Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

**Note:** Most Aetna HMO and QPOS plans exclude coverage of surgical operations, procedures or treatment of obesity unless approved by Aetna. Some Aetna plans entirely exclude coverage of surgical treatment of obesity. Please check benefit plan descriptions for details.

I. **Roux-en-Y Gastric Bypass (RYGB), Laparoscopic Adjustable Silicone Gastric Banding (LASGB), Sleeve Gastrectomy, Biliopancreatic Diversion (BPD) and Duodenal Switch (DS) Procedures:**

Aetna considers open or laparoscopic short or long-limb Roux-en-Y gastric bypass (RYGB), open or laparoscopic sleeve gastrectomy, open or laparoscopic biliopancreatic diversion (BPD) with or without duodenal switch (DS), or laparoscopic adjustable silicone gastric banding (LASGB) medically necessary when the selection criteria listed below are met.

**Selection criteria:**

A. Must meet either 1 (adults) or 2 (adolescents):
1. For adults aged 18 years or older, presence of persistent severe obesity, documented in contemporaneous clinical records, defined as any of the following:

   a. Body mass index (BMI) (see appendix) exceeding 40; or
   b. BMI greater than 35 in conjunction with any of the following severe co-morbidities:

      i. Clinically significant obstructive sleep apnea (i.e., person meets the criteria for treatment of obstructive sleep apnea set forth in CPB 0004 - Obstructive Sleep Apnea in Adults (../1_99/0004.html)); or
      ii. Coronary heart disease, with objective documentation (by exercise stress test, radionuclide stress test, pharmacologic stress test, stress echocardiography, CT angiography, coronary angiography, heart failure or prior myocardial infarction); or
      iii. Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of 3 anti-hypertensive agents of different classes); or
      iv. Type 2 diabetes mellitus

2. For adolescents who have completed bone growth (generally age of 13 in girls and age of 15 in boys), presence of obesity with severe co-morbidities:

   a. BMI exceeding 40 with one or more of the following serious co-morbidities:

      i. Clinically significant obstructive sleep apnea; or
      ii. Type 2 diabetes mellitus; or
      iii. Pseudotumor comorbidities

   b. BMI exceeding 50 with one or more of the
following less serious co-morbidities:

i. Medically refractory hypertension; or
ii. Dyslipidemias; or
iii. Nonalcoholic steatohepatitis; or
iv. Venous stasis disease; or
v. Significant impairment in activities of daily living; or
vi. Intertriginous soft tissue infections; or
vii. Stress urinary incontinence; or
viii. Gastroesophageal reflux disease; or
ix. Weight-related arthropathies that impair physical activity; or
x. Obesity-related psychosocial distress.

B. Member has attempted weight loss in the past without successful long-term weight reduction; and

C. Member must meet either criterion 1 (physician-supervised nutrition and exercise program) or criterion 2 (multi-disciplinary surgical preparatory regimen):

1. **Physician-supervised nutrition and exercise program:**
   Member has participated in physician-supervised nutrition and exercise program (including dietician consultation, low calorie diet, increased physical activity, and behavioral modification), documented in the medical record at each visit. This physician-supervised nutrition and exercise program must meet all of the following criteria:

  a. Member’s participation in a physician-supervised nutrition and exercise program must be documented in the medical record by an attending physician who supervised the member’s participation. The nutrition and exercise program may be administered as part of the surgical preparative regimen, and participation in the nutrition and exercise program may be supervised
by the surgeon who will perform the surgery or by some other physician. Records must document compliance with the program; the member must not have a net gain in weight during the program. **Note:** A physician’s summary letter is not sufficient documentation. Documentation should include medical records of physician’s contemporaneous assessment of patient’s progress throughout the course of the nutrition and exercise program. For members who participate in a physician-administered nutrition and exercise program (e.g., MediFast, OptiFast), program records documenting the member’s participation and progress may substitute for physician medical records; **and**

b. Nutrition and exercise program must be supervised and monitored by a physician working in cooperation with dieticians and/or nutritionists, with a substantial face-to-face component (must not be entirely remote); **and**

c. Nutrition and exercise program(s) must be for a cumulative total of 6 months (180 days) or longer in duration and occur within 2 years prior to surgery, with participation in one program of at least 3 consecutive months. (Precertification may be made prior to completion of nutrition and exercise program as long as a cumulative of 6 months participation in nutrition and exercise program(s) will be completed prior to the date of surgery.)

or

2. **Multi-disciplinary surgical preparatory regimen:**
   Proximate to the time of surgery (within 6 months prior to surgery), member must participate in organized multi-disciplinary surgical preparatory regimen of at least 3 consecutive months (90 days) duration meeting all of the following criteria, in order to improve surgical outcomes, reduce the
potential for surgical complications, and establish the member's ability to comply with post-operative medical care and dietary restrictions:

a. Behavior modification program supervised by qualified professional; and
b. Consultation with a dietician or nutritionist; and
c. Documentation in the medical record of the member's participation in the multi-disciplinary surgical preparatory regimen at each visit. Records must document compliance with the program; the member must not have a net gain in weight during the program. (A physician's summary letter, without evidence of contemporaneous oversight, is not sufficient documentation. Documentation should include medical records of the physician's initial assessment of the member, and the physician's assessment of the member's progress at the completion of the multi-disciplinary surgical preparatory regimen.); and
d. Exercise regimen (unless contraindicated) to improve pulmonary reserve prior to surgery, supervised by exercise therapist or other qualified professional; and
e. Program must have a substantial face-to-face component (must not be entirely delivered remotely); and
f. Reduced-calorie diet program supervised by dietician or nutritionist.

and

D. For members who have a history of severe psychiatric disturbance (schizophrenia, borderline personality disorder, suicidal ideation, severe depression) or who are currently under the care of a psychologist/psychiatrist or who are on psychotropic medications, pre-operative psychological clearance is necessary in order to exclude members who are unable to provide informed consent or
who are unable to comply with the pre- and post-operative regimen. **Note:** The presence of depression due to obesity is not normally considered a contraindication to obesity surgery.

### II. Vertical Banded Gastroplasty (VBG):

Aetna considers open or laparoscopic vertical banded gastroplasty (VBG) medically necessary for members who meet the selection criteria for obesity surgery and who are at increased risk of adverse consequences of a RYGB due to the presence of any of the following co-morbid medical conditions:

A. Demonstrated complications from extensive adhesions involving the intestines from prior major abdominal surgery, multiple minor surgeries, or major trauma; or  
B. Hepatic cirrhosis with elevated liver function tests; or  
C. Inflammatory bowel disease (Crohn's disease or ulcerative colitis); or  
D. Poorly controlled systemic disease (American Society of Anesthesiology (ASA) Class IV) (see Appendix); or  
E. Radiation enteritis.

Aetna considers VBG experimental and investigational when medical necessity criteria are not met.

### III. Repeat Bariatric Surgery:

Aetna considers removal of a gastric band medically necessary when recommended by the member’s physician.

Aetna considers surgery to correct complications from bariatric surgery medically necessary, such as obstruction, stricture, erosion, or band slippage.

Aetna considers repeat bariatric surgery medically necessary for members whose initial bariatric surgery was medically necessary (i.e., who met medical necessity criteria for their
initial bariatric surgery), and who meet any of the following medical necessity criteria:

A. Conversion to a sleeve gastrectomy, RYGB or BPD/DS is considered medically necessary for members who have not had adequate success (defined as loss of more than 50% of excess body weight) 2 years following the primary bariatric surgery procedure and the member has been compliant with a prescribed nutrition and exercise program following the procedure; or

B. Revision of a primary bariatric surgery procedure that has failed due to dilation of the gastric pouch, dilated gastrojejunal stoma, or dilation of the gastrojejunostomy anastomosis is considered medically necessary if the primary procedure was successful in inducing weight loss prior to the dilation of the pouch or GJ anastomosis, and the member has been compliant with a prescribed nutrition and exercise program following the procedure; or

C. Replacement of an adjustable band is considered medically necessary if there are complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments; or

D. Conversion from an adjustable band to a sleeve gastrectomy, RYGB or BPD/DS is considered medically necessary for members who have been compliant with a prescribed nutrition and exercise program following the band procedure, and there are complications that cannot be corrected with band manipulation, adjustments or replacement.

IV. Experimental and Investigational Bariatric Surgical Procedures:
Aetna considers each of the following procedures experimental and investigational because the peer-reviewed medical literature shows them to be either unsafe or inadequately studied:

- AspireAssist aspiration therapy
- “Band over bypass” or LASGB revision of prior Roux-en-Y gastric bypass
- "Band over sleeve" or LASGB revision of prior sleeve gastrectomy
- Bariatric surgery as a treatment for idiopathic intracranial hypertension
- Bariatric surgery as a treatment for infertility
- Bariatric surgery as a treatment for type-2 diabetes in persons with a BMI less than 35
- Conversion of sleeve gastrectomy to Roux-en-Y gastric bypass as a treatment of gastro-esophageal reflux disease (GERD)
- Gastric bypass as a treatment for gastroparesis
- Gastoplasty, more commonly known as “stomach stapling” (see below for clarification from vertical band gastroplasty)
- Laparoscopic gastric plication (also known as laparoscopic greater curvature plication [LGCP]), with or without gastric banding
- LASGB, RYGB, and BPD/DS procedures not meeting the medical necessity criteria above
- Liposuction (suction-assisted lipectomy; ultrasonic assisted liposuction)
- Loop gastric bypass
- Mini gastric bypass
- Natural orifice transoral endoscopic surgery (NOTES) techniques for bariatric surgery including, but may not be limited to, the following:
  - Gastrointestinal liners (endoscopic duodenal-jejunal bypass, endoscopic gastrointestinal bypass devices; e.g., EndoBarrier and the ValenTx Endo Bypass
Intragastric balloon (e.g., the ReShape Integrated Dual Balloon System); or
- Restorative obesity surgery, endoluminal (ROSE) procedure for the treatment of weight regain after gastric bypass surgery; or
- Transoral gastroplasty (TG) (vertical sutured gastroplasty; endoluminal vertical gastroplasty; endoscopic sleeve gastroplasty); or
- Use of any endoscopic closure device (Over the Scope clip [OTSC] system set, Apollo OverStitch endoscopic suturing system, StomaphyX endoluminal fastener and delivery system) in conjunction with NOTES;

- Open adjustable gastric banding
- Prophylactic mesh placement for prevention of incisional hernia after open bariatric surgery
- Roux-en-Y gastric bypass as a treatment for gastroesophageal reflux in non-obese persons
- Sclerotherapy for the treatment of dilated gastrojejunostomy following bariatric surgery
- Silastic ring vertical gastric bypass (Fobi pouch)
- Vagus nerve blocking (e.g., the VBLOC device, also known as the Maestro Implant or the Maestro Rechargeable System)
- VBG, except in limited circumstances noted above.

**Cholecystectomy:**

As a high incidence of gallbladder disease (28 %) has been documented after surgery for morbid obesity, Aetna considers routine cholecystectomy medically necessary when performed in concert with elective bariatric procedures.

**Liver Biopsy:**

Aetna considers routine liver biopsy for bariatric surgery not medically necessary in the absence of signs or symptoms of
liver disease (e.g., elevated liver enzymes, enlarged liver).

See also CPB 0039 - Weight Reduction Medications and Programs (../1_99/0039.html).

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

Rationale for Pre-surgical Preparatory Regimen:

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

Given the importance of patient compliance on diet and self-care in improving patient outcomes after surgery, the patient’s refusal to even attempt to comply with a nutrition and exercise regimen prior to surgery portends poor compliance with nutritional and self-care requirements after surgery. Therefore, the appropriateness of obesity surgery in non-compliant patients should be questioned.

The patient must be committed to the appropriate work-up for the procedure and for continuing long-term post-operative medical management, and must understand and be adequately prepared for the potential complications of the procedure.

There is rarely a good reason why obese patients (even super obese patients) can not delay surgery in order to undergo behavioral modification to improve their dietary and exercise habits in order to reduce surgical risks and improve surgical outcomes. The patient may be able to lose significant weight
prior to surgery in order to improve the outcome of surgery.

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

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

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

Ideally, the surgical center where surgery is to be performed should be accomplished in bariatric surgery with a demonstrated commitment to provide adequate facilities and equipment, as well as a properly trained and funded appropriate bariatric surgery support staff. Minimal standards in these areas are set by the institution and maintained under the direction of a qualified surgeon who is in charge of an
experienced and comprehensive bariatric surgery team. This team should include experienced surgeons and physicians, skilled nurses, specialty-educated nutritionists, experienced anesthesiologists, and, as needed, cardiologists, pulmonologists, rehabilitation therapists, and psychiatric staff. The American College of Surgeons (ACS) has stated that the surgeon performing the bariatric surgery be committed to the multidisciplinary management of the patient, both before and after surgery. The ACS recommended: "They develop skills in patient education and selection and are committed to long-term patient management and follow-up. There is active collaboration with multiple patient care disciplines including nutrition, anesthesiology, cardiology, pulmonary medicine, orthopedic surgery, diabetology, psychiatry, and rehabilitation medicine. Appropriate technical skills in the performance of bariatric surgical procedures are acquired."

Although not a requirement for coverage, ideally, the bariatric surgeon should be board certified by the American Board of Surgery or in the process of certification within 5 years after completion of an accredited residency program in general or gastrointestinal surgery, and recertification has been obtained by the American Board of Surgery on an every 10-year basis, if applicable. Appropriate qualifications for a bariatric surgeon include either fellowship training or extended mentoring by an experienced surgeon, preferably by members of international/national bariatric societies, in all aspects of bariatric surgery, advanced laparoscopic techniques, and additional training in re-operative techniques.

A number of studies have demonstrated a relationship between surgical volumes and outcomes of obesity surgery. Most recently, an assessment by the Canadian Agency for Drugs and Technologies in Health (CADTH) (Klarenbach et al, 2010) stated that their volume-outcome review found that higher surgical volumes were associated with better clinical outcomes. CADTH was not, however, able to identify specific thresholds for surgical volume that were associated with better clinical outcomes.
A Multidisciplinary Care Task Group (Saltzman et al, 2005) conducted a systematic review of the literature to provide evidence-based guidelines for patient selection and to recommend the medical and nutritional aspects of multi-disciplinary care required to minimize peri-operative and post-operative risks in patients with severe obesity who undergo weight loss surgery. The Task Group recommended multi-disciplinary screening of weight loss surgery patients to ensure appropriate selection; pre-operative assessment for cardiovascular, pulmonary, gastrointestinal, endocrine, and other obesity-related diseases associated with increased risk for complications or mortality; pre-operative weight loss and cessation of smoking; peri-operative prophylaxis for deep vein thrombosis and pulmonary embolism (PE); pre-operative and post-operative education and counseling by a registered dietitian; and a well-defined post-surgical diet progression. The authors explained that obesity-related diseases are often undiagnosed before weight loss surgery, putting patients at increased risk for complications and/or early mortality. Multi-disciplinary assessment and care to minimize short- and long-term risks include: comprehensive medical screening; appropriate pre-, peri-, and post-operative preparation; collaboration with multiple patient care disciplines (e.g., anesthesiology, pulmonary medicine, cardiology, and psychology); and long-term nutrition education/counseling.

A Multidisciplinary Care Task Group (Saltzman et al, 2005) recommended that operative candidates must be committed to the appropriate work-up for the procedure and to continued long-term post-operative medical management. They must also be able to understand, and be adequately prepared for, potential complications. The Multidisciplinary Care Task Group recommended the use of patient selection criteria from the NIH Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity, which are consistent with those of other organizations. These include: BMI greater than or equal to 40 kg/m2 or BMI greater than or equal to 35 kg/m2 in the presence of significant co-morbidities, a well-informed and motivated patient with a strong desire for substantial weight
loss, failure of non-surgical approaches to long-term weight loss, and acceptable operative risks.

The Task Group recommended that all weight loss surgery patients be encouraged to lose weight before surgery, and to promote 5 to 10% pre-operative weight loss in patients with a BMI greater than 50 kg/m² or obesity-related comorbidities (Saltzman et al, 2005). The Task Group recommended to decide on a case-by-case basis whether to proceed with surgery in patients who are unable to lose weight. The Task Group stated that registered dietitians are best qualified to provide nutritional care, including pre-operative assessment and post-operative education, counseling, and follow-up. Weight loss surgery patients need to learn important new skills, including self-monitoring and meal planning. Many forms of weight loss surgery require patients to take lifelong nutritional supplements and to have lifelong medical monitoring. Dedicated dietitians can help patients during their pre-operative education on new dietary requirements and stipulations and their post-surgical adjustment to those requirements. The Task Group also recommended a pre-operative assessment for micronutrient deficiencies.

