



# BARIATRIC SURGERY

**Policy Number:** 2016M0067B

**Effective Date:** September 1, 2016

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### INSTRUCTIONS:

*“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”*

**RELATED MEDICAL PRODUCTS:** BioEnterics® LAP-BAND System; Lap-Band Adjustable Gastric Banding System (Allergan); REALIZE™ Adjustable Gastric Band (REALIZE Band); Endo Gia Universal Auto Suture; StomaphyX™ endoluminal fastener and delivery system (EndoGastric Solutions); Trans-oral gastroplasty (TOGA).

**SEARCH TERMS:** Morbid obesity, super-obesity, sleeve gastrectomy, body mass index, BMI, obesity-related co-morbidities, Roux-en-Y, gastric bypass, gastric banding, LAGB, LSG, RYGB, biliopancreatic diversion, BPD/duodenal switch.

**POLICY DESCRIPTION:**

Obesity is an increase in body weight beyond the limitation of skeletal and physical requirements, as a result of an excessive accumulation of fat in the body. In general, 20% to 30% above "ideal" body weight, according to standard life insurance tables, constitutes obesity. Body mass index (BMI) is a method used to quantitatively evaluate body fat by reflecting the presence of excess adipose tissue. Morbid obesity is further defined as a condition of consistent and uncontrollable weight gain.

Bariatric surgery procedures are performed to treat comorbid conditions associated with morbid obesity. Two types of surgical procedures are employed. Malabsorptive procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur. Restrictive procedures restrict the size of the stomach and decrease intake. Surgery can combine both types of procedures.

With or without bariatric surgery, successful obesity management requires adoption and lifelong practice of healthy eating and physical exercise (e.g., lifestyle modification) by the obese patient. Without adequate patient motivation and/or skills needed to make such lifestyle modifications, the benefit of bariatric surgical procedures is severely jeopardized and not medically reasonable or necessary.

**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Bariatric surgery, as a primary treatment for weight loss, **may be considered MEDICALLY NECESSARY** when **ALL** of the following criteria have been met, as defined by the National Heart Lung and Blood Institute (NHLBI).

**1. Surgical Eligibility:**

- A. Patients with body mass index (BMI) equal to or > 40 kg/m<sup>2</sup> (Class III obesity), OR
- B. Patients with BMI = 35-39.9 kg/m<sup>2</sup> who also have one or more of the following high-risk medical comorbid conditions (Class II obesity) such as:
  - Type II diabetes mellitus (by American Diabetes Association diagnostic criteria), OR
  - Cardiovascular disease (e.g., history of stroke, myocardial infarction, congestive heart failure, or a surgical intervention such as cardiopulmonary bypass or percutaneous transluminal coronary angioplasty), OR
  - Refractory hyperlipidemia (acceptable levels of lipids unachievable with diet and maximum doses of lipid lowering medications), OR
  - Refractory hypertension (defined as blood pressure of 140 mmHg systolic and/or 90 mmHg diastolic despite medical treatment with maximal doses of three antihypertensive medications), OR
  - Obesity-induced cardiomyopathy, OR
  - Clinically significant obstructive sleep apnea (OSA), confirmed on polysomnography with an apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) equal to or > 30 (American Academy of Sleep Medicine (AASM) Task Force definition), OR

- Obesity-related hypoventilation syndrome or Pickwickian syndrome, OR
  - Severe arthropathy of spine and/or weight-bearing joints that interferes with daily functioning (when the obesity itself prohibits the appropriate surgical treatment and management of the joint dysfunction), OR
  - Pseudotumor cerebri (documented idiopathic intracerebral hypertension), OR
  - Nonalcoholic hepatic steatosis without prior evidence of active inflammation, AND
2. Documentation of an attempt of weight loss control through a structured diet program an appropriate exercise program, prior to bariatric surgery, which includes physician or other professional health care provider supervision, notes and/diet or weight loss logs for a minimum of 6 months, AND
  3. Psychological evaluation ruled out major mental health disorders which would contraindicate surgery and determine patient compliance with post-operative follow-up care and dietary guidelines, AND
  4. Correctable endocrine disorders and/or other medical conditions have been ruled out.
  5. Request of ONE of the following bariatric surgical procedures:
    - Open or Laparoscopic Roux-en-Y gastric bypass (RYGBP); gastrojejunal anastomosis
    - Laparoscopic adjustable gastric banding (LAGB); Laparoscopic adjustable silicone gastric banding
    - Gastric sleeve procedure (also known as laparoscopic vertical gastrectomy or laparoscopic sleeve gastrectomy)
    - Vertical banded gastroplasty (gastric banding; gastric stapling)
    - Biliopancreatic bypass (Scopinaro procedure)
    - Open or laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS), or Gastric Reduction Duodenal Switch (BPD/GRDS)

*Note:* Robotic assisted gastric bypass surgery is non-preferentially equivalent, but not superior to other types of minimally invasive bariatric surgery

**OBESITY IN ADOLESCENTS**

In adolescents, the treatment of clinically severe obesity **may be considered MEDICALLY NECESSARY** when ALL of the above criteria have been met (as defined by the NHLBI) and who have:

- Achieved greater than 95% of estimated adult height based on documented individual growth pattern, AND
- A minimum Tanner stage of 4

**SURGICAL REVISION OR A SECOND BARIATRIC SURGERY**

- Surgical revision, adjustment or alteration of a prior bariatric procedure may be **MEDICALLY NECESSARY** for complications of the original surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when the complication causes abdominal pain, inability to eat or drink, or vomiting of prescribed meals.
- Repeat bariatric surgery is generally **NOT MEDICALLY NECESSARY**. A second bariatric surgery may be

considered for inadequate weight loss if the original criteria for bariatric surgery (BMI, co-morbidities and patient selection criteria) continue to be met.

**The following services are considered EXPERIMENTAL AND/OR INVESTIGATIONAL as treatments for obesity:**

- Bariatric surgical procedures in a person who has not attained an adult level of physical development and maturation. Further studies are needed to determine the safety and efficacy and to demonstrate the impact of the surgery on physical, sexual and reproductive maturation, and the long-term follow-up data on co-morbidities improvement in this age group.
- Transoral endoscopic surgery such as trans-oral gastropasty [TOGA®], Endoluminal [ROSE] procedure, StomaphyX, and Restorative Obesity Surgery.
- The mini-gastric bypass (MGB), also known as laparoscopic mini-gastric bypass (LMGBP). Further studies are needed to determine the safety and efficacy of mini-gastric bypass surgery.
- Vagus nerve blocking (VNB) or vagal blocking therapy. Further studies are needed to determine the safety and efficacy of Vagus nerve blocking as a treatment option for obesity.
- Intra-gastric balloon. Further studies are needed to determine the safety and efficacy of intra-gastric balloon as a treatment option for obesity.
- Gastrointestinal liners (EndoBarrier).
- Laparoscopic greater curvature plication, also known as total gastric vertical plication. Further studies are needed to evaluate the safety and efficacy of this procedure for the treatment of obesity.
- Bariatric surgery to treat other obesity associated diseases (e.g., gynecological abnormalities, osteoarthritis, gallstones, urinary stress incontinence or as a treatment for gastroesophageal reflux (including for Barrett’s esophagus or gastroparesis, and others). There is insufficient published clinical evidence to support bariatric surgery for the treatment of these obesity associated diseases that generally do not lead to life threatening consequences. Although, bariatric surgery may improve symptoms of co-morbidities such as gastroesophageal reflux disease and obstructive sleep apnea, the primary purpose of bariatric surgery is to achieve weight loss.

**Associated surgeries that are not covered:**

- Panniculectomy after bariatric surgery is generally considered cosmetic and is not covered. See Panniculectomy and Abdominoplasty policy for details (2015M0060A).

