 2008. Accessed Apr 24, 2017. Available at URL address: https://www.accessdata.fda.gov/cdrh_docs/pdf8/K081853.pdf

213. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). LAP-BAND® Adjustable Gastric Banding (LAGB®) System - P000008. June 5, 2001. Accessed Apr 14, 2016. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cf

214. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. REALIZE™ Adjustable Gastric Band. - P070009. September 28, 2007. Accessed Apr 14, 2016. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

215. U. S. Food and Drug Administration (FDA). FDA approves implanted stomach band to treat severe obesity [FDA Talk Paper]. U.S. Food and Drug Administration (FDA). Accessed Apr 14, 2016. Available at URL address: http://www.fda.gov

216. U. S. Food and Drug Administration (FDA). FDA News Release: Feb. 16, 2011. FDA expands use of banding system for weight loss. Accessed Apr 14, 2016. Available at URL address: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm245617.htm

217. U. S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness Data. MAESTRO® Rechargeable System - P130019. January 14, 2015. Accessed Apr 14, 2016. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

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

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

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

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

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

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

224. Washington State Health Care Authority. Health Technology Assessment Program (HTA): Bariatric Surgery, Final Evidence Report. April 10, 2015. Accessed Apr 13, 2015. Available at URL address: http://www.hca.wa.gov/hta/Documents/bariatric_final_rpt_040315.pdf

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

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

227. Yan Y, Sha Y, Yao G, Wang S, Kong F, Liu H, et al. Roux-en-Y Gastric Bypass Versus Medical Treatment for Type 2 Diabetes Mellitus in Obese Patients: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Medicine (Baltimore). 2016 Apr;95(17):e3462. doi: 10.1097/MD.0000000000003462.

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