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

Anderin et al (2015) found that weight loss before bariatric surgery is associated with marked reduction of risk of postoperative complications. The investigators reported that the degree of risk reduction seems to be related to amount of weight lost and patients in the higher range of BMI are likely to benefit most from pre-operative weight reduction. The investigators noted that a pre-operative weight-reducing regimen is usually adhered to in most centers performing
bariatric surgery for obesity, and that the potential to reduce post-operative complications by such a routine is yet to be defined. The investigators analyzed data from the Scandinavian Obesity Registry on 22,327 patients undergoing primary gastric bypass from January 1, 2008, to June 30, 2012. In all patients, median pre-operative total weight change was −4.8 %. Corresponding values in the 25th, 50th, and 75th percentile were 0.5, −4.7, and −9.5 %, respectively. Complications were noted in 9.1 % of the patients. When comparing patients in the 75th with those in the 25th percentile of pre-operative weight loss, the risk of complications was reduced by 13 %. For specific complications, the corresponding risks were reduced for anastomotic leakage by 24 %, for deep infection/abscess by 37 %, and for minor wound complications by 54 %. Similarly, however, less pronounced risk reductions were found when comparing patients in the 50th with those in the 25th percentile of pre-operative weight loss. For patients in the highest range of body mass index (BMI), the risk reduction associated with pre-operative weight loss was statistically significant for all analyzed complications, whereas corresponding risk reductions were only occasionally encountered and less pronounced in patients with lower BMI.

Body Mass Index as a Criterion for Candidacy for Obesity Surgery:

Surgery for severe obesity is usually considered an intervention of last resort with patients having attempted other forms of medical management (such as behavior change, increased physical activity and drug therapy) but without achieving permanent weight loss (Colquitt et al, 2002; NIH, 1995). Surgery is indicated for persons with severe obesity (BMI of 40 kg/m² or more) or for persons with a BMI of 35 kg/m² or more and serious co-morbidities such as diabetes, coronary heart disease, or obstructive sleep apnea. Ideally patients selected for surgery should have no major perioperative risk factors, a stable personality, no eating disorders, and have lost some weight prior to surgery. The patient’s ability to lose weight
prior to surgery makes surgical intervention easier and also provides an indication of the likelihood of compliance with the severe dietary restriction imposed on patients following surgery.

*Rationale for Six-Month Nutrition and Exercise Program Prior to Surgery:*

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

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

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

The NIH Consensus Conference (1998) has stated that the patient should begin a nutrition and exercise program prior to surgery: “An integrated program must be in place to provide guidance on diet, physical activity, and behavioral and social support both prior to and after the surgery.”
The American Dietetic Association (1997), in their position statement obesity surgery, recommends dietetic counseling and behavioral modification commencing prior to, not after, surgery: "Careful dietetics evaluation is needed to determine if the patient will be able to comply with the postoperative diet. A preoperative behavior change program with psychological evaluation should be required."

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

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

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

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

A Multidisciplinary Care Task Group (Saltzman et al, 2005) conducted a systematic review of the literature and recommended an attempt at modest weight loss before obesity surgery, citing evidence that modest reductions in weight (5 to 10 % of initial weight) reduce factors known to increase surgical
risk (e.g., sleep disordered breathing, hypertension, hyperglycemia), and that with weight loss, obese patients had significantly shorter operating room times and length of stay. The Task Group stated that registered dietitians are best qualified to provide nutritional care, including pre-operative assessment and nutritional education and counseling.

*Contraindications to Obesity Surgery:*

Surgery for severe obesity is a major surgical intervention with a risk of significant early and late morbidity and of perioperative mortality (Colquitt, 2002; Oelschlager and Pellegrini, 2003). Contraindications for these surgical procedures include peri-operative risk of cardiac complications, poor myocardial reserve, significant chronic obstructive airways disease or respiratory dysfunction, non-compliance of medical treatment, psychological disorders of a significant degree that a psychologist/psychiatrist would have thought would be exacerbated or interfere with the long-term management of the patient after the operation, significant eating disorders, or severe hiatal hernia/gastroesophageal reflux.

A Multidisciplinary Care Task Group (Saltzman et al, 2005) identified contraindications to weight loss surgery, including unstable or severe coronary artery disease, severe pulmonary disease, portal hypertension with gastric or intestinal varices, and/or other conditions thought to seriously compromise anesthesia or wound healing. The Task Group also noted that weight loss surgery is contraindicated in those who are unable to comprehend basic principles of weight loss surgery or follow operative instructions. The Task Group stated that any combination of the following factors -- revisional surgery, male, greater than 50 years of age, BMI greater than 50 kg/m2, and obstructive sleep apnea, hypertension, and type 2 diabetes -- indicates high risk.

*Requirement that Obesity be Persistent:*

Obesity surgery is not indicated for persons with transient

**Obesity Surgery in Children and Adolescents:**

According to available guidelines, obesity surgery is generally indicated for persons age 18 and older (AACE, 1998). Children and adolescents are rapidly growing, and are therefore especially susceptible to adverse long-term consequences of nutritional deficiencies from the reduced nutrient intake and malabsorption that is induced by obesity surgery. It is not known whether the benefits of obesity surgery in children and adolescents outweigh the increased risks.

According to a panel of experts (Inge et al, 2004; Lawson et al, 2006), bariatric surgery may be an appropriate treatment for severe obesity in adolescents who have completed bone growth. According to the recommendations by the expert panel, potential candidates for bariatric surgery should be referred to centers with multi-disciplinary weight management teams that have expertise in meeting the unique needs of overweight adolescents. Consideration for bariatric surgery is generally warranted only when adolescents have experienced failure of 6 months of organized weight loss attempts and have met certain criteria: severe obesity (a BMI of 40) and severe co-morbidities, or super obesity (BMI of 50) and less severe co-morbidities that may be remedied with weight loss; and have attained a majority of skeletal maturity (generally 13 years of age for girls and 15 years of age for boys). Surgery should only be performed at facilities that are equipped to collect long-term data on clinical outcomes. The panel recommended the Roux-en-Y gastric bypass method of surgery over the simpler, newer technique of implanting an adjustable gastric band since gastric bands are less effective and younger patients would probably need replacement as they age.
**Requirement for Physician Supervision of Program Documented in Medical Record:**

Aetna’s policy states that the patient should participate in a medically supervised nutrition and exercise program and/or a comprehensive multidisciplinary preoperative preparatory regimen, and that this participation be documented in the medical record. As is true generally, physicians should document their assessment of the patient, what health interventions are prescribed, and their assessment of the patient’s progress. There is established evidence that medical supervision of a nutrition and exercise program increases the likelihood of success (Blackburn, 1993). The American Medical Association Council on Scientific Affairs recommends that “any person considering a weight loss program first consult a physician for a physical examination and an objective evaluation of the proposed weight loss program as it relates to the individual’s physical condition … Various health organizations recommend that physicians assess their patients for overweight and that patients receive appropriate counseling about safe weight management and the benefits of physical activity and a healthy diet [citing guidelines from the National Heart, Lung and Blood Institute, the AACE/ACE, the Institute of Medicine of the National Academy of Sciences, the U.S. Preventive Services Task Force, the American Obesity Association, the American Medical Association, and an expert committee of pediatric experts convened by the Health Resources and Services Administration]” (Lyznicki et al, 2001). “If treatment is indicated, physicians can help patients develop weight loss or management plans tailored to individual needs; this includes setting reasonable weight loss goals; selecting appropriate weight loss programs; referring patients to ancillary personnel when appropriate; and providing monitoring, support and encouragement” (Lyznicki et al, 2001).

**Requirement for Psychological Evaluation:**

Candidates for obesity surgery who have a history of severe psychiatric disturbance (schizophrenia, borderline personality...
disorder, suicidal ideation, severe depression) or who are currently under the care of a psychologist/psychiatrist or who are on psychotropic medications should undergo a comprehensive evaluation by a licensed psychologist or psychiatrist to assess the patient’s suitability for surgery, the absence of significant psychopathology that can limit an individual’s understanding of the procedure or ability to comply with life-long follow-up (e.g., defined noncompliance with previous medical care, active substance abuse, schizophrenia, borderline personality disorder, uncontrolled depression).

**Routine Liver Biopsy for Bariatric Surgery**

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), with input from the Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery (ASMBS), have issued the following guideline for liver biopsy as a part of preoperative medical evaluation bariatric surgery: “The liver may be assessed by hepatic profile and ultrasound. In cases of suspected cirrhosis, biopsy may be indicated.”

The American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic & Bariatric Surgery’s clinical practice guidelines on “The perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient” (Mechanick et al, 2013) stated that “Consideration can be made for liver biopsy at the time of surgery to document steatohepatitis and/or cirrhosis that may otherwise be unknown due to normal appearance and/or liver function tests (Grade D)” (Grade D recommendation is based on expert opinion because of a lack of conclusive clinical evidence; if a 2/3 consensus cannot be reached, then the recommendation grade is D).

An UpToDate review on “Bariatric operations for management of obesity: Indications and preoperative preparation” (Lim, 2015) states that “For patients suspected to have nonalcoholic fatty liver disease (NAFLD) on the basis of hepatomegaly on the physical examination, liver function tests are obtained. In
addition, radiographic imaging is obtained, such as an ultrasound or a computed tomography scan, or a biopsy may be required to evaluate for cirrhosis”.

Cazzo et al (2014) stated that non-alcoholic fatty liver disease (NAFLD) is common among subjects who undergo bariatric surgery and its post-surgical improvement has been reported. This study aimed to determine the evolution of liver disease evaluated through NAFLD fibrosis score 12 months after surgery. It is a prospective cohort study which evaluated patients immediately before and 12 months following Roux-en-Y gastric bypass (RYGB). Mean score decreased from 1.142 to 0.066; surgery led to a resolution rate of advanced fibrosis of 55%. Resolution was statistically associated with female gender, percentage of excess weight loss, post-surgical BMI, post-surgical platelet count, and diabetes resolution. The authors concluded that as previously reported by studies in which post-surgical biopsies were performed, RYGB leads to a great resolution rate of liver fibrosis. Since post-surgical biopsy is not widely available and has a significant risk, calculation of NAFLD fibrosis score is a simple tool to evaluate this evolution through a non-invasive approach.

Shalhub et al (2004) noted that non-alcoholic steatohepatitis (NASH) commonly occurs in obese patients and predisposes to cirrhosis. Prevalence of NASH in bariatric patients is unknown. The aim of this study was to determine the role of routine liver biopsy in managing bariatric patients. Prospective data on patients undergoing Roux-en-Y gastric bypass (RYGBP) was analyzed. One 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. A total of 242 patients underwent open and laparoscopic RYGBP from 1998 to 2001. Routine liver biopsies (68 consecutive patients) and selective liver biopsies (additional 86/174, 49%) were obtained. Findings of cirrhosis on frozen section changed the operation from a distal to a proximal RYGBP. The two groups were similar
in age, gender, and BMI. The group with the routine liver biopsies showed a statistically significant larger preponderance of NASH (37 % versus 32 %). Both groups had a similar prevalence of cirrhosis. Neither BMI nor liver enzymes predicted the presence or severity of NASH. The authors concluded that routine liver biopsy documented significant liver abnormalities in a larger group of patients compared with selective liver biopsies, thereby suggesting that liver appearance is not predictive of NASH. Liver biopsy remains the gold-standard for diagnosing NASH. The authors recommended routine liver biopsy during bariatric operations to determine the prevalence and natural history of NASH, which will have important implications in directing future therapeutics for obese patients with NASH and for patients undergoing bariatric procedures.

Oliveira et al (2005) stated that pathogenesis of non-alcoholic fatty liver disease (NAFLD) remains incompletely known, and oxidative stress is one of the mechanisms incriminated. The aim of this study was to evaluate the role of liver oxidative stress in NAFLD affecting morbidly obese patients. A total of 39 consecutive patients with BMI > 40 kg/m2 submitted to Roux-en-Y gastric bypass were enrolled, and wedge liver biopsy was obtained during operation. Oxidative stress was measured by concentration of hydroperoxides (CEOOH) in liver tissue. Female gender was dominant (89.7 %) and median age was 43.6 +/- 11.1 years. Histology showed fatty liver in 92.3 %, including 43.6 % with NASH, 48.7 % with isolated steatosis and just 7.7 % with normal liver. Liver cirrhosis was present in 11.7 % of those with NASH. Concentration of CEOOH was increased in the liver of patients with NASH when compared to isolated steatosis and normal liver (0.26 +/- 0.17, 0.20 +/- 0.01 and 0.14 +/- 0.00 nmol/mg protein, respectively) (p < 0.01). Liver biochemical variables were normal in 92.3 % of all cases, and no difference between NASH and isolated steatosis could be demonstrated. The authors concluded that (i) non-alcoholic steatosis, steatohepatitis and cirrhosis were identified in substantial numbers of morbidly obese patients; (ii) concentration of hydroperoxides was increased in
steatohepatitis, consistent with a pathogenetic role for oxidative stress in this condition.

Arun et al (2007) stated that NAFLD is a chronic condition that can progress to cirrhosis and hepatocellular cancer. The most progressive form of NAFLD is NASH. Currently, the only method to diagnose NASH is with a liver biopsy; however, sampling error may limit diagnostic accuracy. These researchers investigated the discordance of paired liver biopsies in individuals undergoing gastric bypass. Two liver biopsies, composite size of > or = 25 mm and > or = 8 portal tracts (PTs), were obtained from the left lobe in 31 subjects. Group 1 included specimens at least 15 mm in length with > or = 4 PTs compared to a second biopsy of at least 10 mm and > or = 4 PTs (Group 2). The mean specimen size (number of PTs) for group 1 was 20.4 +/- 4.2 mm (11.7 +/- 5.5 PTs) and group 2 was 16.1 +/- 5.3 mm (8.2 +/- 4.1 PTs). Prevalence of NASH was 26 % in Group 1 and 32 % in Group 2. Sampling discordance was greatest for portal fibrosis (26 %), followed by zone 3 fibrosis (13 %) and ballooning degeneration (3 %). The negative predictive values from Group 1 liver biopsies for NASH and portal fibrosis were only 83 % and 67 %, respectively. The authors concluded that the results demonstrate that significant sampling variability exists in class 2 and 3 obese individuals undergoing screening liver biopsies for NAFLD. The degree and histopathological discordance is dependent upon zonal location and types of injury. Nevertheless, a 25-mm biopsy specimen without zone 3 cellular ballooning or fibrosis appears adequate to exclude the diagnosis of NASH.

Roux-en-Y Gastric Bypass (RYGB) and Vertical Banded Gastroplasty (VBG):

Surgery for obesity, termed bariatric surgery, includes gastric restrictive procedures and gastric bypass. The gastric restrictive procedures include vertical banded gastroplasty accompanied by gastric banding which attempt to induce weight loss by creating an intake-limiting gastric pouch by segmenting the stomach along its vertical axis. The process of digestion is more
or less normal. In the United States, the primary operative choice for severely obese patients has recently shifted from vertical banded gastroplasty (VBG) to the Roux-en-Y gastric bypass (RYGB) (Fisher and Schauer, 2002; Mason et al, 1997). Vertical banded gastroplasty (VBG), a purely restrictive procedure, has fallen into disfavor because of inadequate long-term weight loss.

Roux-en-Y gastric bypass (RYGB) combines restriction and malabsorption principles, and combines gastric segmentation along its vertical axis with a Roux-en-Y procedure, such that the food bypasses the duodenum and proximal small bowel. Long-limb RYGB is similar to standard RYGB, except that the limb through which food passes is longer and is often used to treat super obese individuals. Because the normal flow of food is disrupted, available literature indicates that there is a greater potential for metabolic complications compared to gastric restrictive surgeries, including iron deficiency anemia, vitamin B-12 deficiency and hypocalcemia, all of which can be corrected by oral supplementation. Several studies have suggested that RYGB is a more effective weight loss procedure than VBG, offering the best combination of maximum weight control and minimum nutritional risk (Sugerman et al, 1989; Howard et al, 1995). Pories et al (1995) reported 57.7 %, 54.7 %, and 49.2 % excess weight loss with RYGB at 5, 10, and 14 years, respectively, in a large series with 95 % follow-up. Thus, the RYGB is “the current procedure of choice for patients requiring surgery for morbid obesity” (Barrow; 2002). An assessment conducted by the French National Technology Assessment Agency (ANAES, 2001; Msika, 2003) found that surgical mortality for RYGB and VBG is about the same. However, RYGB is associated with significantly more weight loss, and has become the procedure of choice for obesity surgery.

Gentileschi et al (2002) systematically reviewed the published literature on open and bariatric laparoscopic obesity surgery and concluded that the available evidence indicates that laparoscopic VBG and laparoscopic RYGB are as effective as
their open counterparts.

An assessment of laparoscopic RYGB by the BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2005) stated that among available bariatric surgical procedures, RYGB appears to have the most favorable risk-to-benefit ratio, and that the overall risk-to-benefit ratio of laparoscopic RGBY is similar to that of open RGBY. The assessment found that open and laparoscopic RYGB induces similar amounts of weight loss. However, the assessment found that the profile of adverse events differs between the two approaches. Laparoscopic RYGB is a less invasive approach that results in a shorter hospital stay and earlier return to usual activities. The assessment found that the estimated mortality rate was low for both procedures, but somewhat lower for laparoscopic surgery than open surgery (0.3 % versus 1.1 %). Laparoscopic RGBY had a higher rate of postoperative anastomotic leaks than open RGBY (3.7 % versus 1.9 %), and a somewhat higher rate of bleeding (4.1 % versus 2.4 %). The report found, on the other hand, that open surgery had higher rates of cardiopulmonary complications (2.6 % versus 1.0 %) and wound infections (11.0 % versus 4.7 %). Regarding long-term adverse events, the rates of reoperation (9.9 %) and anastomotic problems (8.0 %) may be higher for laparoscopic RGBY than for open RGBY (6.0 % and 2.0 %, respectively), while the rate of incisional hernia is higher for open RGBY than laparoscopic RGBY (9.0 % versus 0 %).