**Clinical Considerations:**

- **Body Mass Index (BMI):** The National Heart, Lung and Blood Institute (NHLBI) classify the ranges of BMI in adults as follows:
  1. <18.5 - Underweight
  2. 18.5 to 24.9 kg/m<sup>2</sup> - Normal
  3. 25-29.9 kg/m<sup>2</sup> - Overweight
  4. 30-34.9 kg/m<sup>2</sup> - Obesity Class I
  5. 35-39.9 kg/m<sup>2</sup> - Obesity Class II
  6. > 40 kg/m<sup>2</sup> –Extreme Obesity Class III
- **Treatments for Obesity:** First-line treatments for obesity include: dietary therapy, physical activity, and

behavior modification. Surgery is an option for well-informed and motivated patients who have clinically severe obesity (BMI  $\geq$  40) or a BMI  $\geq$  35 and serious comorbid conditions and have been unsuccessful to medical treatment.

A patient will be deemed to have been unsuccessful with medical treatment of obesity if all of the following requirements/documentation are met:

1. The patient meets BMI requirements stated in the medical policy (at the time of surgery).
  2. The patient has been provided with knowledge and tools needed to achieve such lifelong lifestyle changes, exhibits understanding of the needed changes, and has demonstrated to the clinicians involved in his or her care to be capable and willing to undergo the changes.
  3. The patient has made a diligent effort to achieve healthy body weight with such efforts described in the medical record and certified by the operating surgeon.
  4. The patient has failed to maintain a healthy weight despite adequate participation in a structured dietary program overseen by a registered nurse, licensed dietician/nutritionist, and under the supervision of a physician.
- **Preoperative Evaluation and Documentation:** An extensive preoperative evaluation is essential in the work-up of the morbidly obese patient. The goals of screening are to identify comorbidities best managed before surgery (thus reducing perioperative morbidity and mortality) and to diagnose previously unrecognized comorbidities. It should include cardiac and pulmonary disease screening and clearance (e.g., CXR, ECG, pulmonary function testing, sleep studies, and stress testing) if indicated.
    1. **Evaluation by a surgical team.** with appropriate documentation and assertion by the operating surgeon that the member understands the surgical procedure chosen, the side effects, the risks, and the weight loss expectations/results.
    2. **Evaluation by a psychiatrist or psychologist.** An objective examination by a mental health professional experienced in the evaluation and management of bariatric surgery candidates. Psychosocial evaluation identifies potential contraindications to surgical intervention, such as substance abuse or poorly controlled psychiatric illness.
  - **Lifetime postoperative care:** The member is committed to participation in close nutritional monitoring during rapid weight loss, long-term lifestyle changes, diet prescription, and medical surveillance after surgical therapy.
    1. **Dietary issues:** Consultation for postoperative meal initiation and progression should be arranged with a dietician who is knowledgeable of the postoperative bariatric diet.
    2. **Exercise and lifestyle changes:** Patients should be advised to incorporate moderate aerobic physical activity to include a minimum of 150 minutes per week and goal of 300 minutes per week, including strength training 2 to 3 times per week.
  - **Contraindications to Bariatric Surgery:** The following conditions should be considered contraindications to bariatric surgery:
    1. Non-compliance with medical treatment of obesity or treatment of other chronic medical condition.
    2. Patients who do not understand the nature of the surgery or the postoperative lifestyle requirements, including patients with major mental disorders, such as: schizophrenia, uncontrolled

depression, active suicidal ideation or personality disorders can interfere with the ability to comprehend informed consent for bariatric surgery and/or to comply with the recommended post-surgical follow-up. A variety of serious illnesses could be exacerbated by caloric restriction, including anorexia nervosa or bulimia nervosa.

3. Diseases or conditions that reduce life expectancy and are unlikely to be improved with weight reduction, including cancer and end-stage renal, hepatic, or cardiopulmonary disease.
4. Active substance abuse or alcoholism and noncompliance with previous medical care.
5. Failure to cease tobacco use. Tobacco use should be avoided at all times by all patients. In particular, patients who smoke cigarettes should stop, preferably at least 6 weeks before bariatric surgery. Also, tobacco use should be avoided after bariatric surgery given the increased risk of poor wound healing, anastomotic ulcer, and overall impaired health.
6. Candidates for bariatric surgery should avoid pregnancy preoperatively and for 12 to 18 months postoperatively.

**AUDIENCE:**

- A. **Targeted Population:** Obese members who may be considered as candidates for bariatric or gastrointestinal surgery.
- B. **Targeted Clinical Specialties:** Surgery (Bariatric or Gastrointestinal Surgery), Cardiology, Endocrinology, Family Practice, Gastroenterology, Internal Medicine, Nutrition, Psychiatry, Pulmonary Medicine, Sleep Medicine, Pediatrics.

**BENEFIT CONSIDERATIONS:**

*All reviewers must first identify member eligibility, any federal or state regulatory requirements, and refer to the member-specific benefit document (EOC) for coverage information on the service, prior to the use of the policy.*

1. **Plan Document Language (Coverage Limitations, Exclusions, and Definitions):**
2. **Managed Care Guidelines:** Prior-authorization and/or notification required.
3. **Setting(s):** Inpatient.

**BACKGROUND:**

Obesity has significant medical importance due to its high prevalence and associated health risks. In the United States, more than 72 million adults and 17% of children are obese. Obesity is defined as a body mass index (BMI)  $\geq 30$  kilograms per square meter ( $\text{kg}/\text{m}^2$ ), morbid obesity as a BMI  $\geq 40$   $\text{kg}/\text{m}^2$ , super-obesity as a BMI  $\geq 50$   $\text{kg}/\text{m}^2$ , and super super-obesity as a BMI  $\geq 60$   $\text{kg}/\text{m}^2$ . If current trends continue, it is estimated that 40% of the U.S. population will be obese by the year 2025. The incidence of super-obesity is increasing at a greater rate than that of obesity in general. Obesity is associated with elevated morbidity and mortality and with increased risk for diabetes and cardiovascular disease. Bariatric surgery may be

indicated for individuals who are unable to control their weight with conservative measures.

Body mass index (BMI) is the most common measure used to measure relative weight in comparison in adults and children. The National Heart, Lung and Blood Institute (NHLBI) classify the ranges of BMI in adults as follows (NHLBI, 1998):

<u>Classification</u>	<u>BMI</u>
Underweight	< 18.5 kg/m <sup>2</sup>
Normal weight	18.5–24.9 kg/m <sup>2</sup>
Overweight	25–29.9 kg/m <sup>2</sup>
Obesity (Class 1)	30–34.9 kg/m <sup>2</sup>
Obesity (Class 2)	35–39.9 kg/m <sup>2</sup>
Extreme Obesity (Class 3)	≥ 40 k/m <sup>2</sup>

BMI is a calculated number devised by using the formula - weight in kilograms divided by height in meters squared (kg/m<sup>2</sup>). Super-obesity is used to define a patient who has a body weight exceeding ideal body weight by 225% or more, or a BMI of 50 kg/m<sup>2</sup> or greater.

In children, an absolute scale for BMI is not used. Instead, a percentile scale is used, based on the child's age and sex. The appropriate terminology for children ages 2 to 18 is as follows:

- "Underweight" for children with a BMI at less than the 5th percentile
- "Healthy weight" for children with a BMI from the 5th to the 84th percentile
- "Overweight" for children with a BMI from the 85th to the 94th percentile
- "Obesity" for children with a BMI greater than or equal to the 95th percentile

**Obesity Treatment**

First-line treatments for obesity include dietary therapy, physical activity, and behavior modification. Low-calorie diets, exercise programs, behavioral modification regimens and medical treatment have generally been unsuccessful in long-term weight management for obese individuals. Pharmacotherapy is an option for patients who do not respond to these measures but results in very modest reductions in weight.

