Clinical Policy Bulletin: Obesity Surgery

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Policy

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 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); or 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:

- “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
- Gastric bypass as a treatment for gastroparesis
- Gastrointestinal liners (EndoBarrier)
- Gastroplasty, more commonly known as “stomach stapling” (see below for clarification from vertical band gastroplasty)
- Intragastric balloon
- Laparoscopic gastric plication (also known as laparoscopic greater curvature plication [LGCP])
- LASGB, RYGB, and BPD/DS procedures not meeting the medical necessity criteria above
- Loop gastric bypass
- Mini gastric bypass
- 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)
- Transoral endoscopic surgery (e.g., using the OverStitch suturing device or the StomaphyX device/procedure)
- Vagus nerve blocking
- 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.

See also CPB 0039 - Weight Reduction Medications and Programs.

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 lifestyle 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 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.

**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 (body mass index (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; Oelschager 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 increases in weight (Collazo-Clavell, 1999). According to the Guidelines of the American Association of Clinical Endocrinologists and the American College of Endocrinology (1998), “Surgical treatment of obesity may be considered only in carefully selected patients [where] … obesity has been present for at least 5 years.” Guidelines on obesity surgery from the Massachusetts Department of Health and Human Services (2006) state that surgery candidates should be severely obese for at least 5 years.

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).

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

Surgery for obesity, termed bariatric surgery, includes gastric restrictive procedures and gastric bypass. The gastric restrictive procedures include vertical banded gastropasty 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 gastropasty (VBG) to the Roux-en-Y gastric bypass (RYGB) (Fisher and Schauer,
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. 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 RGBY induces similar amounts of weight loss. However, the assessment found that the profile of adverse events differs between the two approaches. Laparoscopic RGBY 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 ileocecal 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 ASMBMS 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 ASMBMS 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."

**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 needs to be validated by well-designed clinical studies.

**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 body mass index, 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 fundoscopy 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 body mass index 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.

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/m(2) (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.

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:

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 esophagogastroduodenoscopy 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/m); 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 follow-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-jejunalostomy, 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. http://www.clinicaltrials.gov/ct2/show/NCT01871896?term=OverStitch&rank=4.

Appendix

Note: Calculation of BMI:

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

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

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.

*BMI = weight (kg) * [height (m)]^2

Table: American Society of Anesthesiologists Physical Status Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
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http://qawww.aetna.com/cpb/medical/data/100_199/0157_draft.html 10/22/2014
<table>
<thead>
<tr>
<th>ASA Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Healthy patient</td>
</tr>
<tr>
<td>II</td>
<td>Mild systemic disease, no functional limitation</td>
</tr>
<tr>
<td>III</td>
<td>Severe systemic disease, definite functional limitation</td>
</tr>
<tr>
<td>IV</td>
<td>Severe systemic disease that is a constant threat to life</td>
</tr>
<tr>
<td>V</td>
<td>Moribund patient unlikely to survive 24 hours with or without operation</td>
</tr>
<tr>
<td>E</td>
<td>Emergency status: In addition to indicating underlying ASA status (I-V), any patient undergoing an emergency procedure is indicated by the suffix &quot;E&quot;. For example, a fundamentally healthy patient undergoing an emergency procedure is classified as I-E. If the patient is undergoing an elective procedure, the &quot;E&quot; designation is not used.</td>
</tr>
</tbody>
</table>


**CPT Codes / HCPCS Codes / ICD-9 Codes**

**CPT codes covered if selection criteria are met:**

- 00797
- 43644
- 43645
- 43770
- 43771
- 43772
- 43773
- 43774
- 43775
- 43842
CPT codes not covered for indications listed in the CPB (not all-inclusive) [incorrect for reporting bariatric surgery]:

0312T
0313T
0317T
43620
43621
43622
43631
43632
43633
43634
+ 43635

Other CPT codes related to the CPB:

43659
43999
47562 - 47620

Other HCPCS codes related to the CPB:

S2083 Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
S9449 Weight management classes, non-physician provider, per session
S9451 Exercise classes, non-physician provider, per session
S9452 Nutrition classes, non-physician provider, per session

**ICD-9 codes covered if selection criteria are met:**

- 278.00 Obesity, unspecified
- 278.01 Morbid obesity
- 278.02 Overweight
- 278.8 Other hyperalimentation
- 539.09 Other complications of gastric band procedure [dilated gastrojejunal stoma]
- 539.89 Other complications of other bariatric procedure [dilated gastrojejunal stoma]
- V45.86 Bariatric surgery status
- V53.51 Fitting and adjustment of gastric lap band
- V85.35 - V85.39 Body Mass Index 35.0 - 39.9, adult [see criteria]
- V85.41 - V85.45 Body Mass Index 40.0 and over, adult
- V85.54 Body Mass Index, pediatric, greater than or equal to 95th percentile for age [indicates BMI of 30 or above]

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

- 536.3 Gastroparesis
- 606.0 - 606.9 Infertility, male
- 628.0 - 628.9 Infertility, female

**Sclerotherapy for Dilated Gastrojejunostomy:**

**CPT codes not covered for indications listed in the CPB:**

43236
43253

**ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):**

- 536.8 Dyspepsia and other specified disorders of function of stomach [dilated gastrojejunostomy]
- 539.09 Other complications of gastric band procedure [dilated gastrojejunostomy]
- 539.89 Other complications of other bariatric procedure [dilated gastrojejunostomy]
- 564.89 Other functional disorders of intestine [dilated gastrojejunostomy]

**Other ICD-9 codes related to the CPB:**

V45.86 Bariatric surgery status
The above policy is based on the following references:

45. Schneider WL. Laparoscopic adjustable gastric banding for clinically severe (morbid) obesity. Health Technology Brief. HTA 7: Series B. Edmonton, AB: Alberta Heritage
Foundation for Medical Research (AHFMR); December 2000. Available at:  


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