An assessment by the Institute for Clinical Systems Improvement (ICSI, 2005) found that large studies have shown that RYGB may result in weight loss of 60 % to 70 % of excess weight. It also found that VBG shows substantial weight loss efficacy but less than that for RYGB. In addition, VBG has a high rate of serious morbidity, including a re-operation rate of up to 30 % from stoma obstruction and staple-line disruption. Therefore, the evidence supports the overall superiority of RYGB over VBG in safety and efficacy for bariatric surgery.

A decision memorandum from the Centers for Medicare and Medicaid Services (CMS, 2006) concluded that the evidence is
sufficient that open and laparoscopic RYGB is reasonable and necessary for Medicare beneficiaries who have a BMI greater than 35 and have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. The assessment concluded that the evidence is not adequate to conclude that open or laparoscopic vertical banded gastroplasty is reasonable and necessary and they are therefore non-covered for all Medicare beneficiaries.

A systematic evidence review by the Canadian Agency for Drugs and Technologies in Health (CADTH) (Klarenbach et al, 2010) found that, although data from large, adequately powered, long-term randomized controlled trials are lacking, bariatric surgery seems to be more effective than standard care for the treatment of severe obesity in adults. Procedures that are mainly diversionary (e.g., biliopancreatic diversion (BPD)) result in the greatest amounts of weight loss, hybrid procedures are of intermediate effectiveness (e.g., RYGB), and restrictive procedures (e.g., adjustable gastric banding) result in the least amounts of weight loss. RYGB and adjustable gastric banding tended to lead to trade-offs between the risk of adverse events and the need for procedure conversion or reversals.

*Biliopancreatic Diversion (BPD) (Jejunoileal Bypass, Scopinaro Procedure) and Duodenal Switch (DS) Procedures:*

While appropriate surgical procedures for severe obesity primarily produce weight loss by restricting intake, intestinal bypass procedures produce weight loss by inducing a malabsorptive effect. Biliopancreatic bypass or diversion (BPD) (also called jejunoileal bypass or the Scopinaro procedure) consists of a subtotal gastrectomy and diversion of the biliopancreatic juices into the distal ileum by a long Roux-en-Y procedure; the result is a 200-cm long alimentary tract, a 300- to 400-cm biliary tract, and after these 2 tracts are joined at the distal anastomosis, there is a 50-cm common absorptive alimentary tract. The BPD was designed to address some of the drawbacks of the original intestinal bypass procedures, which
resulted in unacceptable metabolic complications of diarrhea, hyperoxaluria, nephrolithiasis, cholelithiasis and liver failure.

The duodenal switch (DS) is a variant of the BPD procedure with a vertical subtotal gastrectomy and pylorus preservation, which eliminates the "dumping syndrome". The duodenum is divided just beyond the pylorus. The small bowel is then divided, and the end going to the cecum of the colon is connected to the short stump of the duodenum. This becomes the "enteral limb". The other end, leading from the gallbladder and pancreatic ducts, is connected onto the enteral limb at about 75 to 100 cm from the iliocecal valve. This limb is the "biliopancreatic limb". The last 75-100 cm then becomes the "common channel", measuring about 10 % of the total small bowel length and is the only portion that can absorb fat. Some have advocated use of the DS procedure in the super-obese (i.e., persons with BMI greater than 50) because of the substantial weight loss induced by this procedure. Patients who have this operation must have lifelong medical follow-up, since the side effects can be subtle, and can appear months to years after the surgery.

A decision memorandum from the Centers for Medicare and Medicaid Services (CMS, 2006) concluded that open or laparoscopic BPD with or without DS are reasonable and necessary for Medicare beneficiaries.

**Gastroplasty ("Stomach Stapling"):**

Gastroplasty, more commonly known as "stomach stapling" and not to be confused with vertical banded gastroplasty (VBG), is a technically simple operation, accomplished by stapling the upper stomach to create a small pouch into which food flows after it is swallowed. The outlet of this pouch is restricted by a band of synthetic mesh, which slows its emptying, so that the person having it feels full after only a few bites of food. According to the available literature, patients who have this procedure seldom experience any satisfaction from eating, and tend to seek ways to get around the operation by eating more.
This causes vomiting, which can tear out the staple line and destroy the operation. Overall, clinical studies have shown that about 40% of persons who have this operation do not achieve loss of more than half of their excess body weight. In the long-term, 5 or more years after surgery, only about 30% of patients have maintained a successful weight loss. Studies have reported that many patients must undergo another revisional operation to obtain the results they seek.

*Sleeve Gastrectomy:*

Sleeve gastrectomy is a 70 to 80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume (CMS, 2005). It is often the first step in a 2-stage procedure when performing RYGB or duodenal switch.

A decision memorandum from the Centers for Medicare and Medicaid Services (CMS, 2012) found that open or laparoscopic sleeve gastrectomy may be reasonable and necessary for beneficiaries with a BMI greater than or equal to 35 with comorbidities.

A systematic evidence review prepared for *Clinical Evidence* concluded that the effectiveness of sleeve gastrectomy for morbid obesity is unknown (DeLaet and Schauer, 2009). The evidence review found no clinically important results from randomized controlled clinical trials about sleeve gastrectomy compared with non-surgical treatment, or compared with vertical banded gastroplasty or biliopancreatic diversion. They found low quality evidence that sleeve gastrectomy may be more effective than gastric banding at increasing weight loss at 1 and 3 years, and moderate quality evidence that sleeve gastrectomy seems more effective than gastric bypass at increasing mean excess-weight loss at 1 to 2 years.

A systematic evidence review of sleeve gastrectomy by the Australia and New Zealand Horizon Scanning Network
(ANZHSN) (Lee, 2007) found that the evidence showed that laparoscopic sleeve gastrectomy can induce substantial excess weight loss at least as effectively as LASGB (in one study up to 3-years post surgery) but less effectively than gastric bypass and duodenal switch in the short-term. The report noted, however, that these results should be viewed in light of the ease and simplicity of laparoscopic sleeve gastrectomy relative to the other more invasive procedures. The report found a comparable reduction in co-morbidities in patients who underwent laparoscopic sleeve gastrectomy or RYGB, most notably in resolution rates of diabetes within 4 months after surgery despite laparoscopic gastric banding patients being significantly more obese than the RYGB patients in the study. Evidence suggested that, compared to LASGB, laparoscopic sleeve gastrectomy had lower complication rates but more severe complications. The report found laparoscopic sleeve gastrectomy safer than laparoscopic RYGB or intragastric balloon implantation. The report stated that evidence of the safety of laparoscopic sleeve gastrectomy compared with duodenal switch is conflicting possibly because of differences in baseline patient characteristics. The report stated that the incidence of gastric sleeve dilatation appears to be an uncommon event, but the evidence is far from conclusive at this point. The report noted that one study found that laparoscopic sleeve gastrectomy and LASGB had significantly shorter operative times compared to RYGB and duodenal switch. Laparoscopic sleeve gastrectomy had a significantly longer length of stay compared to LASGB, but a significantly shorter length of stay compared to RYGB and duodenal switch. The report found that knowledge gaps include: comparing the effectiveness of laparoscopic sleeve gastrectomy to established bariatric procedures in super-obese (BMI greater than or equal to 50) as a stand alone procedure; long-term (greater than 5 years) safety, durability of weight loss and comorbidity data for laparoscopic sleeve gastrectomy relative to existing bariatric procedures; and effects of laparoscopic sleeve gastrectomy on plasma ghrelin levels and subsequent effect on appetite. More recently, a review of the literature by the Veterans Health Administration
Technology Assessment Program (Adams, 2008) found no new literature that would not alter the conclusions of the ANZHSN review.

A randomized controlled clinical trial comparing short-term (1-year) outcomes of laparoscopic sleeve gastrectomy to laparoscopic RYGB found comparable reductions in body weight and BMI (Karamanakos et al, 2008). However, power calculations were not reported, and the study (n = 32) was likely under-powered to detect clinically significant differences in effectiveness between the 2 procedures. This study was poorly reported, failing to discuss inclusion criteria for the trial and adverse events associated with the procedures.

An earlier retrospective study by Lee et al (2007) (n = 846) found similar rates of short-term weight loss in persons who elected sleeve gastrectomy and persons who elected RYGB or duodenal switch procedures. However, the lack of randomization and retrospective nature of the study results in a substantial risk of bias in the results.

The strongest arguments for sleeve gastrectomy relate to the comparatively poor outcomes of LASGB, which is the competing option for persons wishing to undergo a restrictive (non-malabsorptive) procedure. A randomized clinical study by Himpens et al (2006) compared laparoscopic sleeve gastrectomy to LASGB (n = 80). Although median weight loss was significantly greater after 1 and 3 years with sleeve gastrectomy (65 lbs) than with LASGB (37.5 lbs), the total weight loss with either procedure was insufficient for most potential candidates. The study also found that sleeve gastrectomy was associated with more severe complications than LASGB. The study was also poorly reported, including failure to discuss randomization and blinding procedures, and whether any subjects did not comply with randomization or were lost to follow-up. Clinical studies have reported long-term reoperation rates with LASGB of up to 60 % (see, e.g., Scozzari et al, 2009; Camerini et al, 2004; Tweddle et al, 2004; Morino et al, 2002). Australia has reported that the costs of
band adjustments with LASGB has exceeded the costs of the primary LASGB procedure.

A Cochrane review of the evidence for bariatric surgical procedures (Colquitt et al, 2009) found that, although the effects of the available bariatric procedures compared with medical management and with each other are uncertain, "limited" evidence suggests that sleeve gastrectomy results in weight loss similar to RYGB and greater than with LASGB. The assessment stated that information from the included trials did not allow the authors to reach any conclusions about the safety of these procedures compared with each other. The assessment noted that, due to limited evidence and poor quality of the trials comparing each pair of procedures, these conclusions should be viewed with caution.

In a position statement, the American Society for Metabolic and Bariatric Surgery (2009) determined that sleeve gastrectomy is an "approved bariatric surgical procedure" despite finding only "limited" intermediate term data and a lack of long-term data on the effectiveness of the procedure. The ASMBS position statement explained that the Society has accepted sleeve gastrectomy as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients, primarily super-obese patients with an average BMI of 60 kg/m². The ASMBS reached this conclusion despite not knowing what proportion of super-obese patients will achieve satisfactory outcomes with sleeve gastrectomy alone without conversion to RYGB or duodenal switch, and despite a lack of evidence that accomplishing RYGB or duodenal switch as a staged procedure results in better outcomes (fewer risks) than accomplishing these procedures as a single surgery.

An assessment by the California Technology Assessment Forum (CTAF) (Walsh, 2010) concluded that sleeve gastrectomy does not meet CTAF technology assessment criteria for improvement in health outcomes for the treatment of obesity. The CTAF assessment reported that the results of multiple case series and
retrospective studies have suggested that sleeve gastrectomy as a primary procedure is associated with a significant reduction in excess weight loss. The CTAF assessment reported that the complication rate from sleeve gastrectomy ranged from 0% to 4.1% and complications included leaks, bleeding, strictures and mortality. The CTAF assessment found few comparative studies of sleeve gastrectomy. CTAF identified only 2 randomized controlled trials that have compared sleeve gastrectomy to another surgical procedure (citing Himpens et al, 2006; Karamanakos et al, 2008). These trials included a total of 112 participants who were followed from 1 to 3 years. Among the 80 subjects followed for 3 years, there were a similar number of complications in the sleeve gastrectomy and the RYGB groups, although the complications in the sleeve gastrectomy group were more severe. The CTAF assessment stated that, "[t]o date, long term outcomes from registry studies are relatively limited, but longer term follow-up will provide additional important information."

An assessment of surgical treatment for obesity from the Canadian Agency for Drugs and Technologies in Health (CADTH) (Klarenbach et al, 2010) also concluded that the evidence base for sleeve gastrectomy is limited.

Loop Gastric Bypass:

Although the basic concept of gastric bypass remains intact, numerous variations are being performed at this time. Recent data demonstrate that surgeons are moving from simple gastroplasty procedures, favoring the more complex gastric bypass procedures as the surgical treatment of choice for the severely obese patient. The gastric bypass operation can be modified, to alter absorption of food, by moving the Roux-en-Y-connection distally down the jejunum, effectively shortening the bowel available for absorption of food. The weight loss effect is then a combination of the very small stomach, which limits intake of food, with malabsorption of the nutrients, which are eaten, reducing caloric intake even further. In a sense, this procedure combines the least desirable features of the gastric
bypass with the most troublesome aspects of the biliopancreatic diversion. Although patients can have increased frequency of bowel movements, increased fat in their stools, and impaired absorption of vitamins, recent studies have reported good results. The loop gastric bypass developed years ago has generally been abandoned by most bariatric surgeons as unsafe. Although easier to perform than the RYGB, it has been shown to create a severe hazard in the event of any leakage after surgery, and seriously increases the risk of ulcer formation, and irritation of the stomach pouch by bile.

*Laparoscopic Adjustable Silicone Gastric Banding (LASGB):*

Recent advances in laparoscopy have renewed the interest in gastric banding techniques for the control of severe obesity. Laparoscopic adjustable silicone gastric banding (LASGB) has become an attractive method because it is minimally invasive and allows modulation of weight loss. Available brands of LASGB include the Lap-Band System (Allergan, Inc., Irvine, CA) and the Realize Adjustable Gastric Band (Ethicon Endo-Surgery, Cincinnati, OH). The claimed advantage of LASGB is the adjustability of the band, which can be inflated or deflated percutaneously according to weight loss without altering the anatomy of the stomach. This method entails encircling the upper part of the stomach using bands made of synthetic materials, creating a small upper pouch that empties into the lower stomach through a narrow, non-stretchable stoma. The reduced capacity of the pouch and the restriction caused by the band diminish caloric intake, depending on important technical details, thus producing weight loss comparable to vertical gastroplasties, without the possibility of staple-line disruption and lesser incidence of infectious complications. However, distension of the pouch, slippage of the band and entrapment of the foreign material by the stomach have been described and are worrisome.

A decision memorandum from the CMS (2006) found that there was sufficient evidence to support LASGB as reasonable and necessary for Medicare beneficiaries with a BMI greater
than 35 and co-morbid medical conditions. Sustained weight loss was well documented, ranging from an approximate mean of 30 to 50 % excess weight loss in LASGB, compared to an approximate mean of 50 % excess weight loss in RYGB. The CMS decision memorandum found that short-and-long-term mortality associated with both LASGB and RYGB were low (less than 2 %) in this younger age group.

Regarding performing adjustable gastric banding as an open procedure, the CMS decision memorandum (2006) concluded that the evidence is not adequate to conclude that open adjustable gastric banding is reasonable and necessary and therefore this procedure remains noncovered for Medicare beneficiaries.

*Mini Gastric Bypass:*

The "mini gastric bypass" has been promoted as a new surgical treatment for severe obesity. It involves laparoscopic construction of a large and elongated gastric pouch and a loop gastric bypass with distal diversion (200 cm or up to 50 % of the small bowel) to reduce food absorption. While the name mini gastric bypass implies "small" and "simple", this is a major surgical procedure. The mini-gastric bypass uses a jejunal loop directly connected to a small gastric pouch, instead of a Roux-en-Y anastomosis. In this way, the mini-gastric bypass is similar to the loop gastric bypass; the latter procedure that has been abandoned by bariatric surgeons because of its inherent risks. Specifically, performing a loop, rather than a Roux-en-Y, anastomosis to a small gastric pouch in the stomach may permit reflux of bile and digestive juice into the esophagus where it can cause esophagitis and ulceration, and may thus increase the risk of esophageal cancer. The Roux-en-Y modification of the loop bypass was designed to divert bile downstream, several feet below the gastric pouch and esophagus to minimize the risk of reflux. The trend towards use of Roux-en-Y and away from loop gastric bypass was based on sound surgical experience of multiple surgeons with large series of patients. The published evidence supporting the
mini-gastric bypass comes from descriptive reports and case series; the potential biases inherent in reports of case series are well known in clinical epidemiology. The evidence for the mini-gastric bypass has come from a single investigator, thus raising questions about the generalization and validity of the reported findings. The mini-gastric bypass has not been subjected to a prospective clinical outcome study in peer-reviewed publication.

*Silastic Ring Vertical Gastric Bypass (Fobi Pouch):*

The Fobi pouch, developed by California surgeon Mathias A.L. Fobi, is a modification of gastric bypass surgery. The modifications to gastric bypass surgery are designed to prevent post-surgical enlargement of the gastric pouch and stoma.