Obesity drugs currently on the market have provided weight loss of only about 3%-10% of a patient's total body weight and have been associated with undesirable adverse events. The failure rate of conservative nonsurgical treatment is estimated to be 95% (CDC, 2007). Therefore, this makes bariatric surgery an attractive treatment option. However, 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.

Surgical treatment of obesity offers two main weight-loss approaches: restrictive and malabsorptive. Restrictive methods are intended to cause weight loss by restricting the amount of food that can be consumed by reducing the size of the stomach. Malabsorptive methods are intended to cause weight loss by limiting the amount of food that is absorbed from the intestines into the body. A procedure can have restrictive features, malabsorptive features, or both. The surgical approach can be open or laparoscopic. The clinical decision on which surgical procedure to use is made based on a medical assessment of the patient's unique situation.

Today, the most commonly used bariatric technique is the Roux-en-Y gastric bypass (RYGB) and current use of the term "gastric bypass" typically refers to RYGB. Among bariatric procedures, gastric bypass is considered to be the gold standard. Four other main types of bariatric surgery are currently practiced: sleeve gastrectomy, vertical banded gastroplasty (VBG), adjustable silicone gastric banding (ASGB), and

biliopancreatic diversion (BPD) with or without duodenal switch. All five procedures may be performed by open or laparoscopic technique.

According to the guidelines for bariatric surgery from the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic and Bariatric Surgery (ASMBS), all patients seeking bariatric surgery should have a comprehensive preoperative evaluation. This assessment is to include an obesity-focused history, physical examination, and pertinent laboratory and diagnostic testing. A detailed weight history should be documented, including a description of the onset and duration of obesity, the severity, and recent trends in weight. Causative factors to note include a family history of obesity, use of weight-gaining medications, and dietary and physical activity patterns. A brief summary of personal weight loss attempts, commercial plans, and physician-supervised programs should be reviewed and documented, along with the greatest duration of weight loss and maintenance. This information is useful in substantiating that the patient has made reasonable attempts to control weight before considering obesity surgery. The guidelines state that preoperative weight loss should be considered for patients in whom reduced liver volume can improve the technical aspects of surgery (Mechanick, et al., 2008).

The following are descriptions of the most commonly used bariatric surgical procedures:

1. **Roux-en-Y Gastric Bypass (RYGBP):** The RYGBP achieves weight loss by gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. RYGBP procedures can be open or laparoscopic.
2. **Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS):** The BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD/DS or BPD/GRDS is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis. BPD/DS or BPD/GRDS procedures can be open or laparoscopic.
3. **Adjustable Gastric Banding (AGB):** AGB achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. AGB procedures are laparoscopic only.
4. **Sleeve Gastrectomy:** Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP. Sleeve gastrectomy procedures can be open or laparoscopic
6. **Vertical Gastric Banding (VGB):** The VGB achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense

of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VGB procedures are essentially no longer performed.

7. **Gastric balloon:** A medical device developed for use as a temporary adjunct to diet and behavior modification to reduce the weight of patients who fail to lose weight with those measures alone. It is inserted into the stomach to reduce the capacity of the stomach and to affect early satiety.
8. **Gastrointestinal liners:** Such as the EndoBarrier system, utilize an endoscopically implanted sleeve into the stomach to reduce the stomach size. The sleeve is then removed after weight loss has been achieved.
9. **Laparoscopic greater curvature plication (LGCP):** Also known as total gastric vertical plication (TGVP) is a relatively new restrictive procedure that involves folding and suturing the stomach onto itself to decrease the size of the stomach. This procedure is a modification of the gastric sleeve which requires surgical resection of stomach.

Many patients elect surgery to remove redundant skin or redundant skin and adipose tissue are common following bariatric surgery. Physiologic functional impairment as a consequence of such redundant tissue is uncommon. However, many patients consider their physical appearance unacceptable as a result of redundant skin and adipose tissue.

Bariatric surgery will frequently ameliorate symptoms of co-morbidities such as gastroesophageal reflux disease and obstructive sleep apnea. However, the primary purpose of bariatric surgery in obese persons is to achieve weight loss.

**REGULATORY STATUS:**

**1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

In general, surgical procedures are not regulated by the US Food and Drug Administration (FDA).

- Gastric banding, however, involves the use of an adjustable or nonadjustable gastric band, which is subject to FDA marketing approval. In 2001, the BioEnterics® LAP-BAND System was approved by FDA for marketing under the premarket approval process for surgical treatment for severely obese adults for whom more conservative treatments (e.g., diet, exercise, and behavioral modification) have failed. The LAP-BAND System is indicated for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40 or a BMI of at least 35 with one or more severe co-morbid conditions, or those who are 100 pounds or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Tables (use the midpoint for medium frame). It is indicated for use only in severely obese adult patients who have failed more conservative weight-reduction alternatives, such as supervised diet, exercise and behavior modification programs.

Additional information is available at:

[http://www.accessdata.fda.gov/cdrh\\_docs/pdf/P000008b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/P000008b.pdf). Accessed August 5, 2016.

- In February 2011, the FDA approved the Lap-Band Adjustable Gastric Banding System, by Allergan, for weight reduction in obese patients, with a Body Mass Index (BMI) of at least 40 kg/m<sup>2</sup> or less obese patients who have at least a body mass index (BMI) of 30 kg/m<sup>2</sup> and one or more additional obesity-related co-morbid condition, such as diabetes or hypertension. Additional information is available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf/p000008s017a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/p000008s017a.pdf). Accessed August 5,

2016. For coverage information, please refer to the Coverage Rationale section of this policy. On September 28, 2007, the FDA approved the REALIZE™ Adjustable Gastric Band (REALIZE Band) manufactured by Ethicon Endo-Surgery, Inc. The REALIZE Band also consists of a silicone band, tubing, and an injection port. Additional information is available at:

[http://www.accessdata.fda.gov/cdrh\\_docs/pdf7/P070009b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070009b.pdf). Accessed August 5, 2016.

In October, 2010, the manufacturer voluntarily recalled the REALIZE Band due to the potential for a small ancillary component called the Strain Relief to move out of its intended position. The device has been changed to add a silicone adhesive to bond the strain relief sleeve and the locking connector components of the injection port. Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=95101> Accessed August 5, 2016.

Adjustable gastric bands are contraindicated in patients younger than 18 years of age.

- Surgical stapling devices are used in all bariatric surgical procedures except gastric banding. These devices have been approved by FDA for use in various general surgical procedures. One device is the Endo Gia Universal Auto Suture, which inserts six parallel rows of staples into tissue. Other surgical staplers are manufactured by Ethicon Endo-Surgery. Additional information, product code GDW and GAG, is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm>. Accessed August 5, 2016.
- StomaphyX was granted 510(k) marketing approval on March 9, 2007. EndoGastric Solutions StomaphyXTM endoluminal fastener and delivery system is substantially equivalent in intended use and method of operation to a combination of the LSI Solutions Flexible Suture Placement Device and the Bard Endoscope Suturing System/Bard Endocinch. According to the FDA, the StomaphyX system is indicated for use in endoluminal trans-oral tissue approximation and ligation in the gastrointestinal tract. Additional information is available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf6/K062875.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062875.pdf). Accessed August 5, 2016.
- Transoral gastroplasty (TOGA) is not currently FDA approved.
- Gastrointestinal liners (e.g., EndoBarrier) have not received FDA approval.

**2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

**Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (NCD 100.1)**

**Nationally Covered Indications**

Effective for services performed on and after 2/21/2006 the following procedures are covered for Medicare beneficiaries who have a body-mass index  $\geq 35$ , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity:

- Roux-en-Y gastric bypass (RYGBP), open and laparoscopic
- Biliopancreatic Diversion with Duodenal Switch (BPD/DS), open and laparoscopic
- Gastric Reduction Duodenal Switch (BPD/GRDS)
- Laparoscopic adjustable gastric banding (LAGB)

**Comorbid Conditions:** Though the conditions listed below need not be immediately life-threatening for Medicare to cover bariatric surgery, the condition must not be trivial or easily controlled with non-

invasive means (such as medication) and must be of sufficient severity as to pose considerable short- or long-term risk to function and/or survival.

- Type II diabetes mellitus (by American Diabetes Association diagnostic criteria)
- Refractory hypertension (defined as blood pressure of 140 mmHg systolic and/or 90 mmHg diastolic despite medical treatment with maximal doses of three antihypertensive medications)
- Refractory hyperlipidemia (acceptable levels of lipids unachievable with diet and maximum doses of lipid lowering medications)
- Obesity-induced cardiomyopathy
- Clinically significant obstructive sleep apnea
- Obesity-related hypoventilation
- Pseudotumor cerebri (documented idiopathic intracerebral hypertension)
- Severe arthropathy of spine and/or weight-bearing joints (when obesity prohibits appropriate surgical management of joint dysfunction treatable but for the obesity)
- Hepatic steatosis without prior evidence of active inflammation

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determine that Type 2 diabetes mellitus is co-morbidity for purposes of this NCD.

**Excerpt from Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity - Facility Certification Requirement (CAG-00250R3) Decision Summary:**

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to conclude that continuing the requirement for certification for bariatric surgery facilities would not improve health outcomes for Medicare beneficiaries. Therefore, CMS has decided to remove this certification requirement effective for dates of service on or after September 25, 2013.

A list of approved facilities and their approval dates are listed and maintained on the CMS Coverage Web site at <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Bariatric-Surgery.html>, and published in the Federal Register.

**Regulatory Updates**

Prior to June 27, 2012, the laparoscopic sleeve gastrectomy was a non-covered surgical procedure for Medicare beneficiaries. On June 27, 2012 CMS issued the following decision memo (CAG-00250R2): Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions are satisfied:

- A. The beneficiary has a body-mass index (BMI) > 35 kg/m<sup>2</sup>,
- B. The beneficiary has at least one co-morbidity related to obesity, and
- C. The beneficiary has been previously unsuccessful with medical treatment for obesity.
  1. Laparoscopic sleeve gastrectomy will be covered if all the requirements of the NCD, including the June 2012 Decision Memo and all its diagnoses as coded in the LCD are met.
  2. HCPCS code 43775 (lap sleeve gastrectomy) was previously a Non-covered Service (N). Effective June 27, 2012 HCPCS code 43775 is Carrier Priced (C).

**Nationally Non-Covered Indications**

Treatments for obesity alone remain non-covered.  
 Supplemented fasting is not covered under the Medicare program as a general treatment for obesity.  
 The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:

- Open adjustable gastric banding
- Open and laparoscopic vertical banded gastroplasty
- Intestinal bypass surgery
- Gastric balloon for treatment of obesity (since the long term safety and efficacy of the device in the treatment of obesity has not been established)

**Reference NCDs:**

- NCD 100.8 Intestinal Bypass Surgery
- NCD 100.11 Gastric Balloon for Treatment of Obesity
- NCD 100.14 Surgery for Diabetes
- NCD 210.12 Intensive Behavioral Therapy for Obesity
- NCD 40.5 Treatment of Obesity

**3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

**Bariatric (weight loss surgery) Services**

- Covered service with authorization, doctor’s orders and a mental health evaluation. Members may need to meet other specific conditions. Talk to your doctor about whether you meet the required conditions for this service.
- Not covered services include excess skin excision

**CLINICAL EVIDENCE:**

**1. EVIDENCE FROM AVAILABLE PUBLISHED STUDIES:**

The criteria for patient selection for bariatric surgery were relatively uniform among various authors and corresponded to criteria recommended by the American Society for Bariatric Surgery (ASBS) and the Society of American Gastrointestinal Endoscopic Surgeons (SAGES). These criteria include (ASBS, 2005):

- BMI 35 to 40 with obesity-related co-morbid medical conditions
- BMI > 40 without co-morbidity if the weight adversely affects the patient
- Demonstration that dietary attempts at weight control have been ineffective

Sjostrom et al. (2004) published a prospective controlled study of patients that had gastric surgery (average BMI of 41) and matched them with conventionally treated obese control subjects. Two treatment groups were identified: those who had surgery two years prior (4,047 patients) and those who had it 10 years prior (1,703). After two years, the weight had increased by 0.1% in the control group and decreased by 23.4% in the surgery group. After ten years, the weight in the control group had increased by 1.6% and had decreased in the surgical group by 16.1%. In addition to total weight loss, they measured laboratory values and lifestyle changes. The authors concluded that bariatric surgery appears to be a viable option for the treatment of severe obesity and resulted in long term weight loss, improved lifestyle and improvement in risk factors that were elevated at baseline.

Obese individuals with metabolic syndrome (MS), a clustering of risk factors that include high levels of

triglycerides and serum glucose, low level of high-density-lipoprotein cholesterol, high blood pressure and abdominal obesity, are at high risk of developing coronary heart disease and type 2 diabetes mellitus. A study by Lee et al. (2004) concluded that MS is prevalent in 52.2% of morbidly obese individuals and that significant weight reduction one year post surgery markedly improved all aspects of metabolic syndrome with a cure rate of 95.6%. They also note that obesity surgery performed by laparoscopic surgery is recommended for obese patients with MS.

Buchwald et al. (2004) also found in their meta-analysis that substantial majority of patients with type 2 diabetes mellitus, hyperlipidemia, hypertension and obstructive sleep apnea experienced complete resolution or improvement after bariatric surgery. Post-operative mortality was 0.1%-1.1% depending on the surgery type with lowest mortality in the restrictive techniques and highest for biliopancreatic diversion method.

Dixon, et al. (2008) conducted an unblinded randomized controlled trial to determine if surgically induced weight loss results in better glycemic control and less need for diabetes medications than conventional approaches to weight loss and diabetes control. A total of 60 patients were randomized into the 2 groups; 30 receiving surgical treatment and 30 receiving conventional treatment. Remission of type 2 diabetes, at 2 year follow-up, was reduced 73% in the surgical group and 13% in the conventional therapy group.

Christou, et al. (2004) concluded that bariatric surgery not only decreased risk factors, but also decreased overall mortality. They performed a matched cohort study of 1,035 patients who had bariatric surgery with 5,746 obese patients who did not have surgery. Subjects with medical conditions other than morbid obesity were not included. The participants were followed for 5 years. The mortality rate in the treatment group was 0.68% compared with 6.17% of the controls which results in a reduction in the relative risk of death by 89%.

Pregnancy after bariatric surgery was examined by Sheiner, et al. (2004) who concluded that previous bariatric surgery had a high correlation with Cesarean delivery. There was no correlation with other indicators of adverse perinatal outcomes such as dystocia, Apgar scores, perinatal complications or perinatal mortality, etc. Weight loss therapy is not appropriate for most pregnant or lactating women.

Shen, et al. (2004) studied the impact of patient follow-up on weight loss after bariatric surgery. They found that weight loss was correlated with the number of follow-up visits completed in the first year post surgery. They concluded that patient follow-up plays a significant role in the amount of weight loss after bariatric surgery and that patient motivation and surgeon commitment for long term follow-up is critical for successful weight loss after bariatric surgery.