In a traditional gastric bypass procedure, surgeons create a smaller stomach by stapling off a large section. A problem with the traditional procedure is that the staples can break down, causing the stomach to regain its original shape -- and patients to start gaining weight again. Also, the stomach opening that leads into the intestines, which in surgery is made smaller to allow less food to pass through, often stretches as the years go by. With the Fobi pouch, there is no use of staples; rather, the stomach is bisected and hand-sewn them to maintain the separation. A synthetic band is placed around the stomach opening to keep it from stretching.

However, there is a paucity of direct comparative studies of the Fobi pouch to traditional gastric bypass surgery, causing colleagues to "question whether his technique is really an improvement on the traditional procedure" (Davis, 2000). All of the published literature has been limited to descriptive articles, case series, and a prospective non-randomized controlled study. These studies were from a single group of investigators, raising questions about the generalization of the findings.

*Intragastric Balloon:*
The intragastric balloon (also known as the silicone intragastric balloon or SIB) has been developed as a temporary aid for obese patients who have had unsatisfactory results in their clinical treatment for obesity and super obese patients with higher surgical (Fernandes et al, 2004). Intragastric balloon is intended to reduce gastric capacity, causing satiety, making it easier for patients to take smaller amounts of food. Randomized, controlled clinical studies, however, have found no increase in weight loss with the intragastric balloon plus dieting versus dieting alone (Rigaud et al, 1995; Geliebter et al, 1991; Mathus-Vliegen et al, 1990; Lindor et al, 1987). One non-randomized controlled clinical study that reported positive results reported that results were not maintained after gastric balloon removal (Ramhamadany et al, 1989). In addition, the intragastric balloon has been associated with potentially severe adverse effects, including gastric erosion, reflux, and obstruction. An assessment of the intragastric balloon from the Canadian Coordinating Office for Health Technology Assessment (2006) concluded that “[m]ore data on the benefits, harms, and cost-effectiveness are required before the intragastric balloon can be compared with other short-term weight loss interventions, including low-calorie diets.”

On July 28, 2015, the Food and Drug administration (FDA) approved the ReShape Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, CA) to treat obesity without the need for invasive surgery. This new device is intended to facilitate weight loss in obese adult patients by occupying space in the stomach, which may trigger feelings of fullness, or by other mechanisms that are not yet understood. The ReShape Dual Balloon device is delivered into the stomach via the mouth through a minimally invasive endoscopic procedure. The outpatient procedure usually takes less than 30 minutes while a patient is under mild sedation. Once in place, the balloon device is inflated with a sterile solution, which takes up room in the stomach. The device does not change or alter the stomach’s natural anatomy. Patients are advised to follow a medically supervised diet and exercise plan to augment their weight loss efforts while using the ReShape Dual Balloon and to
maintain their weight loss following its removal. It is meant to be temporary and should be removed 6 months after it is inserted.

The ReShape Dual Balloon was studied in a clinical trial with 326 obese participants aged 22 to 60 (with a BMI of 30 kg/m2 to 40 kg/m2) who had at least 1 obesity-related health condition. In the study (Ponce et al, 2015), 187 individuals randomly selected to receive the ReShape Dual Balloon lost 14.3 pounds on average (6.8 % of their total body weight) when the device was removed at 6 months, while the control group (who underwent an endoscopic procedure but were not given the device) lost an average of 7.2 pounds (3.3 % of their total body weight). Six months following the device removal, patients treated with the ReShape Dual Balloon device kept off an average of 9.9 pounds of the 14.3 pounds they lost. Potential side effects for the procedure include headache, muscle pain, and nausea from the sedation and procedure; in rare cases, severe allergic reaction, heart attack, esophageal tear, infection, and breathing difficulties can occur. Once the device is placed in the stomach, patients may experience vomiting, nausea, abdominal pain, gastric ulcers, and feelings of indigestion. This device should not be used in patients who have had previous gastro-intestinal or bariatric surgery or who have been diagnosed with inflammatory intestinal or bowel disease, large hiatal hernia, symptoms of delayed gastric emptying or active H. Pylori infection; those who are pregnant or use aspirin daily should also avoid the device.

http://www.fda.gov/NewsEvents/Newsroom
/PressAnnouncements/ucm456296.htm

There is a lack of data on the durability of the results with the ReShape Integrated Dual Balloon System. It is unclear what benefit there is from a temporary reduction in weight. An UpToDate review on “Obesity in adults: Overview of management” (Bray, 2015) does not mention intragastric balloon as a therapeutic option. Furthermore, an UpToDate
review on "Bariatric surgical operations for the management of severe obesity: Descriptions" (Lim, 2015) lists intragastric balloon as an investigational procedure. It states that “As much as 33% excess weight loss has been reported in trials conducted outside of the United States with devices not approved by the FDA. After 5 years of surveillance, however, only 23% of patients maintained more than 20% of their excess weight loss”.

StomaphyX:

In March 2007, the FDA granted 510(k) pre-marketing clearance to the StomaphyX (EndoGastric Solutions, Inc.), an endoluminal fastener and delivery system used to tighten esophageal tissue. There is only limited evidence on the effectiveness of the StomaphyX in bariatric surgery repair/revision.

Overcash (2008) reported 2 cases of the safe and successful use of the StomaphyX device to alter the flow of gastric contents and repair gastric leaks resulting from bariatric revision surgery. Both patients were at a high risk and could not undergo another open or laparoscopic surgery to correct the leaks that were not healing. The author reported that the StomaphyX procedures lasted approximately 30 mins, were performed without any complications, and resulted in the resolution of the gastric leaks in both patients. The findings of these cases need to be validated by well-designed clinical studies.

In a prospective, single-center, randomized, single-blinded study, Eid et al (2014) examined the safety and effectiveness of endoscopic gastric plication with the StomaphyX device versus a sham procedure for revisional surgery in RYGB (performed at least 2 years earlier) patients to reduce regained weight. These researchers planned for 120 patients to be randomized 2:1 to multiple full-thickness plications within the gastric pouch and stoma using the StomaphyX device with SerosFuse fasteners or a sham endoscopic procedure and followed up for 1 year. The primary efficacy end-point was reduction in pre-RYGB excess weight by 15% or more excess BMI (calculated as weight in
kilograms divided by height in meters squared) loss and BMI less than 35 at 12 months after the procedure. Adverse events were recorded. Enrollment was closed prematurely because preliminary results indicated failure to achieve the primary efficacy end-point in at least 50% of StomaphyX-treated patients. One-year follow-up was completed by 45 patients treated with StomaphyX and 29 patients in the sham treatment group. Primary efficacy outcome was achieved by 22.2% (10) with StomaphyX versus 3.4% (1) with the sham procedure (p < 0.01). Patients undergoing StomaphyX treatment experienced significantly greater reduction in weight and BMI at 3, 6, and 12 months (p ≤ 0.05). There was one causally related adverse event with StomaphyX, that required laparoscopic exploration and repair. The authors concluded that StomaphyX treatment failed to achieve the primary efficacy target and resulted in early termination of the study.

Bariatric Surgery and Pregnancy:

The American College of Obstetricians and Gynecologists' practice bulletin on bariatric surgery and pregnancy (ACOG, 2009) stated that bariatric surgery should not be considered a treatment for infertility.

Bariatric Surgery for the Treatment of Idiopathic Intracranial Hypertension:

Fridley et al (2011) reviewed the literature on the effectiveness of bariatric surgery for obese patients with idiopathic intracranial hypertension (IIH) with regard to both symptom resolution and resolution of visual deficits. The published literature was reviewed using manual and electronic search techniques. Data from each relevant manuscript were gathered, analyzed, and compared. These included demographic data, pre- and post-operative symptoms, pre- and post-operative visual field deficits, bariatric procedure type, absolute weight loss, changes in BMI, and changes in cerebrospinal fluid (CSF) opening pressure. A total of 11 relevant publications (including 6 individual case reports) were
found, reporting on a total of 62 patients. The Roux-en-Y gastric bypass was the most common bariatric procedure performed. Fifty-six (92%) of 61 patients with recorded post-operative clinical history had resolution of their presenting IIH symptoms following bariatric surgery. Thirty-four (97%) of 35 patients who had undergone pre- and post-operative funduscopy were found to have resolution of papilledema post-operatively. Eleven (92%) of 12 patients who had undergone pre- and post-operative formal visual field testing had complete or nearly complete resolution of visual field deficits, and the remaining patient had stabilization of previously progressive vision loss. In 13 patients both pre- and post-operative CSF pressures were recorded, with an average post-operative pressure decrease of 254 mm H(2)O. Changes in weight loss and BMI varied depending on the reported post-operative follow-up interval. The authors concluded that the published Class IV evidence suggested that bariatric surgery may be an effective treatment for IIH in obese patients, both in terms of symptom resolution and visual outcome. They stated that prospective, controlled studies are needed for better elucidation of its role.

Levin and colleagues (2015) stated that IIH occurs most frequently in young, obese women. Gastric bypass surgery has been used to treat morbid obesity and its co-morbidities, and IIH has recently been considered among these indications. These investigators presented a case report of a 29-year old female with a maximum BMI of 50.3 and a 5-year history of severe headaches and moderate papilledema due to IIH. She also developed migraine headaches. After a waxing and waning course and various medical treatments, the patient underwent laparoscopic Roux-en-Y gastric bypass surgery with anterior repair of hiatal hernia. Dramatic improvement in IIH headaches occurred by 4 months post-procedure and was maintained at 1 year, when she reached her weight plateau with a BMI of 35. Pre-surgery migraines persisted. This added to the small number of case reports and retrospective analyses of the successful treatment of IIH with gastric bypass surgery, and brought this data from the surgical literature into the
neurological domain. It offered insight into an early time course for symptom resolution, and explored the impact of weight-loss surgery on migraine headaches. The authors concluded that this treatment modality should be further investigated prospectively to analyze the rate of headache improvement with weight loss, the amount of weight loss needed for clinical improvement, and the possible correlation with improvement in papilledema.

Handley et al (2015) systematically reviewed the effect of bariatric weight reduction surgery as a treatment for IIH. These investigators performed a comprehensive literature search using the following databases: MEDLINE, EMBASE, PubMed, Scopus, Web of Sciences, and the Cochrane Library. No restrictions were placed on these searches, including the date of publication. A total of 85 publications were identified, and after initial appraisal, 17 were included in the final review. Overall improvement in symptoms of IIH after bariatric surgery was observed in 60 of the 65 patients observed (92%). Post-operative lumbar puncture opening pressure was shown to decrease by an average of 18.9 cmH2 O in the 12 patients who had this recorded. The authors concluded that bariatric surgery for weight loss is associated with alleviation of IIH symptoms and a reduction in intracranial pressure. Furthermore, an improvement was observed in patients where conventional treatments, including neurosurgery, were ineffective. They stated that further prospective randomized studies with control groups and a larger number of participants are lacking within the published studies to date.

*Laparoscopic Gastric Plication:*

Pujol Gebelli et al (2011) stated that laparoscopic gastric plication is a new technique derived from sleeve gastrectomy. Plication of the greater curvature produces a restrictive mechanism that causes weight loss. The results of the first cases where this technique has been applied in this hospital were presented. A review was made of patients operated on in the authors' hospital between November 2009 and
December 2010. Plication of the gastric greater curvature was performed under general anesthetic and by laparoscopy using 3 lines of sutures and with an orogastric probe as a guide. Results of the morbidity, mortality and weight loss were presented. A total of 13 patients were operated on (7 women). The maximum BMI varied between 37.11 kg/m² and 51.22 kg/m² at the time of the operation. The most frequently found morbidity was nausea and vomiting. Two patients required further surgery due intractable vomiting and total dysphagia; in 1 the plication unfolded, and in the 2nd it was converted into vertical gastrectomy. The authors concluded that laparoscopic gastric plication is a new surgical technique which gives equivalent short-term results as vertical gastrectomy. It is a reproducible and reversible technique with results and indications still to be validated.

Brethauer et al (2011) presented the results of a feasibility study using laparoscopic gastric plication for weight loss achieved without stapling or banding. After institutional review board approval, 2 methods were used to achieve laparoscopic gastric volume reduction. In the 1st group (anterior plication [AP]), the anterior gastric wall was folded inward from the fundus to the antrum using 2 rows of running sutures. The greater and lesser curvatures were approximated to create an intraluminal fold of the stomach. In the 2nd group (greater curvature plication [GCP]), the short gastric vessels were divided, and the greater curvature was folded inward, with 2 suture lines to reduce the gastric capacity by a large intraluminal gastric fold. The average pre-operative body mass index was 43.3 kg/m² (range of 36.9 to 49.0), and 3 patients were men. Of the 15 patients, 9 underwent AP. For the 9 patients who underwent AP, the 6- and 12-month endoscopic evaluations demonstrated comparable-size plications over time, except for in 1 patient, who had a partially disrupted fold. Of the 6 patients who underwent GCP, the 6- and 12-month follow-up endoscopic examinations demonstrated a durable intraluminal fold, except for in 1 patient, with a partial disruption at the distal fold owing to a broken suture. For patients completing 1 year of follow-up, the percentage of
excess weight loss was 23.3 % +/- 24.8 % in the AP group (n = 5) and 53.4 % +/- 22.7 % in the GCP group (n = 6). No bleeding or infectious complications developed. The 1st patient in the GCP group required re-operation and plication reduction owing to gastric obstruction. The authors concluded that their initial experience has suggested that a reduction in gastric capacity can be achieved by way of plication of the anterior stomach and greater curvature. The early weight loss results have been encouraging, with better weight loss in patients who underwent GCP. They stated that the use of laparoscopic GCP warrants additional investigation as a primary bariatric procedure.

Huang et al (2012) noted that the laparoscopic adjustable gastric band has been widely accepted as 1 of the safest bariatric procedures to treat morbid obesity. However, because of variations in the results and the complications that tend to arise from port adjustment, alternative procedures are needed. These researchers have demonstrated, in a university hospital setting, the safety and feasibility of a novel technique, laparoscopic adjustable gastric banded plication, designed to improve the weight loss effect and decrease gastric band adjustment frequency. These investigators enrolled 26 patients from May 2009 to August 2010. Laparoscopic adjustable gastric banded plication was performed using 5-port surgery. They placed Swedish bands using the pars flaccida method, divided the greater omentum, and performed gastric plication below the band to 3 cm from the pylorus using a single-row continuous suture. The data were collected and analyzed pre- and post-operatively. The mean operative time was 87.3 mins without any intra-operative complications. The average post-operative hospitalization was 1.33 days. The mean excess weight loss at 1, 3, 6, 9, and 12 months after surgery was 21.9 %, 31.9 %, 41.3 %, 55.2 %, and 59.5 %, respectively. The mean follow-up time was 8.1 months (range of 2 to 15), and the gastric band adjustment rate was 1.1 times per patient during this period. Two complications developed: (i) gastrogastric intussusception and (ii) tube kinking at the subcutaneous layer. Both cases were corrected by reoperation. No mortality was
observed. The authors concluded that laparoscopic adjustable gastric banded plication provides both restrictive and reductive effects and is reversible. The technique is safe, feasible, and reproducible and can be used as an alternative bariatric procedure. Moreover, the authors stated that comparative studies and long-term follow-up are needed to confirm their findings.

Ji et al (2014) conducted a systematic review of the currently available literature regarding the outcomes of laparoscopic gastric plication (LGP) for the treatment of obesity. The authors' systematic review yielded 14 studies encompassing 1,450 LGP patients. Peri-operative data were collected from each study and recorded. Mean pre-operative BMI ranged from 31.2 to 44.5 kg/m², and 80.8 % of the patients were female. Operative time ranged from 50 to 117.9 mins (average of 79.2 mins). Hospital stay varied from 0.75 to 5 days (average of 2.4 days). The percentage of EWL (% EWL) for LGP varied from 31.8 % to 74.4 % with follow-up from 6 months to 24 months. No mortality was reported in these studies and the rate of major complications requiring re-operation ranged from 0 % to 15.4 % (average of 3.7 %). The authors concluded that early reports with LGP were promising with a favorable short-term safety profile. However, it remains unclear if weight loss following LGP is durable in the long-term. They stated that additional prospective comparative trials and long-term follow-up are needed to further define the role of LGP in the surgical management of obesity.

In a prospective study, Zeinoddini (2014) evaluated safety and effectiveness of LGP on adolescents. Measured parameters included %EWL, percentage of BMI loss (%BMIL), obesity related co-morbidities, operative time, and length of hospitalization and complications. Laparoscopic gastric plication was performed in 12 adolescents (9 females and 3 males). Mean (SD) age of the patients was 13.8 ± 1 year. Mean pre-operative weight and BMI were 112.4 ± 19.7 kg and 46.0 ± 4 kg/m², respectively. Mean (SD) %EWL and %BMIL were 68.2 ± 9.9 % and 79.0 ± 9.0 %, respectively after 2 years. All medical
co-morbidities were improved after LGP. There were no deaths. One patient required replication 4 days post-operatively due to obstruction at the site of the last knot. No other major complications were observed. No patient required re-hospitalization. The authors concluded that LGP has the potential of being an ideal weight loss surgery for adolescents, resulting in excellent weight loss and minimal psychological disruption. It is associated with a minimal risk of leakage, bleeding, and nutritional deficiency. However, they stated that large well-designed studies with long-term follow-up are needed.