An analysis of outcome data for a subset of participants enrolled in the Swedish Obese Subjects (SOS) study found that obese individuals who received surgical treatment for their condition experienced significant weight loss and reductions in the incidence of cardiovascular risk factors, including diabetes, hypertriglyceridemia, and hyperuricemia, at both 2-year and 10-year follow-up, compared with contemporaneously matched controls who received nonsurgical treatment for their obesity. The SOS study enrolled 4047 obese individuals, defined as a body mass index (BMI) 34 for men and 38 for women, between the ages of 37 and 60 years who, according to personal preference and surgical eligibility, underwent bariatric surgery (n=2010) or nonsurgical treatment (n=2037) for their condition. Patients who preferred surgical treatment and met eligibility requirements for bariatric surgery underwent fixed or variable banding, vertical banded gastroplasty, or gastric bypass surgery.

Nonsurgical treatment varied among centers. However, among enrolled patients, 10-year outcomes were available for 851 surgically treated patients who were contemporaneously matched with 852 control subjects and 2-year outcomes were available for 1845 surgically treated patients and 1660 controls. At 2-year follow-up, a significant 23.4% weight reduction was observed among patients who were surgically treated compared with a 0.1% mean weight increase among patients in the control group. At 10-year follow-up, patients who underwent bariatric surgery maintained a significantly greater percentage of weight loss compared with the control group (-16.1% versus +1.6%, respectively;  $P < 0.001$ ). Postoperative mortality among the 2010 patients who underwent surgery was 0.25% (Hayes, 2005). Fifteen year follow-up by Sjostrom et al. (2007) showed that there were 129 deaths in the control group and 101 deaths in the surgery group.

Patients should have a clear understanding of expected benefits, risks, and long term consequences of surgical treatment as they require appropriate lifelong follow-up with nutritional counseling and biochemical surveillance. Care of the postoperative bariatric surgery patient is recommended for the lifetime of the patient with at least three follow-up visits with the bariatric surgery team within the first year. Laparoscopic adjustable gastric banding will require more frequent visits for band adjustment. Surgery should only be performed as part of a bariatric program intent on maintaining long-term follow-up as well as long-term evaluation.

Greenberg et al. (2005) found a high incidence of depression, negative body image, eating disorders, and low quality of life (QoL) in patients with severe obesity. Although their investigation showed there are no predictive relationships between preoperative psychological evaluations and postoperative weight loss, they recommended that all bariatric surgery candidates be evaluated by a licensed mental health care provider experienced in the treatment of severely obese patients and working with a multidisciplinary team. In another study of clients followed for 1 year after weight loss surgery, perceived obesity-related health problems, motivation, and sense of coherence (SoC) predicted better weight loss. A history of sexual abuse correlated with poorer weight loss, whereas intrinsic motivational factors appeared to predict greater weight loss after surgery (Ray et al., 2003). Although research supports the association of psychological problems such as depression and personality disorder with less successful obesity surgery outcomes, rarely are the psychological problems cited as contraindications for surgery (Greenberg et al., 2005). Furthermore, the goal of psychological assessment should be the development of pre- and postsurgical treatment plans that address psychosocial barriers to postoperative success. Professional consensus is that bariatric surgery should be performed only in motivated, educated patients who have participated in a combined multidisciplinary assessment and only after behavior-based interventions have failed (Bachman et al., 2005).

Absolute contraindications include patients with active substance abuse. A signed physician statement indicating that the patient is substance free is recommended.

The following conditions should be considered relative contraindications to bariatric surgery: Major mental disorders, such as schizophrenia, uncontrolled depression, active suicidal ideation or personality disorders can interfere with the ability to comprehend informed consent for bariatric surgery and/or to comply with the recommended post-surgical follow-up. A variety of serious illnesses could be exacerbated by caloric restriction, including anorexia nervosa or bulimia nervosa.

**Gastric Bypass (Roux-en-Y; Gastrojejunal Anastomosis)**

The most commonly performed restrictive approach is the RYGB, which combines gastric restrictive and malabsorptive features. The Roux-en-Y bypass (RYGB) procedure involves restricting the size of the stomach by stapling shut 90% of the lower stomach. In addition, the proximal intestinal anatomy is rearranged, thereby bypassing the duodenum resulting in a malabsorptive effect. This can be an open or laparoscopic procedure.

Long-limb Roux-en-Y gastric bypass (LLRGB) is similar to standard RYGBP, except that the "Roux" limb (through which only food passes) is greater than 100 cm instead of the usual 45 to 100 cm. Consequently, the common limb (which empties both food and digestive fluids) is shorter, thereby permitting less food absorption. Several authors assert that this procedure should be performed for patients with a BMI of greater than 50 instead of the RYGB.

In an 18 year retrospective cohort study by Adams et al. (2007), 9949 patients who had undergone gastric bypass surgery and 9628 severely obese persons who applied for driver's licenses were studied. From these subjects, 7925 surgical patients and 7925 severely obese control subjects were matched for age, sex, and body-mass index. The authors concluded that long-term total mortality after gastric bypass surgery, particularly deaths from diabetes, heart disease, and cancer, was significantly reduced. However, the rate of death from causes other than these diseases was higher in the surgery group than in the control group. Review of the data showed that a substantial number of severely obese persons have unrecognized presurgical mood disorders or post-traumatic stress disorder or have been victims of childhood sexual abuse. This is leading some bariatric surgery centers to recommend that all patients undergo psychological evaluation and, if necessary, treatment before surgery and psychologically related surveillance postoperatively. Despite an improved quality of life after gastric bypass surgery, certain unrecognized presurgical conditions may reappear after surgery. Therefore, further research is needed to explore the optimal approach to evaluating candidates for surgery, including the possible need for psychological evaluation and psychiatric treatment before surgery, and aggressive follow-up after surgery.

Adverse events include gastrointestinal leak after RYGBP and LLRGB. Some patients require re-operation to correct problems with the original surgery, including stenosis around the anastomosis site, causing post-prandial abdominal pain and vomiting. Other reasons for re-operation include gastrointestinal leak after RYGBP (Kellum, 1998).

**Adjustable Silicone Gastric Banding (ASGB)**

The adjustable silicone gastric banding (ASGB) procedure involves placing an inflatable silicone band around the upper portion of the stomach. The silicone band contains a saline reservoir that can be filled or emptied under fluoroscopic guidance to change the caliber of the gastric opening. Laparoscopic or open techniques can complete the ASGB procedure. Adverse events include band leakage after AGB.

Other procedures that are used include the nonadjustable gastric banding (NAGB). This procedure was the precursor to the AGB and is similar to it. However, it differs in that the band diameter cannot be adjusted. Some surgeons still perform NAGB.

**Biliopancreatic Diversion with Duodenal Switch**

Biliopancreatic diversion (BPD) (also known as the Scopinaro procedure) is primarily malabsorptive but has a temporary restrictive component. As in RYGB, three "limbs" of intestine are created: one through which food passes, one that permits emptying of fluids (e.g., bile) from digestive organs, and a common

limb through which both food and digestive fluids pass. This procedure involves removal of the greater curvature of the stomach instead of the distal portion. The two limbs meet in a common channel measuring only 50 to 100 cm, thereby permitting relatively little absorption. Use of BPD/DS has been increasing steadily during the past five years. In addition, biliopancreatic diversion (BPD) with or without a duodenal switch has been done laparoscopically.

A single-center, nonblinded, randomized, controlled trial performed by Mingrone et al (2012), with 60 patients between the ages of 30 and 60 years with a body-mass index BMI of 35 or more, a history diabetes for at least 5 years, and a glyated hemoglobin level of 7.0% or more were randomly assigned to receive conventional medical therapy or undergo either gastric bypass or biliopancreatic diversion. The primary end point was the rate of diabetes remission at 2 years (defined as a fasting glucose level of <100 mg per deciliter [5.6 mmol per liter] and a glyated hemoglobin level of <6.5% in the absence of pharmacologic therapy). In severely obese patients with type 2 diabetes, bariatric surgery resulted in better glucose control than did medical therapy. Preoperative BMI and weight loss did not predict the improvement in hyperglycemia after these procedures.