Sclerotherapy for Dilated Gastrojejunostomy:

The textbook Townsend: Sabiston Textbook of Surgery (2012) states that, in regard to investigational bariatric procedures, “endoscopic incisionless surgery has focused on patients after Roux-en-Y gastric bypass (RYGB) who have inadequate weight loss or significant weight regain and who have a dilated gastrojejunostomy. It is thought that these patients lose restriction because of the dilated gastrojejunostomy and thus overeat. Surgeons have tried endoscopic injection of sclerosing agents to create scar and a smaller anastomosis, with variable effects.”

In 2008, Loewen and Barba evaluated the injection of morrhuate sodium as sclerotherapy to decrease the diameter of the gastrojejunostomy anastomosis following gastric bypass. A total of 71 patients underwent sclerotherapy at their gastrojejunostomy from July 2004 to August 2006. A retrospective review was performed of this group, including chart review, follow-up data with weight checks, and telephone interview findings. The average age of the patients was 45 years and all but 4 patients were women. Sclerotherapy was done an average of 2.9 years after gastric bypass. The starting weight at endoscopy was an average of 218 lb-18 lb heavier than the average nadir weight. The average diameter of the gastrojejunostomy was 2.3 cm. An average of 13 mL morrhuate sodium was injected circumferentially. Repeat therapy was
performed in 35 patients (49%). No hospital admissions or complications occurred in relation to the procedure. During the 12-month follow-up period, 72% of patients maintained or lost weight. The analysis showed a high body mass index (at endoscopy) to be the only predictive factor for successful weight maintenance or loss. The authors reported, “a randomized controlled study is necessary to validate these findings.”

In a 2007 article, Spaulding, Osler and Patlak studied endoscopic sclerotherapy with sodium morrhuate of a dilated gastrojejunostomy in 147 gastric bypass patients. In a retrospective review, 32 patients were identified for whom > or =12 months of postprocedure data were available. Their weight trends before and after treatment were assessed by paired t test. A total of 32 patients who were gaining weight after gastric bypass underwent sclerotherapy of their dilated gastrojejunostomy. The timing of treatment ranged from 10 to 140 months (average 56) after Roux-en-Y gastric bypass. Before sclerotherapy, patients were gaining weight at a rate of .36 kg/mo. After treatment, they were losing weight at a rate of .39 kg/mo. After treatment, 56.3% of patients began to lose weight, 34.4% had their weight stabilize, and 9.4% continued to gain weight.

Gastrointestinal Liners (EndoBarrier) for the Treatment of Obesity:

Endoscopic duodenal-jejunal bypass is the endoscopic placement of a duodenal-jejunal bypass sleeve (eg, EndoBarrier) which lines the first section of the small intestine causing food to be absorbed further along the intestine. Once implanted, the device is purported to influence gastrointestinal hormones and satiety. It is suggested to promote weight loss in individuals who are potential candidates for bariatric surgery, but are too heavy to safely undergo the procedure.

An UpToDate review on " Bariatric surgical operations for the management of severe obesity: Descriptions " (Lim, 2015) lists
“Endoscopic gastrointestinal bypass devices” as investigational. It states that “Endoscopic gastrointestinal bypass devices (EGIBD) -- A barrier device is deployed to prevent luminal contents from being absorbed in the proximal small intestine. The EndoBarrier is 60-cm long and it extends from the proximal duodenum to the mid-jejunum and thus mimics a duodenojejunal bypass. It is a safe procedure but is hallmarked by an up to 20% rate of early removal due to patient intolerance. The ValenTx is a 120-cm barrier device that extends from the gastroesophageal junction to the jejunum. This too has a high rate of early removal, but excess weight loss at 3 months was reported to be 40%, and significant improvement was seen in 7 out of 7 diabetic patients within those 3 months. Data are still lacking about the longevity of these endobarriers and their outcomes once the barrier is removed”.

The EndoBarrier, an endoscopically delivered duodeno-jejunal bypass liner (DJBL), is a plastic flexible tube that is placed in the duodenal bulb, directly behind the pylorus. It extends from the duodenum to the proximal jejunum. Recent studies have suggested that the use of EndoBarrier has resulted in significant weight reduction in comparison to control-diet patients.

Schouten et al (2010) noted that the endoscopically placed duodenal-jejunal bypass sleeve or EndoBarrier Gastrointestinal Liner has been designed to achieve weight loss in morbidly obese patients. These researchers reported on the first European experience with this device. A multi-center, randomized clinical trial was performed. A total of 41 patients were included and 30 underwent sleeve implantation; 11 patients served as a diet control group. All patients followed the same low-calorie diet during the study period. The purpose of the study was to determine the safety and effectiveness of the device. A total of 26 devices were successfully implanted. In 4 patients, implantation could not be achieved. Four devices were explanted prior to the initial protocol end point because of migration (n = 1), dislocation of the anchor (n = 1), sleeve obstruction (n = 1), and continuous epigastric pain (n = 1). The
remaining patients all completed the study. Mean procedure
time was 35 mins (range of 12 to 102) for a successful
implantation and 17 mins (range of 5 to 99) for explantation. There were no procedure related adverse events. During the
study period the 26 duodenal-jejunal bypass sleeve patients
(100 %) had at least 1 adverse event, mainly abdominal pain
and nausea during the first week after implantation. Initial
mean BMI was 48.9 and 47.4 kg/m2 for the device and control
patients, respectively. Mean excess weight loss after 3 months
was 19.0 % for device patients versus 6.9 % for control patients
(p < 0.002). Absolute change in BMI at 3 months was 5.5 and
1.9 kg/m2, respectively. Type 2 diabetes mellitus was present
at baseline in 8 patients of the device group and improved in 7
patients during the study period (lower glucose levels, HbA1c,
and medication requirements). The authors concluded that the
EndoBarrier Gastrointestinal Liner is a feasible and safe
non-invasive device with excellent short-term weight loss
results. The device also has a significant positive effect on type
2 diabetes mellitus. Moreover, they stated that long-term
randomized and sham studies for weight loss and treatment of
diabetes are necessary to determine the role of the device in
the treatment of morbid obesity.

Gersin et al (2010) examined the effects of an endoscopic DJBL
for pre-operative weight loss in bariatric surgery candidates. A
total of 21 obese subjects in the DJBL arm and 26 obese
subjects in the sham arm composed the intent-to-treat
population. The subjects in the sham arm underwent an
esophagastroduodenoscopy and mock implantation. Both
groups received identical nutritional counseling. The primary
endpoint was the difference in the percentage of excess weight
loss (EWL) at week 12 between the 2 groups. Secondary
endpoints were the percentage of subjects achieving 10 % EWL,
total weight change, and device safety. A total of 13 DJBL arm
subjects and 24 sham arm subjects completed the 12-week
study. EWL was 11.9 % +/- 1.4 % and 2.7 % +/- 2.0 % for the
DJBL and sham arms, respectively (p < 0.05). In the DJBL arm,
62 % achieved 10 % or more EWL compared with 17 % of the
subjects in the sham arm (p < 0.05). Total weight change in the
DJBL arm was -8.2 +/- 1.3 kg compared with -2.1 +/- 1.1 kg in the sham arm (p < 0.05). Eight DJBL subjects terminated early because of gastrointestinal bleeding (n = 3), abdominal pain (n = 2), nausea and vomiting (n = 2), and an unrelated preexisting illness (n = 1). None had further clinical symptoms after DJBL explantation. The authors concluded that the DJBL achieved endoscopic duodenal exclusion and promoted significant weight loss beyond a minimal sham effect in candidates for bariatric surgery. The main drawbacks of this study were: (i) study personnel were not blinded, and (ii) there was a lack of data on caloric intake.

Escalona et al (2012) evaluated safety, weight loss, and cardio-metabolic changes in obese subjects implanted with the DJBL for 1 year. Morbidly obese subjects were enrolled in a single-arm, open-label, prospective trial and implanted with the DJBL. Primary endpoints included safety and weight change from baseline to week 52. Secondary endpoints included changes in waist circumference, blood pressure, lipids, glycemic control, and metabolic syndrome. The DJBL was implanted endoscopically in 39 of 42 subjects (mean age of 36 +/- 10 years; 80 % female; mean weight of 109 +/- 18 kg; mean BMI of 43.7 +/- 5.9 kg/m2); 24 completed 52 weeks of follow-up. Three subjects could not be implanted due to short duodenal bulb. Implantation time was 24 +/- 2 mins. There were no procedure-related complications and there were 15 early endoscopic removals. In the 52-week completer population, total body weight change from baseline was -22.1 +/- 2.1 kg (p < 0.0001) corresponding to 19.9 +/- 1.8 % of total body weight and 47.0 +/- 4.4 % excess of weight loss. There were also significant improvements in waist circumference, blood pressure, total and low-density lipoprotein cholesterol, triglycerides, and fasting glucose. The authors concluded that the DJBL is safe when implanted for 1 year, and results in significant weight loss and improvements in cardio-metabolic risk factors. They stated that these results suggested that this device may be suitable for the treatment of morbid obesity and its related comorbidities. Main drawbacks of this study were its small sample size and only 24 of 39 subjects (62 %) completed
the 52-week followed-up.

Verdam et al (2012) stated that the prevalence of obesity is increasing worldwide. Its primary treatment consists of lifestyle changes. In severely obese (BMI greater than 40 kg/m2 or greater than or equal to 35 kg/m2 with co-morbidity) patients though, bariatric surgery has been found to be the only way to achieve permanent weight loss. Operations such as the placement of a gastric band or a gastric bypass can, however, lead to complications and necessitate secondary interventions. In search of less invasive treatments, placement of the EndoBarrier duodenal jejunal bypass liner appears to be a promising, safe and effective method for facilitating weight loss. Concomitant positive effects on cardiovascular risk factors including diabetes type 2 were observed. The authors noted that a multi-center trial is currently underway to examine the mechanism behind these effects.

Mathus-Vliegen (2012) stated that the EndoBarrier is a unique concept that starts to ameliorate the symptoms of diabetes mellitus type 2, soon after positioning. Weight-loss results are moderate, with 85 % of patients showing a more than 10 % excess weight loss in the 12 weeks pre-operatively. Sufficient implant training is required, but problems can still occur (e.g., due to a short duodenal bulb length). The stability of the anchors and the tolerability of the device still leave much to be desired. In 25 % of patients the EndoBarrier is explanted early, because of migration, physical symptoms, gastrointestinal hemorrhage, rotation and obstruction. Only 7 studies on the EndoBarrier are available and these are mostly small in size, short-term and with limited follow-up, and many questions regarding the safety and long-term effects of the device remain. The author concluded that this calls for a large, long-term, randomized, placebo-controlled, double-blind trial. Lessons should have been learned from the disastrous results with intra-gastric balloon implantation before commercializing another such product.

The OverStitch Suturing Device:
Bolton et al (2013) stated that weight regain secondary to VBG pouch dilation is a typical referral for bariatric surgeons. In this study these investigators compared an endoluminal pouch reduction (StomaphyX) to RYGB for revision. A retrospective review was completed for patients with a previous VBG presenting with weight regain between 2003 to 2010. A total of 30 patients were identified (StomaphyX; n = 14). Significant post procedure BMI loss was seen in each cohort (RYGB, 47.7 ± 7 kg/m(2) to 35 ± 7 kg/m(2); StomaphyX 43 ± 10 kg/m(2) to 40 ± 9 kg/m(2), p = 0.0007). Whereas nausea and headache were the only complications observed in StomaphyX patients, the RYGB group had a 43.5 % complication rate and 1 mortality. Complications following RYGB include: incisional hernia (13 %), anastomotic leak (8.7 %), respiratory failure (8.7 %), fistula (8.7 %), and perforation (4.35 %). The median length of stay following RYGB was 6 days compared to 1.5 ± 0.5 days following StomaphyX. The authors concluded that the findings of this study suggested that while RYGB revision may achieve greater weight loss, the complication rates and severity is discouraging. StomaphyX may be a safe alternative. Moreover, they stated that further technical modifications of the device and longer follow-up may clarify the role of this approach.

Goyal et al (2013) examined if endoluminal reduction of gastric pouch and stoma using StomaphyX results in sustained weight loss in patients who regain weight after gastric bypass. Retrospective chart review was performed on 59 post-gastric bypass patients who underwent revision of gastric pouch using StomaphyX from 2007 to 2008. Post-procedure weight at 1 week, 1 month, and 6 months follow-up as well as weight at the time of the review was recorded for each patient. Average weight loss and excess body weight loss (EBWL) were 2.6 ± 2.3 kg and 7.3 ± 7.1 % (n = 42) at 1 week, 3.7 ± 2.9 kg and 11.6 ± 12.1 % (n = 31) at 1 month, and 3.8 ± 4.5 kg and 11.5 ± 17.9 % (n = 10) at 6 months, respectively. At the time of review, the average follow-up was 41 months, average weight loss was 1.7 ± 9.7 kg, and EBWL was 4.3 ± 29.8 % (n = 53). Endoscopy in 12 patients at average 18 months follow-up showed no sustained reduction in pouch and stoma size. The authors concluded that
StomaphyX resulted in weight loss that is not sustained on long-term follow-up. Pouch and stoma tend to regain their pre-procedure size on follow-up. They stated that StomaphyX cannot be recommended as a weight loss strategy in post-gastric bypass patients who regain weight.

Campos et al (2012) stated that RYGB may result in stenosis of the gastro-jejunal anastomosis (GJA). There is currently no well-defined management protocol for this complication. Through systematic review, these investigators analyzed the results of endoscopic dilation in patients with stenosis, including complication and success rates. The PubMed database was searched for relevant studies published each year from 1988 to 2010, and 23 studies were identified for analysis. Only papers describing the treatment of anastomotic stricture after RYGB were included, and case-reports featuring less than 3 patients were excluded. The mean age of the trial populations was 42.3 years and mean pre-operative BMI was 48.8 kg/m². A total of 1,298 procedures were undertaken in 760 patients (81 % female), performing 1.7 dilations per patient. Through-the-scope balloons were used in 16 studies (69.5 %) and Savary-Gilliard bougies in 4 studies. Only 2 % of patients needed surgical revision after dilation; the reported complication rate was 2.5 % (n = 19). Annual success rate was greater than 98 % each year from 1992 to 2010, except for a 73 % success rate in 2004; 7 studies reported complications, perforation being the most common, reported in 14 patients (1.82 %) and requiring immediate operation in 2 patients. Other complications were also reported: 1 esophageal hematoma, 1 Mallory-Weiss tear, 1 case of severe nausea and vomiting, and 2 cases of severe abdominal pain. The authors concluded that endoscopic treatment of stenosis is safe and effective; however, further high-quality randomized controlled trials are needed to confirm these findings.

Thompson et al (2013) stated that weight regain or insufficient loss after RYGB is common. This is partially attributable to dilatation of the gastro-jejunostomy, which diminishes the restrictive capacity of RYGB. Endoluminal interventions for GJ
reduction are being explored as alternatives to revision surgery. These researchers performed a randomized, blinded, sham-controlled trial to evaluate weight loss after sutured transoral outlet reduction (TORe). Patients with weight regain or inadequate loss after RYGB and GJ diameter greater than 2 cm were assigned randomly to groups that underwent TORe (n = 50) or a sham procedure (controls, n = 27). Intra-operative performance, safety, weight loss, and clinical outcomes were assessed. Subjects who received TORe had a significantly greater mean percentage weight loss from baseline (3.5 %; 95 % confidence interval [CI]: 1.8 % to 5.3 %) than controls (0.4 %; 95 % CI: 2.3 % weight gain to 3.0 % weight loss) (p = 0.021), using a last observation carried forward intent-to-treat analysis. As-treated analysis also showed greater mean percentage weight loss in the TORe group than controls (3.9 % and 0.2 %, respectively; p = 0.014). Weight loss or stabilization was achieved in 96 % subjects receiving TORe and 78 % of controls (p = 0.019). The TORe group had reduced systolic and diastolic blood pressure (p < 0.001) and a trend toward improved metabolic indices. In addition, 85 % of the TORe group reported compliance with the healthy lifestyle eating program, compared with 53.8 % of controls; 83 % of TORe subjects said they would undergo the procedure again, and 78 % said they would recommend the procedure to a friend. The groups had similar frequencies of adverse events. The authors concluded that a multi-center randomized trial provided Level I evidence that TORe reduces weight regain after RYGB. These results were achieved using a superficial suction-based device; greater levels of weight loss could be achieved with newer, full-thickness suturing devices. These researchers stated that TORe is one approach to avoid weight regain; moreover, they noted that a longitudinal multi-disciplinary approach with dietary counseling and behavioral changes are needed for long-term results.