**Vertical Gastrectomy (Sleeve Gastrectomy)**

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 stated that, "[t]o date, long term outcomes from registry studies are relatively limited, but longer term follow-up will provide additional important information."

A Cochrane Database Systematic Review by Colquitt et al. (2009) found that stand-alone sleeve gastrectomy appears to result in greater weight loss than adjustable gastric banding. The evidence suggests that weight loss following gastric bypass is similar to stand-alone sleeve gastrectomy and banded gastric bypass.

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

A randomized, nonblinded, single-center trial, Schauer, et. al. (2012) evaluated the efficacy of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes. The mean age of the patients was 49±8 years, and 66% were women. The average glyated hemoglobin level was 9.2±1.5%. The primary end point was the proportion of patients with a glyated hemoglobin level of 6.0% or less 12 months after treatment. In obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery achieved glycaemic control in significantly more patients than medical therapy alone.

Further study will be necessary to assess the durability of these results.

A prospective, randomized, double blind study by Karamanakos, et al. (2008) evaluated 32 patients (16 LRYGBP; 16 LSG) to compare the effects of laparoscopic Roux-en-Y gastric bypass (LRYGBP) with laparoscopic sleeve gastrectomy (LSG) on body weight, appetite, fasting, and postprandial ghrelin and peptide-YY (PYY) levels. Patients were reevaluated on the 1st, 3rd, 6th, and 12th postoperative month. Blood samples were collected after an overnight fast and in 6 patients in each group after a standard 420 kcal mixed meal. Body weight and body mass index (BMI) decreased markedly ( $P < 0.0001$ ) and comparably after either procedure. After LRYGBP fasting ghrelin levels did not change significantly compared with baseline ( $P = 0.19$ ) and did not decrease significantly after the test meal. On the other hand, LSG was followed by a marked reduction in fasting ghrelin levels ( $P < 0.0001$ ) and a significant suppression after the meal. Fasting PYY levels increased after either surgical procedure ( $P < \text{or} = 0.001$ ). Appetite decreased in both groups but to a greater extent after LSG. In addition, patients in the LRYGBP group had an increase in appetite after 12 months whereas the LSG group maintained a reduced appetite during the same timeframe. The authors concluded that LSG has better outcomes than LRYGBP with regard to appetite suppression and excess weight loss due to reduced ghrelin levels and increased PYY levels after LSG. This study is limited by small sample size and short term follow-up; however the strengths are that this is a double blind, randomized study.

A prospective randomized by Himpens, et al. (2006) compared the laparoscopic adjustable gastric band (GB) with sleeve gastrectomy (SG) in 80 patients (40 GB and 40 SG). Weight loss, feeling of hunger, sweet eating, gastroesophageal reflux disease (GERD), complications and re-operations were recorded postoperatively in both groups at 1 and 3 years. Loss of feeling of hunger after 1 year was registered in 42.5% of patients with GB and in 75% of patients with SG ( $P=0.003$ ); and after 3 years in 2.9% of patients with GB and 46.7% of patients with SG ( $P<0.0001$ ). Loss of craving for sweets after 1 year was achieved in 35% of patients with GB and 50% of patients with SG (NS); and after 3 years in 2.9% of patients with GB and 23% of patients with SG (NS). GERD appeared de novo after 1 year in 8.8% of patients with GB and 21.8% of patients with SG (NS); and after 3 years in 20.5% of patients with GB and 3.1% of patients with SG (NS). Postoperative complications requiring re-operation were necessary for 2 patients after SG. Late complications requiring re-operation after GB included 3 pouch dilations treated by band removal in 2 and 1 laparoscopic conversion to Roux-en-Y gastric bypass (RYGBP), 1 gastric erosion treated by conversion to RYGBP, and 3 disconnections of the system treated by reconnection. Inefficacy affected 2 patients after GB, treated by conversion to RYGBP and 2 patients after SG treated by conversion to duodenal switch. The authors concluded that patients with sleeve gastrectomy had better overall weight loss, loss of hunger and sweets than those who underwent gastric banding; however the number of re-operations is important in both groups, but the severity of complications appears higher in SG.

Rubin et al. (2008) conducted a prospective study of 120 consecutive morbidly obese patients to review the rate of postoperative complications and the lack of consensus as to surgical technique for laparoscopic sleeve gastrectomy (LSG). Patients underwent LSG using the following technique: (1) division of the vascular supply of the greater gastric curvature and application of the linear stapler-cutter device beginning at 6-7 cm from the pylorus so that part of the antrum remains; (2) inversion of the staple line by placement of a seroserosal continuous suture close to the staple line; (3) use of a 48 French bougie so as to avoid possible stricture; (4) firing of the stapler parallel to the bougie to make the sleeve as narrow as possible and prevent segmental dilatation. Mean follow-up was 11.7 months.

Intraoperative difficulties were encountered in 4 patients. There were no postoperative complications, no hemorrhage from the staple line, no anastomotic leakage or stricture, and no mortality. The authors concluded that the procedure evaluated was safe and effective; however, long-term results are still pending. This study is limited by lack of randomization, short follow-up, and lack of comparison to other bariatric surgical procedures.

In a non-randomized study of vertical gastrectomy by Lee et al. (2007), 846 patients undergoing primary laparoscopic bariatric procedures were compared. Of the 846 patients, 271 opted for the Band, 216 underwent vertical gastrectomy, 303 had Roux-en-Y, and 56 had duodenal switch operation. In the study, vertical gastrectomy patients experienced a similar rate of weight loss compared to Roux-en-Y and duodenal switch. There were also fewer complications with vertical gastrectomy (7.4%) than Roux-en-Y (22.8%) and duodenal switch (48.2%) with the Band procedure having the fewest complications (6.6%). The authors conclude that long-term efficacy of vertical gastrectomy is unclear but is promising. Further studies are needed to determine long-term results.

A retrospective review by Lalor, et al. (2008) examined laparoscopic sleeve gastrectomy (LSG) as a primary or revision bariatric procedure in 148 patients with a mean body mass index (BMI) of 44. All but 3 cases were completed laparoscopically (98%). Major complications occurred in 4 patients (2.9%) and involved 1 leak (0.7%) and 1 case of hemorrhage (0.7%), each requiring reoperation; 1 case of postoperative abscess (0.7%), and 1 case of sleeve stricture that required endoscopic dilation (0.7%). One late complication of choledocholithiasis and bile duct stricture required a Whipple procedure. LSG was used as a revision surgery in 16 patients (9%); of these, 13 underwent LSG after complications related to laparoscopic adjustable gastric banding, 1 underwent LSG after aborted laparoscopic Roux-en-Y gastric bypass, and 2 underwent LSG after failed jejunoileal bypass. One of the revision patients developed a leak and an abscess (7.1%) requiring reoperation; 1 case was aborted, and 2 cases were converted to an open procedure secondary to dense adhesions. No deaths occurred in either group. Seven patients (4.9%) required readmission within 3 months after surgery. The authors concluded that LSG is a relatively safe surgical option for weight loss as a primary procedure and as a primary step before a secondary non-bariatric procedure in high-risk patients; however, additional studies are needed to evaluate the clinical evidence of postoperative reflux, gastric sleeve dilation, and long-term maintenance of weight loss. This study did not examine LSG in super-obese patients or those with multiple co-morbidities and is limited by lack of long term follow-up. (Same population also reported by Tucker et al. 2008)

**Vertical Banded Gastroplasty (VBG)**

A Cochrane Database Systematic Review by Colquitt et al. (2009) found that while complication rates for vertical banded gastroplasty are relatively rare, revision rates requiring further surgical intervention are approximately 30%.