Jirapinyo et al (2013) evaluated the technical feasibility, safety, and early outcomes of a procedure using a commercially available endoscopic suturing device to reduce the diameter of the GJA. This was a retrospective analysis of 25 consecutive
patients who underwent TORe for dilated GJA and weight regain. An endoscopic suturing device was used to place sutures at the margin of the GJA in order to reduce its aperture. On chart review, clinical data were available at 3, 6, and 12 months. Patients had regained a mean of 24 kg from their weight loss nadir and had a mean BMI of 43 kg/m² at the time of endoscopic revision. Average anastomosis diameter was 26.4 mm. Technical success was achieved in all patients (100%) with a mean reduction in anastomosis diameter to 6 mm (range of 3 to 10), representing a 77.3% reduction. The mean weight loss in successful cases was 11.5 kg, 11.7 kg, and 10.8 kg at 3, 6, and 12 months, respectively. There were no major complications. The authors concluded that this case series demonstrated the technical feasibility, safety, and effectiveness of performing GJ reduction using a commercially available endoscopic suturing device. They stated that this technique may represent an effective and minimally invasive option for the management of weight regain in patients with RYGB.

Dakin and colleagues (2013) noted that weight recidivism after RYGB is a challenging problem for patients and bariatric surgeons alike. Traditional operative strategies to combat weight regain are technically challenging and associated with a high morbidity rate. Endoluminal interventions are thus an attractive alternative that may offer a good combination of results coupled with lower peri-procedure risk that might one day provide a solution to this increasingly prevalent problem. These investigators systematically reviewed the available literature on endoluminal procedures used to address weight regain after RYGB, with specific attention to the safety profile, effectiveness, cost, and current availability. This retrospective review focused only on endoluminal procedures that were performed for weight regain after RYGB, as opposed to primary endoluminal obesity procedures. Several methods of endoluminal intervention for weight regain were reviewed, ranging from injection of inert substances to suturing and clipping devices. The literature review showed the procedures on the whole to be well-tolerated with limited effectiveness.
The majority of the literature was limited to small case-series. Most of the reviewed devices were no longer commercially available. The authors concluded that endoluminal therapy represents an intriguing strategy for weight regain after RYGB. However, the current and future technologies must be rigorously studied and improved such that they offer durable, repeatable, cost-effective solutions.

Pauli et al (2013) stated that despite advances in many areas of therapeutic endoscopy, the development of an effective endoscopic suturing device has been elusive. These researchers evaluated the safety and effectiveness of a suturing device to place and secure sutures within normal, in-vivo human colonic tissue prior to surgical resection. Patients undergoing elective colectomy were enrolled in this treat-and-resect model. The OverStitch endoscopic suturing device (Apollo Endosurgery, Austin, TX) was used to place sutures in healthy colonic tissue during a 15-min, time-limited period. Following colectomy, the explanted tissue was evaluated to determine the depth of suture penetration and the effectiveness of the suture/cinch element. Clinical and operative data were recorded. A total of 4 patients (50 % female) were enrolled. Seven sutures were successfully placed, incorporating a total of 10 tissue bites in a mean of 13.5 mins. On inspection of the explanted tissue, all sutures were found to be located sub-serosal (no full thickness bites were taken). The suture and cinch elements were judged to be effective in the majority of cases. One device-related issue did not inhibit the ability to oppose tissue or place the cinch. There were no intra-operative or post-operative complications. The authors concluded that the OverStitch permitted safe and effective suturing in an in-vivo human colon model. The sutures were placed at a consistent sub-serosal depth and at no point risked iatrogenic injury to adjacent structures. Technical issues with the device were infrequent and did not inhibit the ability to place sutures effectively.

A clinical trial entitled “Endoscopic Surgery for Bariatric Revision after Weight Loss Failure” is not yet open for
participant recruitment (last verified June 2013). This clinical trial is designed to study the Apollo OverStitch endoscopic suturing device that has already been approved by the FDA as an option for bariatric surgery revision without having to re-operate on the patient. The investigators believe that the endoscopic technique may be able to provide weight loss without having to re-operate on the patient.


Laparoscopic Greater Curvature Plication:

Shen described the surgical technique of laparoscopic greater curvature plication (LGCP) and validated the safety and effectiveness of LGCP for the treatment of obesity in Chinese patients with a relatively low BMI. A total of 22 obese patients (mean age of 33.8 ± 6.0 years; mean BMI of 37.0 ± 7.0 kg/m(2)) underwent LGCP between September 2011 and September 2012. After dissecting the greater omentum and short gastric vessels, the gastric greater curvature plication with 2 rows of non-absorbable suture was performed under the guidance of a 32-F bougie. The data were collected during follow-up examinations performed at 1, 3, 6, and 12 months post-operatively. All procedures were performed laparoscopically. The mean operative time was 84.1 mins (50 to 120 mins), and the mean length of hospital stay was 3.8 days (2 to 10 days). There were no deaths or post-operative major complications that needed re-operation. The mean %EWL was 22.9 % ± 6.9 %, 38.6 % ± 9.8 %, 51.5 % ± 13.5 %, and 61.1 % ± 15.9 % at 1, 3, 6, and 12 months post-operatively. At 6 months, type 2 diabetes was in remission in 2 (50 %) patients, hypertension in 1 (33.3 %) patient, and dyslipidemia in 11 (78.6 %) patients. Decreases in the index for homeostasis model assessment of insulin resistance (HOMA-IR) and in insulin and glucose concentrations were observed. The authors concluded that the early outcomes of LGCP as a novel treatment for obese Chinese with a relatively low BMI were satisfactory with respect
to the effectiveness and low incidence of major complications. They stated that additional long-term follow-up and prospective, comparative trials are still needed.

*Transoral Mucosal Excision Sutured Gastroplasty:*

In a pilot study, Legner et al (2014) examined the effectiveness of transoral mucosal excision sutured gastroplasty for the treatment of gastro-esophageal reflux disease (GERD) and obesity. A total of 8 patients (GERD, n = 3 and obesity = 5) were selected according to a pre-approved study protocol. All GERD patients had pre-procedure manometry and pH monitoring to document GERD as well as quality of life and symptom questionnaires. Obese patients (BMI greater than 35) underwent a psychological evaluation and tests for co-morbidities. Under general anesthesia, a procedure was performed at the gastro-esophageal junction including mucosal excision, suturing of the excision beds for apposition, and suture knotting. One patient with micrognathia could not undergo the required pre-procedural passage of a 60 F dilator and was excluded. The first 2 GERD patients had incomplete procedures due to instrument malfunction. The subsequent 5 subjects had a successfully completed procedure. Four patients were treated for obesity and had an average excess weight loss of 30.3 % at 2-year follow-up. Of these patients, 1 had an 8-mm outlet at the end of the procedure recognized on video review -- a correctable error -- and another vomited multiple times post-operatively and loosened the gastroplasty sutures. The treated GERD patient had resolution of reflux-related symptoms and is off all anti-secretory medications at 2-year follow-up. Her DeMeester score was 8.9 at 24 months. The authors concluded that the initial human clinical experience showed promising results for effective and safe GERD and obesity therapy.

*Laparoscopic Mini-Gastric Bypass:*

Georgiadou et al (2014) summarized the available evidence about the efficacy and safety of laparoscopic mini-gastric
bypass (LMGB). These investigators performed a systematic search in the literature, and PubMed and reference lists were scrutinized (end-of-search date: July 15, 2013). For the assessment of the eligible articles, the Newcastle-Ottawa quality assessment scale was used. A total of 10 eligible studies were included in this study, reporting data on 4,899 patients. According to all included studies, LMGB induced substantial weight and BMI reduction, as well as substantial excess weight loss. Moreover, resolution or improvement in all major associated medical illnesses and improvement in overall Gastrointestinal Quality of Life Index score were recorded. Major bleeding and anastomotic ulcer were the most commonly reported complications. Re-admission rate ranged from 0 % to 11 %, whereas the rate of revision operations ranged from 0.3 % to 6 %. The latter were conducted due to a variety of medical reasons such as inadequate or excessive weight loss, malnutrition, and upper gastro-intestinal bleeding. Finally, the mortality rate ranged between 0 % and 0.5 % among primary LMGB procedures. The authors concluded that LMGB represents an effective bariatric procedure; its safety and minimal post-operative morbidity seem remarkable. They stated that randomized comparative studies seem mandatory for the further evaluation of LMGB.

**Bariatric Surgery for Type-2 Diabetes:**

Zechmeister-Koss et al (2014) applied the GRADE approach to evaluate the safety and effectiveness of the duodenal-jejunal bypass liner (DJBL) for the treatment of (i) patients with obesity greater than or equal to grade II (with co-morbidities) and (ii) patients with type 2 diabetes mellitus + obesity greater than or equal to grade I. These researchers included 10 studies with a total of 342 patients that primarily investigated a prototype of the DJBL. In high-grade obese patients, short-term excess weight loss was observed. For the remaining patient-relevant endpoints and patient populations, evidence was either not available or ambiguous. Complications (mostly minor) occurred in 64 to 100 % of DJBL patients compared to 0 to 27 % in the control groups. Gastro-intestinal bleeding was observed in 4 %
of patients. The authors do not yet recommend the device for routine use.

Parikh et al (2014) compared bariatric surgery versus intensive medical weight management (MWM) in patients with type 2 diabetes mellitus (T2DM) who do not meet current National Institutes of Health criteria for bariatric surgery and examined if the soluble form of receptor for advanced glycation end products (sRAGE) is a biomarker to identify patients most likely to benefit from surgery. A total of 57 patients with T2DM and BMI 30 to 35, who otherwise met the criteria for bariatric surgery were randomized to MWM versus surgery (bypass, sleeve or band, based on patient preference). The primary outcomes assessed at 6 months were change in homeostatic model of insulin resistance (HOMA-IR) and diabetes remission. Secondary outcomes included changes in HbA1c, weight, and sRAGE. The surgery group had improved HOMA-IR (-4.6 versus +1.6; p = 0.0004) and higher diabetes remission (65 % versus 0 %, p < 0.0001) than the MWM group at 6 months. Compared to MWM, the surgery group had lower HbA1c (6.2 versus 7.8, p = 0.002), lower fasting glucose (99.5 vs 157; P = 0.0068), and fewer T2DM medication requirements (20% vs 88%; P < 0.0001) at 6 months. The surgery group lost more weight (7. vs 1.0 BMI decrease, P < 0.0001). Higher baseline sRAGE was associated with better weight loss outcomes (r = -0.641; p = 0.046). There were no mortalities. The authors concluded that surgery was very effective short-term in patients with T2DM and BMI 30 to 35. Baseline sRAGE may predict patients most likely to benefit from surgery. However, they stated that these findings need to be confirmed with larger studies.

Sjostrom et al (2014) noted that short-term studies showed that bariatric surgery causes remission of diabetes. The long-term outcomes for remission and diabetes-related complications are not known. These researchers determined the long-term diabetes remission rates and the cumulative incidence of microvascular and macrovascular diabetes complications after bariatric surgery. The Swedish Obese Subjects (SOS) is a prospective matched cohort study
conducted at 25 surgical departments and 480 primary health care centers in Sweden. Of patients recruited between September 1, 1987, and January 31, 2001, 260 of 2,037 control patients and 343 of 2,010 surgery patients had type-2 diabetes at baseline. For the current analysis, diabetes status was determined at SOS health examinations until May 22, 2013. Information on diabetes complications was obtained from national health registers until December 31, 2012. Participation rates at the 2-, 10-, and 15-year examinations were 81%, 58%, and 41% in the control group and 90%, 76%, and 47% in the surgery group. For diabetes assessment, the median follow-up time was 10 years (interquartile range [IQR], 2 to 15) and 10 years (IQR, 10 to 15) in the control and surgery groups, respectively. For diabetes complications, the median follow-up time was 17.6 years (IQR, 14.2 to 19.8) and 18.1 years (IQR, 15.2 to 21.1) in the control and surgery groups, respectively. Adjustable or non-adjustable banding (n = 61), vertical banded gastroplasty (n = 227), or gastric bypass (n = 55) procedures were performed in the surgery group, and usual obesity and diabetes care was provided to the control group. Main outcome measures were diabetes remission, relapse, and diabetes complications. Remission was defined as blood glucose less than 110 mg/dL and no diabetes medication. The diabetes remission rate 2 years after surgery was 16.4 % (95 % CI: 11.7 % to 22.2 %; 34/207) for control patients and 72.3 % (95 % CI: 66.9 % to 77.2 %; 219/303) for bariatric surgery patients (odds ratio [OR], 13.3; 95 % CI: 8.5 to 20.7; p < 0.001). At 15 years, the diabetes remission rates decreased to 6.5 % (4/62) for control patients and to 30.4 % (35/115) for bariatric surgery patients (OR, 6.3; 95 % CI: 2.1 to 18.9; p < 0.001). With long-term follow-up, the cumulative incidence of microvascular complications was 41.8 per 1,000 person-years (95 % CI: 35.3 to 49.5) for control patients and 20.6 per 1,000 person-years (95 % CI: 17.0 to 24.9) in the surgery group (hazard ratio [HR], 0.44; 95 % CI: 0.34 to 0.56; p < 0.001). Macrovascular complications were observed in 44.2 per 1,000 person-years (95 % CI: 37.5-52.1) in control patients and 31.7 per 1,000 person-years (95 % CI: 27.0 to 37.2) for the surgical group (HR, 0.68; 95 % CI: 0.54 to 0.85; p = 0.001). The authors concluded that in this very
long-term follow-up observational study of obese patients with type 2 diabetes, bariatric surgery was associated with more frequent diabetes remission and fewer complications than usual care. Moreover, they stated that these findings require confirmation in randomized trials.

Yu et al (2015) evaluated the long-term effects of bariatric surgery on type 2 diabetic patients. These investigators searched Cochrane Library, PubMed, and EMBase up to Dec 2013. Randomized controlled trials (RCTs) and cohort studies of bariatric surgery for diabetes patients that reported data with more than 2 years of follow-up were included. They used rigorous methods to screen studies for eligibility and collected data using standardized forms. Where applicable, these investigators pooled data by meta-analyses. A total of 26 studies, including 2 RCTs and 24 cohort studies that enrolled 7,883 patients, proved eligible. Despite the differences in the design, those studies consistently showed that bariatric surgery offered better treatment outcomes than non-surgical options. Pooling of cohort studies showed that BMI decreased by 13.4 kg/m(2) (95% confidence interval (CI): -17.7 to -9.1), fasting blood glucose by 59.7 mg/dl (95% CI: -74.6 to -44.9), and glycated hemoglobin by 1.8% (95% CI: -2.4 to -1.3). Diabetes was improved or in remission in 89.2% of patients, and 64.7% of patients was in remission. Weight loss and diabetes remission were greatest in patients undergoing bilio-pancreatic diversion/duodenal switch, followed by gastric bypass, sleeve gastrectomy, and adjustable gastric banding. The authors noted that bariatric surgery may achieve sustained weight loss, glucose control, and diabetes remission. Moreover, they stated that large randomized trials with long-term follow-up are warranted to demonstrate the effect on outcomes important to patients (e.g., cardiovascular events).

Furthermore, an UpToDate review on “Management of persistent hyperglycemia in type 2 diabetes mellitus” (McCullock, 2014) states that “Surgical treatment of obese patients with diabetes results in the largest degree of sustained weight loss (20 to 30 percent after one to two years) and, in
parallel, the largest improvements in blood glucose control. There are a growing number of unblinded trials comparing bariatric surgery with medical therapy for the treatment of type 2 diabetes. Despite these impressive metabolic results, concerns remain about acute post-operative complications including need for re-operations and re-hospitalizations and rare, but potentially severe, adverse events; the long-term success rates in maintaining weight loss; and the reproducibility of the results in patients with an extensive history of diabetes or with a different surgical team. Some weight regain is typical within two to three years of bariatric procedures, and different bariatric procedures result in different levels of weight loss and corresponding reductions in glycemia. Longer-term follow-up of clinically important endpoints, such as effects on microvascular and macrovascular complications and mortality, are required before laparoscopic banding or other bariatric surgery procedures can be routinely recommended for the treatment of persistent hyperglycemia, resistant to multiple medications, in obesity-related type 2 diabetes.”

**Vagus Nerve Blocking (VBLOC Therapy):**

Vagus/vagal nerve block, vagal blocking for obesity control (VBLOC [eg, Maestro]) involves laparoscopic placement of two leads (electrodes) in contact with vagal nerve trunks and a subcutaneously implanted neuromodulation device which is externally programmed to intermittently send electrical impulses via the implanted electrodes. The electrical impulses are purported to block vagus nerve signals in the abdominal region, inhibiting gastric motility and increasing satiety.

On January 15, 2015, the FDA approved VBLOC vagal blocking therapy, delivered via the Maestro System, for the treatment of adult patients with obesity who have a BMI of at least 40 to 45 kg/m², or a BMI of at least 35 to 39.9 kg/m² with a related health condition (e.g., high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program within the past 5 years).
However, there is currently insufficient evidence to support the VBLOC vagal nerve blocking therapy for the treatment of obesity.