The vertical banded gastroplasty (VBG) also restricts the size of the stomach using a stapling technique but there is no rearrangement of the intestinal anatomy. This also can be an open or laparoscopic procedure. The Magenstrasse and Mill (M&M) Operation is a type of vertical gastroplasty designed to maintain physiological flow of ingesta without the use of implants such as bands or reservoirs. Silastic ring vertical gastroplasty (SRVG) is similar to VBG, except that silastic tubing is used for the band and no "window" is created. The mechanism of weight loss is restrictive, since the size of the stomach is reduced.

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.

Transected silastic ring vertical gastric bypass (TSRVGB), or the "Fobi pouch" procedure, is based on the standard Roux-en-Y procedure, but it employs three modifications. First, the distal stomach is transected vertically from the upper gastric pouch. Second, a silastic ring is placed around the upper pouch to provide gastric restriction. Third, a gastrostomy tube is connected to the distal stomach to permit percutaneous access.

Adverse events include staple-line disruption after VBG. Some patients require re-operation to correct problems with the original surgery, including stenosis around the anastomosis site, causing post-prandial abdominal pain and vomiting (Kellum, 1998).

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 generalizability of the findings.

#### **Robotic-Assisted Gastric Bypass Surgery**

Mohr et al. (2005) conducted a retrospective case study comparing the first 10 patients who underwent a totally robotic laparoscopic Roux-en Y gastric bypass to a retrospective sample of 10 patients who had undergone laparoscopic Roux-en Y gastric bypass surgery. The median surgical times were significantly lower for the robotic procedures. Researchers from the same institution also conducted a RCT to compare a single surgeon's results using the da Vinci system (n=25) with those using traditional laparoscopic Roux-en Y gastric bypass surgery (n=25) when the techniques were learned simultaneously. The mean operating time was again significantly shorter for the robotic procedures. The largest difference was in patients with a BMI >43 kg/m<sup>2</sup> (Sanchez, 2005). The authors concluded that these studies demonstrated the feasibility, safety, and potential superiority of robotic laparoscopic Roux-en Y gastric bypass. In addition, the learning curve may be significantly shorter with the robotic procedure. Further experience is needed to understand the long-term advantages and disadvantages of the totally robotic approach.

Sudan et al. (2007) evaluated the safety, feasibility, and reproducibility of robotic-assisted biliopancreatic diversion with duodenal switch (BPD/DS) in 47 patients with a mean body mass index (BMI) of 45 kg/m<sup>2</sup>. The operating time decreased for the last 10 procedures. Three patients underwent conversion to open surgery, and four patients experienced postoperative leaks with no mortality. No control group was available in this study.

#### **Revision Surgery**

Technical complications and/or inadequate weight loss sometimes lead to conversion of previous banded procedures (adjustable silicone gastric banding or vertical banded gastroplasty) to Roux-en-Y Gastric Bypass (RYGB).

Surgical revision of bariatric surgery should be considered when the patient experiences complications from the original surgery, such as stricture, obstruction, pouch dilatation, erosion, or band slippage when slippage causes abdominal pain, inability to ingest or produces vomiting. Additionally, some patients have failed to achieve adequate weight loss with certain gastric restrictive procedures, such as vertical banded gastroplasty or Lapband, even when fully compliant with postoperative nutritional and exercise recommendations. For many patients, it may take up to two years for patients to reach their maximum weight loss following bariatric surgery. Conversion to Roux-en-Y from a gastric restrictive

procedure is the most common revision surgery performed.

In a retrospective review of 66 open revisions to RYGB, Roller and Provost (2006) found that patients who had undergone one or more previous revisions required longer operative times and hospital stays and also suffered greater blood loss than patients undergoing revision to RYGB for the first time. Patients with previous revisions were also more likely to have complications (16.7% patients versus 9.3%) and had slightly poorer weight loss outcomes (mean %EWL 54.3% versus 60.6%), but the authors considered the complication rate and outcomes in both groups to be acceptable.

In a consensus statement by Buchwald (2005) for the American Society of Bariatric Surgeons, revision of gastric bypass can be functionally totally reversed, though this is rarely required. For all bariatric procedures, pure reversal without conversion to another bariatric procedure is almost certainly followed by a return to morbid obesity. A standard Roux gastric bypass with failed weight loss can be revised to a very long-limb Roux-en-Y procedure. Laparoscopic adjustable gastric banding can be completely reversed with removal of the band, tubing, and port. For failed weight loss, revision procedures include removal of the device and performance of a restrictive-malabsorptive procedure (e.g., gastric bypass) or a primarily malabsorptive procedure (e.g., biliopancreatic diversion and duodenal switch). Vertical banded gastroplasty can be functionally reversed by removal of the ring or the band, allowing the outlet to dilate. Revision of vertical banded gastroplasty for failed weight loss can be achieved by conversion to a gastric bypass or to a duodenal switch.

In general, revision surgery due to inadequate weight loss is reserved for those individuals in whom the original surgery was initially successful in achieving weight loss and who, due to the technical failure of the original procedure (e.g., pouch dilatation), have failed to achieve adequate weight loss in the two years following the original surgery despite being compliant with their prescribed postoperative diet and exercise programs.

**Pediatric and Adolescent Bariatric Surgery**

Overall, there is very little evidence on the role of bariatric surgery in treating morbidly obese pediatric patients. Moreover, the available evidence mostly comes from small, non-randomized studies. There is limited evidence that bariatric surgery leads to clinically significant, long-term sustained weight loss and resolution of obesity-related comorbidities in the pediatric population. The evidence does not permit conclusions regarding morbidity associated with and safety of any bariatric procedure in the pediatric population. There is no evidence regarding the long-term potential impact of bariatric procedures on growth and development

Researchers have raised several special concerns about the appropriateness of bariatric surgery for adolescents (Abu-Abeid, 2003; Dolan, 2003; Sugeran, 2003; Strauss, 2001; Breaux, 1995). One is that the surgery may potentially interfere with physical growth and/or sexual maturation. Therefore, these additional outcomes must be assessed in adolescents who receive bariatric surgery. Also, quality of life is a critical outcome because weight loss in obese adolescents may improve social relationships, self-esteem, physical functioning, or other similar factors. Long-term follow-up can be more difficult with adolescents than with adults because they may be more likely than adults to change addresses. (For example, an adolescent may move to college soon after treatment). Patients lost weight in the long term, but none of the studies reported evidence about resolution of co-morbidities, long-term survival, or quality of life. The low patient enrollment in these studies (a total of n=87 in all five studies) precludes evidence-based conclusions about perioperative mortality, physical growth, or sexual maturation. Two studies reported no impact on maturation with a follow up of 1.7 and 10 years

respectively (Dolan, 2003; Sugerman, 2003). The other three studies did not report on impact on maturation nor would the short follow up time of 1.9 to 5.8 years permit any firm conclusions of impact of surgery and physical, sexual and reproductive maturation (Abu-Abeid, 2003; Strauss, 2001; Breaux, 1995). Some patients experienced adverse events or re-operation, which is expected of any surgery. There are insufficient data to determine the rates of these events.

A systematic review by Pratt et al. (2009) evaluated best practice guidelines for pediatric and adolescent weight loss surgery and recommended modifications to the previously defined patient selection criteria. Bariatric surgery may be considered for adolescents with a BMI  $\geq 35$  and specific obesity-related co-morbidities for which there is clear evidence of important short-term morbidity (i.e., type 2 diabetes, severe steatohepatitis, pseudotumor cerebri, and moderate-to-severe obstructive sleep apnea). In addition, bariatric surgery should be considered for adolescents with extreme obesity (BMI  $\geq 40$ ) and other co-morbidities (mild obstructive sleep apnea, hypertension, insulin resistance, glucose intolerance, dyslipidemia, impaired quality of life or activities of daily living) associated with long-term risks.