In an open-label, 3-center study, Camilleri et al (2008) evaluated the effects of vagal blocking (VBLOC therapy) on excess weight loss (EWL), safety, dietary intake, and vagal function. This clinical trial was conducted in obese subjects (BMI of 35 to 50 kg/m(2)). Electrodes were implanted laparoscopically on both vagi near the esophago-gastric junction to provide electrical block. Patients were followed for 6 months for body weight, safety, electrocardiogram, dietary intake, satiation, satiety, and plasma pancreatic polypeptide (PP) response to sham feeding. To specifically assess device effects alone, no diet or exercise programs were instituted. A total of 31 patients (mean BMI of 41.2 +/- 1.4 kg/m(2)) received the device. Mean EWL at 4 and 12 weeks and 6 months after implant was 7.5 %, 11.6 %, and 14.2 %, respectively (all p < 0.001); 25 % of patients lost greater than 25 % EWL at 6 months (maximum of 36.8 %). There were no deaths or device-related serious adverse events (AEs). Calorie intake decreased by greater than 30 % at 4 and 12 weeks and 6 months (all p < or = 0.01), with earlier satiation (p < 0.001) and reduced hunger (p = 0.005). After 12 weeks, plasma PP responses were suppressed (20 +/- 7 versus 42 +/- 19 pg/ml). Average percent EWL in patients with PP response less than 25 pg/ml was double that with PP response greater than 25 pg/ml (p = 0.02). Three patients had serious AEs that required brief hospitalization, 1 each for lower respiratory tract, subcutaneous implant site seroma, and Clostridium difficile diarrhea. The authors concluded that intermittent, intra-abdominal vagal blocking is associated with significant EWL and a desirable safety profile. This was a small study (n = 31) with shorter-term follow-up (6 months); its findings need to be validated by well-designed studies with larger sample size and longer follow-up.

In a prospective, double-blind, RCT, Sarr et al (2012) examined the feasibility of vagal blockade (VBLOC therapy) to induce weight loss in patients with morbid obesity. A total of 503
subjects were enrolled at 15 centers. After informed consent, 294 subjects were implanted with the vagal blocking system and randomized to the treated (n = 192) or control (n = 102) group. Main outcome measures were percentage EWL (% EWL) at 12 months and serious AEs. Subjects controlled duration of therapy using an external power source; therapy involved a programmed algorithm of electrical energy delivered to the sub-diaphragmatic vagal nerves to inhibit afferent/effferent vagal transmission. Devices in both groups performed regular, low-energy safety checks. Data were mean ± SEM. Study subjects consisted of 90 % females, BMI of 41 ± 1 kg/m(2), and age of 46 ± 1 years. Device-related complications occurred in 3 % of subjects. There was no mortality; 12-month % EWL was 17 ± 2 % for the treated and 16 ± 2 % for the control group.

Weight loss was related linearly to hours of device use; treated and controls with greater than or equal to 12 hours/day use achieved 30 ± 4 and 22 ± 8 % EWL, respectively. The authors concluded that VBLOC therapy to treat morbid obesity was safe, but weight loss was not greater in treated compared to controls; clinically important weight loss, however, was related to hours of device use. Post-study analysis suggested that the system electrical safety checks (low charge delivered via the system for electrical impedance, safety, and diagnostic checks) may have contributed to weight loss in the control group.

In an open-label study, Shikora et al (2013) evaluated the effect of intermittent vagal blocking (VBLOC) on weight loss, glycemic control, and blood pressure (BP) in obese subjects with diabetes mellitus type-2 (DM2). A total of 28 subjects were implanted with a VBLOC device (Maestro Rechargeable System) at 5 centers. Effects on weight loss, HbA1c, fasting blood glucose, and BP were evaluated at 1 week to 12 months; 26 subjects (17 females/9 males, 51 ± 2 years, BMI of 37 ± 1 kg/m(2), mean ± SEM) completed 12 months follow-up. One serious AE (pain at implant site) was easily resolved. At 1 week and 12 months, mean % EWL were 9 ± 1 % and 25 ± 4 % (p < 0.0001), and HbA1c declined by 0.3 ± 0.1 % and 1.0 ± 0.2 % (p = 0.02, baseline 7.8 ± 0.2 %). In DM2 subjects with elevated BP (n = 15), mean arterial pressure reduced by 7 ± 3 mmHg and 8 ± 3


mmHg (p = 0.04, baseline 100 ± 2 mmHg) at 1 week and 12 months. All subjects MAP decreased by 3 ± 2 mmHg (baseline 95 ± 2 mmHg) at 12 months. The authors concluded that VBLOC was safe in obese DM2 subjects and associated with meaningful weight loss, early and sustained improvements in HbA1c, and reductions in BP in hypertensive DM2 subjects. This was a small study (n = 28) with shorter-term follow-up (12 months); its findings need to be validated by well-designed studies with larger sample size and longer follow-up.

Shikora et al (2015) noted that the ReCharge trial is a double-blind, RCT of 239 participants with BMI of 40 to 45 kg/m or 35 to 40 kg/m with one or more obesity-related conditions. Interventions were implantation of either vBloc or sham devices and weight management counseling. Mixed models assessed percent excess weight loss (%EWL) and total weight loss (%TWL) in intent-to-treat analyses. At 18 months, 142 (88%) vBloc and 64 (83%) sham patients remained enrolled in the study. 18-month weight loss was 23 % EWL (8.8 % TWL) for vBloc and 10 % EWL (3.8 % TWL) for sham (p < 0.0001). vBloc patients largely maintained 12-month weight loss of 26 % EWL (9.7 % TWL). Sham regained over 40 % of the 17 % EWL (6.4 % TWL) by 18 months. Most weight regain preceded unblinding. Common adverse events of vBloc through 18 months were heartburn/dyspepsia and abdominal pain; 98 % of events were reported as mild or moderate and 79 % had resolved. The authors concluded that weight loss with vBloc was sustained through 18 months, while sham regained weight between 12 and 18 months. They stated that vBloc is effective with a low rate of serious complications. This study had several drawbacks: (i) frequency of missing data was appreciable at 18 months, (ii) statistical analysis of the ReCharge study was not pre-specified after 12 months, and (iii) all participants were not blinded through 18 months and were unblinded on a rolling basis, making interpretation more difficult. The authors stated that additional long-term data and continued follow-up of the ReCharge study are needed to further characterize the safety and effectiveness profile of vBloc therapy.
NOTES

Natural orifice transluminal endoscopic surgery (NOTES) is being explored for a variety of surgeries, including bariatric procedures. NOTES procedures are incisionless surgeries performed with an endoscope passed through the mouth. Tissue approximation and closure devices are being developed for use in conjunction with various endoscopic procedures, including NOTES. Examples of NOTES techniques for bariatric surgery include, but may not be limited to, endoscopic duodenal-jejunal bypass, intragastric balloon (also called gastric balloon), restorative obesity surgery, endoluminal (ROSE) procedure, and transoral gastroplasty (TG) (also referred to as vertical sutured gastroplasty or endoluminal vertical gastroplasty). Endoscopic closure devices proposed for use in conjunction with NOTES include: Over the Scope Clip (OTSC) System Set, OverStitch Endoscopic Suturing System, and StomaphyX Endoluminal Fastener and Delivery System.

Restorative obesity surgery, endoluminal (ROSE) procedure is suggested for the treatment of weight regain following gastric bypass surgery due to a gradual expansion of the gastric pouch. The stomach is accessed orally via an endoscope and reduced in size using an endoscopic closure device.

Endoscopic Sleeve Gastroplasty:

Transoral gastroplasty (TG), also referred to as vertical sutured gastroplasty or endoluminal vertical gastroplasty, is an incisionless procedure in which the stomach is purportedly restricted with staples or sutures by using endoscopic surgical tools guided through the mouth and esophagus.

In a single-center, pilot feasibility study (n = 4), Abu Dayyeh et al (2013) demonstrated the technical feasibility of transoral endoscopic gastric volume reduction with an endoscopic suturing device in a fashion similar to sleeve gastrectomy for the treatment of obesity. Main outcome measure was technical feasibility. These researchers successfully used an endoscopic
free-hand suturing system in 4 subjects, thus demonstrating the technical feasibility of a novel technique to mimic the anatomic manipulations created by surgical sleeve gastrectomy endoscopically. The authors concluded that endoscopic sleeve gastroplasty (ESG) for treatment of obesity is feasible. The main drawback of this study was that it was a pilot feasibility study with small number of subjects.

Sharaiha et al (2015) stated that novel endoscopic techniques have been developed as effective treatments for obesity. Recently, reduction of gastric volume via endoscopic placement of full-thickness sutures, termed ESG, has been described. These investigators evaluated the safety, technical feasibility, and clinical outcomes for ESG. Between August 2013 and May 2014, ESG was performed on 10 patients using an endoscopic suturing device. Their weight loss, waist circumference, and clinical outcomes were assessed. Mean patient age was 43.7 years and mean BMI was 45.2 kg/m². There were no significant adverse events noted. After 1 month, 3 months, and 6 months, excess weight loss of 18 %, 26 %, and 30 %, and mean weight loss of 11.5 kg, 19.4 kg, and 33.0 kg, respectively, were observed. The differences observed in mean BMI and waist circumference were 4.9 kg/m² (p = 0.0004) and 21.7 cm (p = 0.003), respectively. The authors concluded that ESG is effective in achieving weight loss with minimal adverse events. They stated that this approach may provide a cost-effective out-patient procedure to add to the steadily growing armamentarium available for treatment of this significant epidemic. These findings from a small (n = 10) study need to be validated by well-designed studies.

Lopez-Nava et al (2015) described the ESG used in 50 patients. The goal of this procedure is to reduce the gastric lumen into a tubular configuration, with the greater curvature modified by a line of sutured plications. General anesthesia with endotracheal intubation is needed. An endoscopic suturing system requiring a specific double-channel endoscope delivers full-thickness sets of running sutures from the antrum to the fundus. Patients were admitted and observed, with discharge
planned within 24 hours. Post-procedure out-patient care included diet instruction with intensive follow-up by a multi-disciplinary team. Voluntary oral contrast and endoscopy studies were scheduled to evaluate the gastroplasty at 3, 6, and 12 months. The technique was applied in 50 patients (13 men) with an average BMI of 37.7 kg/m(2) (range of 30 to 47) with 13 having reached 1 year. Procedure duration averaged 66 mins during which 6 to 8 sutures on average were placed. All patients were discharged in less than 24 hours. There were no major intra-procedural, early, or delayed adverse events. Weight loss parameters were satisfactory, mean BMI changes from 37.7 ± 4.6 to 30.9 ± 5.1 kg/m(2) at 1 year, and mean %TBWL was 19.0 ± 10.8. Oral contrast studies and endoscopy revealed sleeve gastroplasty configuration at least until 1 year of follow-up. The authors concluded that ESG is a safe, effective, and reproducible primary weight loss technique. The main drawbacks of this study were its small sample size (n = 50) and short-term follow-up (1 year and only 13 subjects reached 1-year follow-up).

Furthermore, a Cochrane review on "Surgery for weight loss in adults" (Colquitt et al, 2014) as well as an UpToDate review on "Bariatric surgical operations for the management of severe obesity: Descriptions " (Lim, 2015) do not mention endoscopic sleeve gastroplasty as a therapeutic option.

AspireAssist Aspiration Therapy:

In a pilot study, Sullivan and colleagues (2013) evaluated the use of endoscopic aspiration therapy for the treatment of obesity. This method entails endoscopic placement of a gastrostomy tube (A-Tube) and the AspireAssist siphon assembly (Aspire Bariatrics, King of Prussia, PA) to aspirate gastric contents 20 minutes after meal consumption. These researchers performed a study of 18 obese subjects who were randomly assigned (2:1) to groups that underwent aspiration therapy for 1 year plus lifestyle therapy (n = 11; mean BMI, 42.6 ± 1.4 kg/m(2)) or lifestyle therapy only (n = 7; mean BMI, 43.4 ± 2.0 kg/m(2)). Lifestyle intervention comprised a 15-session diet
and behavioral education program; 10 of the 11 subjects who underwent aspiration therapy and 4 of the 7 subjects who underwent lifestyle therapy completed the 1st year of the study. After 1 year, subjects in the aspiration therapy group lost 18.6 % ± 2.3 % of their body weight (49.0 % ± 7.7 % of EWL) and those in the lifestyle therapy group lost 5.9 % ± 5.0 % (14.9 % ± 12.2 % of EWL) (p < 0.04); 7 of the 10 subjects in the aspiration therapy group completed an additional year of therapy and maintained a 20.1 % ± 3.5 % body weight loss (54.6 % ± 12.0 % of EWL). There were no AEs of aspiration therapy on eating behavior and no evidence of compensation for aspirated calories with increased food intake. No episodes of binge eating in the aspiration therapy group or serious AEs were reported. The authors concluded that aspiration therapy appeared to be a safe and effective long-term weight loss therapy for obesity. These preliminary findings from a pilot study need to be validated by well-designed studies.

Forssell and Noren (2015) evaluated the effectiveness of a novel device, the AspireAssist aspiration therapy system, for the treatment of obesity. After 4 weeks taking a very-low-calorie diet, 25 obese men and women (BMI 39.8 ± 0.9 kg/m(2)) had the AspireAssist gastrostomy tube placed during a gastroscopy. A low-profile valve was installed 14 days later and aspiration of gastric contents was performed approximately 20 minutes after meals 3 times per day. Cognitive behavioral therapy was also started. At month 6, mean weight lost was 16.5 ± 7.8 kg in the 22 subjects who completed 26 weeks of therapy (p = 0.001). The mean percentage EWL was 40.8 ± 19.8 % (p = 0.001); 2 subjects were hospitalized for complications: 1 subject for pain after gastrostomy tube placement, which was treated with analgesics, and another because of an aseptic intra-abdominal fluid collection 1 day after gastrostomy tube placement. No clinically significant changes in serum potassium or other electrolytes occurred. The authors concluded that in this study, substantial weight loss was achieved with few complications using the AspireAssist system, suggesting its potential as an attractive therapeutic device for obese patients.
In a prospective observational study, Noren and Forssell (2016) evaluated the safety and effectiveness of the novel AspireAssist Aspiration Therapy System for treatment of obesity, and its effect on patient’s quality of life. A total of 25 obese subjects, mean age of 48 years (range of 33 to 65) were included in this study. A custom gastrostomy tube (A-tube) was percutaneously inserted during a gastroscopy performed under conscious sedation. Drainage and irrigation of the stomach were performed 3 times daily, 20 mins after each meal, for 1 to 2 years. Efficient aspiration required thorough chewing of ingested food. Treatment included a cognitive behavioral weight loss program. Mean BMI at inclusion was 39.8 kg/m² (range of 35 to 49). After 1 year mean (SD) BMI was 32.1 kg/m² (5.4), p < 0.01, and EWL was 54.4 % (28.8), p < 0.01. Quality of life, as measured with EQ-5D, improved from 0.73 (0.27) to 0.88 (0.13), p < 0.01. After 2 years BMI was 31.0 kg/m² (5.1), p < 0.01, and EWL was 61.5 % (28.5), p < 0.01. There were no serious AEs or electrolyte disorders. Compliance was 80 % after 1 year and 60 % after 2 years. The authors concluded that aspiration therapy is a safe and efficient treatment for obesity, and weight reduction improves quality of life. Excess weight was approximately halved in a year, with weight stability if treatment was continued; and long-term results remain to be investigated.

This study by Noren and Forssell (2016; n = 25; 2-year follow-up) appeared to be an extension of their 2015 study (n = 25; 6-month follow-up). It is unclear whether firm conclusions can be drawn from a 25-person observational study.

Furthermore, the authors noted that “Limitation of this study is the combination of aspiration therapy and CBT without any control group. This study only encompasses treatment during 1 to 2 years. Long-term patency is still unknown. It is our belief that once the desired weight goal is achieved many, if not most, patients will need to continue aspiration therapy, albeit possibly at a reduced frequency, to maintain weight stability. In order to determine this, we have started a prospective study in which we will follow 50 patients with AspireAssist and 50 patients with laparoscopic gastric bypass procedure for 5 years”. 
Thompson and colleagues (2016) stated that the AspireAssist System (AspireAssist) is an endoscopic weight loss device that is comprised of an endoscopically placed percutaneous gastrostomy tube and an external device to facilitate drainage of about 30% of the calories consumed in a meal, in conjunction with lifestyle (diet and exercise) counseling. In this 52-week clinical trial, a total of 207 subjects with a BMI of 35.0 to 55.0 kg/m² were randomly assigned in a 2:1 ratio to treatment with AspireAssist plus Lifestyle Counseling (n = 137; mean BMI was 42.2 ± 5.1 kg/m²) or Lifestyle Counseling alone (n = 70; mean BMI was 40.9 ± 3.9 kg/m²). The co-primary end-points were mean percent excess weight loss and the proportion of participants who achieved at least a 25% excess weight loss. At 52 weeks, participants in the AspireAssist group, on a modified intent-to-treat basis, had lost a mean (± S.D.) of 31.5 ± 26.7% of their excess body weight (12.1 ± 9.6% total body weight), whereas those in the Lifestyle Counseling group had lost a mean of 9.8 ± 15.5% of their excess body weight (3.5 ± 6.0% total body weight) (p < 0.001). A total of 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counseling group lost at least 25% of their excess body weight (p < 0.001). The most frequently reported AEs were abdominal pain and discomfort in the peri-operative period and peristomal granulation tissue and peristomal irritation in the post-operative period. Serious AEs were reported in 3.6% of participants in the AspireAssist group. The authors concluded that the weight loss efficacy and safety profile of the AspireAssist System suggested that this treatment approach may bridge the therapeutic gap between more conservative lifestyle modification and the established bariatric surgical procedures for people with class II and III obesity.

The authors noted that this study has several drawbacks: (i) although this was a RCT, subjects could not be blinded as to treatment group because of the nature of the therapy. However, all other aspects of the study protocol, such as weight management counseling and study visits, were the same in the AspireAssist and Lifestyle Counseling groups to minimize any additional potential influences on the outcome measures,
It was possible that bias was introduced into the study by the high number of pre-enrollment withdrawals (approximately 14% in each treatment group) and post-enrollment withdrawals (26% in the AspireAssist group and 48% in the Lifestyle Counseling group), which is a common problem in weight loss intervention studies. However, the baseline and demographic characteristics of the randomized, enrolled, and completer populations were analyzed for homogeneity and were not different in the AspireAssist and Lifestyle Counseling groups. The consistency of study results by using different statistical analyses further indicated that withdrawals did not bias the results, (iii) this report included only 1-year results, and hence did not provide longer term safety and effectiveness of the AspireAssist therapy. However, approximately 90% of the AEs associated with AspireAssist are related to the A-tube, with about 50% occurring within the first week of implantation. The placement and management of the A-tube was similar to percutaneous endoscopic gastrostomy tubes, which have been used in clinical practice for more than 35 years, so the short-term and long-term complications of this device are already well known, and (iv) the study population contained a high percentage of female participants, which is a common problem of weight loss studies. Thus, these findings might not necessarily apply to men with obesity.

On June 14, 2016, the FDA approved the AspireAssist device to assist in weight loss in patients aged 22 and older who are obese, with a BMI of 35 to 55, and who have failed to achieve and maintain weight loss through non-surgical weight-loss therapy. Side effects related to use of the AspireAssist include occasional indigestion, nausea, vomiting, constipation and diarrhea. The AspireAssist is contraindicated in those with certain conditions, including uncontrolled hypertension, diagnosed bulimia, diagnosed binge eating disorder, night eating syndrome, certain types of previous abdominal surgery, pregnancy or lactation, inflammatory bowel disease or stomach ulcers. The AspireAssist is also contraindicated in patients with a history of serious pulmonary or cardiovascular disease, coagulation disorders, chronic abdominal pain or those at a
high-risk of medical complications from an endoscopic procedure. Furthermore, the AspireAssist device it is not indicated for use in short durations in those who are moderately overweight.

**Bariatric Surgery Prior to Total Hip or Knee Arthroplasty to Reduce Post-Operative Complications and Improve Clinical Outcomes for Obese Individuals:**

Smith et al (2016) examined if bariatric surgery prior to total hip arthroplasty (THA) or total knee arthroplasty (TKA) reduces the complication rates and improves the outcome following arthroplasty in obese patients. These researchers performed a systematic literature search of published and unpublished databases on the November 5, 2015. All papers reporting studies comparing obese patients who had undergone bariatric surgery prior to arthroplasty, or not, were included. Each study was assessed using the Downs and Black appraisal tool. A meta-analysis of RR and 95 % CI was performed to determine the incidence of complications including wound infection, deep vein thrombosis (DVT), pulmonary embolism (PE), revision surgery and mortality. From 156 potential studies, 5 were considered to be eligible for inclusion in the study. A total of 23,348 patients (657 who had undergone bariatric surgery, 22,691 who had not) were analyzed. The evidence-base was moderate in quality. There was no statistically significant difference in outcomes such as superficial wound infection (RR 1.88; 95 % CI: 0.95 to 0.37), deep wound infection (RR 1.04; 95 % CI: 0.65 to 1.66), DVT (RR 0.57; 95 % CI: 0.13 to 2.44), PE (RR 0.51; 95 % CI: 0.03 to 8.26), revision surgery (RR 1.24; 95 % CI: 0.75 to 2.05) or mortality (RR 1.25; 95 % CI: 0.16 to 9.89) between the 2 groups. The authors concluded that for most peri-operative outcomes, bariatric surgery prior to THA or TKA did not significantly reduce the complication rates or improve the clinical outcome. They stated that the findings of this study questions the previous belief that bariatric surgery prior to arthroplasty may improve the clinical outcomes for patients who are obese or morbidly obese. This finding is based on moderate quality evidence.
Abdemur et al (2016) stated that laparoscopic sleeve gastrectomy (LSG) as a primary bariatric procedure has gained significant popularity. Conversion to RYGBP or Roux-en-Y esophagojejunostomy (LRYEJ) has been described as a therapeutic option for inadequate weight loss after LSG and unresolved co-morbidities or complications such as leak, stricture, and severe GERD. These researchers determine reasons and outcomes of conversions of LSG to RYGBP. Between January 2004 and August 2014, a total of 1,118 patients underwent primary LSG for morbid obesity. A retrospective review of a prospectively collected database was conducted for laparoscopic conversions of LSG to RYGBP or LRYEJ, describing reasons and outcomes. Conversion to RYGBP was identified in 30 (2.7 %) patients, of whom only 9 (0.8 %) were originally from the authors' institution. Of the entire cohort of revisions, 9 (0.8 %) had intractable GERD; only 4 (0.4 % of total LSGs reviewed) were originally from the authors' institution; 7 (0.6 %) patients were revised for inadequate weight loss: 5 (0.4 %) originally from the authors' institution, 2 (0.2 %) for stricture, and 12 (1.1 %) for leak. Both the stricture and the leak patients were referred from outside institutions. All procedures were performed laparoscopically. The additional mean excess weight loss after conversion to RYGBP was 30.9 % with no mortalities. The authors concluded that the most common reason for conversion was chronic leak. The conversion rate of LSG to RYGBP due to inadequate weight loss, GERD, and stricture was 1.6 % for the entire group, with 0.8 % from the authors' institution. They stated that additional follow-up and studies are needed to define real incidence of GERD after LSG.

El Chaar et al (2016) noted that bariatric surgery is the only proven and effective long-term treatment for morbid obesity, with LSG being the most commonly performed weight loss procedure in the United States. Despite its safety and effectiveness, LSG’s association with both de-novo and
pre-existing GERD remains controversial. Therefore, this retrospective study determined the incidence, indications, and outcomes of revisional surgery following LSG in adult patients at the authors’ institution from 2010 to 2014. Descriptive outcomes were reported due to the small sample size. Of the 630 LSGs performed, 481 patients were included in the analysis (mean age and BMI = 46.2 and 44.3, respectively; 79.5 % female; 82.3 % white). A total of 12/481 patients underwent conversion to a different bariatric procedure due to inadequate weight loss, GERD, or both. The 6/12 patients with GERD-related symptoms and failed medical management underwent conversion to RYGBP following pre-operative wireless Bravo pH monitoring (Given Imaging) to confirm the diagnosis objectively. The other 6/12 patients with inadequate weight loss received either RYGBP or bilio-pancreatic diversion with duodenal switch (BPD/DS) based on personal choice. Overall, 9/12 patients underwent conversion to RYGBP, and 3/12 underwent conversion to BPD/DS. Median time from the initial surgery to conversion was 27 months (range of 17 to 41). Median operating room time was 168 minutes (range of 130 to 268). Median length of stay was 48 hours (range of 24 to 72). The follow-up rate at 3 months was 100 % (12/12 patients).

The authors concluded that the findings of this study showed that some patients may present following LSG with refractory GERD or inadequate weight loss, but that conversion to RYGBP or BPD/DS may be done safely and effectively.

*Prophylactic Mesh Placement for Prevention of Incisional Hernia after Open Bariatric Surgery:*

In a systematic review and meta-analysis, Dasari and colleagues (2016) examined if mesh prevents post-operative incisional hernia (IH) in open and laparoscopic bariatric surgery patients. A total of 7 studies met inclusion criteria. These investigators abstracted data regarding post-operative IH development, surgical site infection, and seroma or wound leakage and performed a meta-analysis. The prophylactic mesh group had significantly decreased odds of developing IH than the standard closure group (odds ratio, 0.30, 95 % CI: 0.13 to .68, p = 0.004).
No included studies evaluated outcomes after prophylactic mesh during laparoscopic bariatric surgery. The authors concluded that prophylactic mesh during open bariatric surgery appeared to be beneficial in reducing post-operative IH without significant increasing the odds of surgical site infection or seroma or wound leakage. Moreover, they stated that higher quality studies, including those in laparoscopic patients, and cost-utility analysis, are needed to support routine use of this intervention.

Appendix

Note: Calculation of BMI:

*BMI is calculated by dividing the patient's weight (in kilograms) by height (in meters) squared:

\[ \text{BMI} = \text{weight (kg)} \times \left[ \text{height (m)} \right]^2 \]

Note: To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to meters, multiply inches by 0.0254.

or

For a simple and rapid calculation of BMI, please click below and it will take you to the Obesity Education Initiative.


Table: American Society of Anesthesiologists Physical Status Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Healthy patient</td>
</tr>
</tbody>
</table>
II Mild systemic disease, no functional limitation

III Severe systemic disease, definite functional limitation

IV Severe systemic disease that is a constant threat to life

V Moribund patient unlikely to survive 24 hours with or without operation

E Emergency status: In addition to indicating underlying ASA status (I - V), any patient undergoing an emergency procedure is indicated by the suffix "E". For example, a fundamentally healthy patient undergoing an emergency procedure is classified as I-E. If the patient is undergoing an elective procedure, the "E" designation is not used.


Table: Criteria for the Diagnosis of Diabetes

- Hemoglobin A1C > 6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay*; or
- Fasting plasma glucose (FPG) >126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours*; or
- 2-hour plasma glucose (PG) >200 mg/dL (11.1 mmol/L) during an oral glucose tolerance test (OGTT). The test should be performed as described by the World Health Organization (WHO), using a glucose load containing the equivalent of 75 grams anhydrous glucose dissolved in water*; or
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose >200 mg/dL (11.1 mmol/L).

*In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

Source: ADA; 2015.
<table>
<thead>
<tr>
<th>CPT codes covered if selection criteria are met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>43644</td>
</tr>
<tr>
<td>43645</td>
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<td>43770</td>
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<tr>
<td>43887</td>
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<tr>
<td>43888</td>
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**CPT codes not covered for indications listed in the CPB (not all-inclusive) [incorrect for reporting bariatric surgery]:**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0312T</td>
<td>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</td>
</tr>
<tr>
<td>0313T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>0317T</td>
<td>Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed</td>
</tr>
<tr>
<td>15876</td>
<td>Suction assisted lipectomy; head and neck, trunk, upper/lower extremities</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>43620</td>
<td>Gastrectomy, total; with esophagoenterostomy</td>
</tr>
<tr>
<td>43621</td>
<td>with Roux-en-Y reconstruction</td>
</tr>
<tr>
<td>43622</td>
<td>with formation of intestinal pouch, any type</td>
</tr>
<tr>
<td>43631</td>
<td>Gastrectomy, partial, distal; with gastroduodenostomy</td>
</tr>
<tr>
<td>43632</td>
<td>with gastrojejunostomy</td>
</tr>
<tr>
<td>43633</td>
<td>with Roux-en-Y reconstruction</td>
</tr>
<tr>
<td>43634</td>
<td>with formation of intestinal pouch</td>
</tr>
<tr>
<td>+ 43635</td>
<td>Vagotomy when performed with partial distal gastrectomy (List separately in addition to code(s) for primary procedure)</td>
</tr>
<tr>
<td>47000</td>
<td>Biopsy of liver, needle; percutaneous [in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged liver)]</td>
</tr>
<tr>
<td>47001</td>
<td>Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (list separately in addition to code for primary procedure) [in the absence of signs or symptoms of liver disease (e.g., elevated liver disease, enlarged liver)]</td>
</tr>
<tr>
<td>47100</td>
<td>Biopsy of liver, wedge [in the absence of signs or symptoms of liver disease (e.g., elevated liver disease, enlarged liver)]</td>
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**Other CPT codes related to the CPB:**

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>43659</td>
<td>Unlisted laparoscopy procedure, stomach</td>
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<tr>
<td>43999</td>
<td>Unlisted procedure, stomach</td>
</tr>
<tr>
<td>47562 - 47620</td>
<td>Cholecystectomy</td>
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</table>

**Other HCPCS codes related to the CPB:**

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2083</td>
<td>Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline</td>
</tr>
<tr>
<td>S9449</td>
<td>Weight management classes, non-physician provider, per session</td>
</tr>
<tr>
<td>S9451</td>
<td>Exercise classes, non-physician provider, per session</td>
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</tbody>
</table>
**Nutrition classes, non-physician provider, per session**

**ICD-10 codes covered if selection criteria are met:**

<table>
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<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E66.01</td>
<td>Morbid (severe) obesity due to excess calories</td>
</tr>
<tr>
<td>E66.09</td>
<td>Obesity, unspecified</td>
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<tr>
<td>E66.3</td>
<td>Overweight</td>
</tr>
<tr>
<td>E67.8</td>
<td>Other specified hyperalimentation</td>
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<tr>
<td>K95.09</td>
<td>Other complications of gastric band procedure [dilated gastrojejunal stoma]</td>
</tr>
<tr>
<td>K95.89</td>
<td>Other complications of other bariatric procedure [dilated gastrojejunal stoma]</td>
</tr>
<tr>
<td>R63.2</td>
<td>Polyphagia</td>
</tr>
<tr>
<td>R63.5</td>
<td>Abnormal weight gain</td>
</tr>
<tr>
<td>Z46.51</td>
<td>Encounter for fitting and adjustment of gastric lap band</td>
</tr>
<tr>
<td>Z68.35</td>
<td>Body mass index [BMI] 35.0 - 39.9 or greater, adult [see criteria]</td>
</tr>
<tr>
<td>Z68.39</td>
<td>Body mass index [BMI] 40 or greater, adult</td>
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<tr>
<td>Z68.41</td>
<td>Body mass index [BMI] pediatric, greater than or equal to 95th percentile for age [BMI of 40 or greater for adolescents who have completed bone growth]</td>
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<tr>
<td>Z98.84</td>
<td>Bariatric surgery status</td>
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**ICD-10 codes not covered for indications listed in the CPB:**

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<th>Description</th>
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<tbody>
<tr>
<td>E11.00</td>
<td>Type II diabetes [not covered for persons with BMI less than 35]</td>
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<tr>
<td>E11.9</td>
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<tr>
<td>K31.84</td>
<td>Gastroparesis</td>
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<tr>
<td>N46.01</td>
<td>Male infertility</td>
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<tr>
<td>N46.9</td>
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<tr>
<td>N97.0</td>
<td>Female infertility</td>
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<td>N97.9</td>
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<tr>
<td>Z68.1</td>
<td>Body Mass Index 0 - 34.9</td>
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<td>Z68.34</td>
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**Sclerotherapy for Dilated Gastrojejunostomy:**
### CPT codes covered when selection criteria are met:

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<th>CPT Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>43236</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance</td>
</tr>
<tr>
<td>43253</td>
<td>Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (eg, anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic ultrasound examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)</td>
</tr>
</tbody>
</table>

### ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K30</td>
<td>Functional dyspepsia [dilated gastrojejunostomy]</td>
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<tr>
<td>K59.8</td>
<td>Other specified functional intestinal disorders [dilated gastrojejunostomy]</td>
</tr>
<tr>
<td>K95.09</td>
<td>Other complications of gastric band procedure [dilated gastrojejunostomy]</td>
</tr>
<tr>
<td>K95.89</td>
<td>Other complications of other bariatric procedure [dilated gastrojejunostomy]</td>
</tr>
</tbody>
</table>

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**The above policy is based on the following references:**


83. National Institutes of Health, National Heart, Lung and Blood Institute, Expert Panel on the Identification,


110. Blackburn GL. Comparison of medically supervised and


141. Rabkin RA. The duodenal switch as an increasing and


150. Inge TH, Krebs NF, Garcia VF, et al. Bariatric surgery for


158. Tice JA. Laparoscopic gastric banding for the treatment of


217. Dixon JB, le Roux CW, Rubino F, Zimmet P. Bariatric


241. Bray GA. Obesity in adults: Overview of management. UpToDate [serial online], Waltham, MA: UpToDate; reviewed December 2014.


263. Lim RB. Bariatric operations for management of obesity: Indications and preoperative preparation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2015.


272. Lim RB. Bariatric surgical operations for the management of severe obesity: Descriptions. UpToDate Inc., Waltham, MA. Last reviewed November 2015.


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Amendment to
Aetna Clinical Policy Bulletin Number: CPB 0157 Obesity Surgery

Surgical treatment of obesity is a covered benefit under the Pennsylvania Medical Assistance Program.