O'Brien et al. (2010) conducted a prospective, randomized controlled study of 42 adolescents to compare the outcomes of gastric banding (n=24) with an optimal lifestyle program (n=18) for adolescent obesity. Patients in the gastric banding group had an estimated weight loss of 78.8% compared to 13.2% in the optimal lifestyle program. Body mass index scores decreased from 42.3 to 29.6 in the gastric banding group compared with 40.4 to 39.1 in the optimal lifestyle program group. Prior to the study, 9 gastric banding patients and 10 lifestyle patients had metabolic syndrome. At 24 month follow-up, none of the patients in the gastric banding group had the metabolic syndrome compared with 4 in the lifestyle group. Eight reoperations were required in 7 patients due to proximal pouch dilatation or tubing injury during follow-up. The authors concluded that use of gastric banding compared with lifestyle intervention resulted in a greater percentage of excess weight loss. Study limitations include small number of study participants as well as a third of the gastric banding patients' required surgical revision due to complications.

A US Food and Drug Administration (FDA) approved clinical trial by Nadler et al. (2009) evaluated the impact on metabolic health following laparoscopic adjustable banding in 45 morbidly obese adolescents. Thirty-nine of the 45 patients had 85 identified co-morbidities. All patients completed a 1 year follow-up with 41 patients completing 2 year follow-up. Mean age was 16.1 + 1.2 years, preoperative weight was 299 + 57 lb, and BMI was 48 + 6.4 kg/m<sup>2</sup>. The estimated weight loss at 6 months was 31 + 16; at 1 year 46 + 21; and 2 years 47 + 22. At 1-year follow-up, patients had a significant decrease in their total and android fat mass. At follow-up, 47 of the 85 identified co-morbidities (55%) were completely resolved and 25 (29%) were improved in comparison with baseline. Improvements in alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, hemoglobin A1c, fasting insulin, triglycerides, and high density lipoprotein, were also seen. The authors concluded that based on these results, laparoscopic adjustable banding is an appropriate surgical option for morbidly obese adolescents.

A retrospective study by Lawson et al. (2006) reported one-year outcomes of Roux-en-Y gastric bypass for morbidly obese adolescents (n=39) aged 13 to 21 years of age. Weight loss of the surgical group was compared to a non-surgical group (n=12). Other outcomes were metabolic changes and complications. Mean BMI in the surgical group decreased from 56.5kg/m<sup>2</sup> to 35.8kg/m<sup>2</sup> at 12 months postoperatively compared to the nonsurgical group at 47.2kg/m<sup>2</sup> to 46.0kg/m<sup>2</sup>. Surgical patients showed significant

improvements in triglycerides (-65 mg/dL), total cholesterol (-28 mg/dL), fasting blood glucose (-12 mg/dL), and fasting insulin (-21 microM/mL]). Fifteen patients experienced complications. Nine had minor complications with no long-term consequences (food obstruction, wound infection, nausea, diarrhea, hypokalemia, or deep vein thrombosis), 4 had at least 1 moderate complication (persistent iron deficiency anemia, peripheral neuropathy secondary to vitamin deficiency, reoperation due to staple line leak, obstruction, or gastrostomy revision, shock or internal hernia) for at least 1 month, and 2 had at least 1 severe medical complication with long-term consequences (including beriberi and death). The authors concluded that postoperatively, adolescents lose significant weight and realize major metabolic improvements. Complication rates and types are similar to those of adults; however, the small sample size of this precludes calculation of complication rates.

Inge, et al. (2004) reviewed the concerns of bariatric surgery in the adolescent population. They concluded that adolescent candidates should be severely obese with a BMI of 50 or more or greater than 40 with co-morbidities, have attained majority of skeletal maturity (generally around 13 years of age for girls and 15 years of age for boys) and have documented failure of previous nonsurgical attempts at weight loss. In addition to these issues and to increase compliance post-surgery, the decisional capacity of the patient, family structure and barriers to adherence must be considered.

**Trans-oral Endoscopic Surgery**

Trans-oral endoscopic surgery is a form of natural orifice transluminal endoscopic surgery (NOTES) which is an emerging experimental alternative to conventional surgery that eliminates abdominal incisions and incision-related complications by combining endoscopic and laparoscopic techniques to diagnose and treat abdominal pathology (McGee, 2006). The NOTES technique involves the use of natural orifice access (e.g., mouth, urinary tract, anus) to perform a surgical procedure which potentially reduces or eliminates common incision-related complications.

The trans-oral gastroplasty (TOGA®) procedure uses flexible staplers introduced through the mouth and esophagus to create a gastric sleeve. The TOGA® sleeve limits the amount of food that can be eaten and gives the patient a feeling of fullness after a small meal.

A clinical trial is currently underway (NCT00661245) to evaluate the safety and effectiveness of the TOGA® System for the treatment of morbid obesity.

StomaphyX is a new and innovative revision procedure for individuals who have had Roux-en-Y gastric bypass surgery and have regained weight due to a stretched stomach pouch or enlarged stomach outlet. The StomaphyX procedure reduces the stomach pouch and stomach outlet (stoma) to the original gastric bypass size without traditional surgery or incisions and with minimal recovery time. It is not performed as a primary method of weight loss surgery, but as a type of revisional bariatric surgery for gastric bypass patients (StomaphyX, 2008).

Currently there is insufficient evidence in the peer-reviewed medical literature to support the use of transluminal endoscopic surgery using devices such as StomaphyX for the management of severe obesity.

A case series by Mullady, et al. (2009) evaluated 20 patients who underwent restorative obesity surgery, endoluminal (ROSE) procedure due to weight regain post gastric bypass, with a confirmed dilated pouch and gastrojejunal anastomosis (GJA) on endoscopy. Seventeen of 20 (85%) patients had an average reduction in stoma diameter of 16 mm (65% reduction) and an average reduction in pouch length of 2.5 cm (36% reduction). The mean weight loss in successful cases was 8.8 kg at 3 months. The

authors concluded that the ROSE procedure is effective in reducing not only the size of the gastrojejunal anastomosis but also the gastric pouch and may provide an endoscopic alternative for weight regain in gastric bypass patients. This study is limited by small sample size and short term follow-up.

**Laparoscopic Mini-Gastric Bypass**

Mini gastric bypass (MGB) is a relatively new procedure that is performed laparoscopically. A gastric tube is constructed by dividing the stomach vertically, down to the antrum. As in the RYGB, food does not enter the distal stomach. At a point about 200 cm distal to the ligament of Treitz, the small intestine is looped back toward the gastric tube and attached. Some surgeons contend that this is similar to an out-of-date procedure called "loop" gastric bypass and do not recommend its use.

A small number of studies in the published literature relate to laparoscopic mini-gastric bypass. These studies were reported by two primary groups, one led by the original surgeon of the procedure and another group based in Taiwan. A total of four abstracts were retrieved including one randomized controlled trial (n=80). Three other descriptive and case series reports of clinical trials were found (n=423 to 2410), though two of these report initial and final results of the same large case series study (Hayes, 2006). The small randomized controlled trial showed that operative times with the mini gastric approach, was 57 minutes less than the laparoscopic Roux-en-Y gastric bypass procedure. The initial findings are promising, but the small sample size, limited two year follow up and lack of identification of patient selection criteria indicate that further study is needed to establish the safety and efficacy of the procedure (Lee, 2005).

**Gastric Electrical Stimulator**

The implantable gastric stimulator (IGS) is a small, battery-powered device similar to a cardiac pacemaker, in a small pocket, created beneath the skin of the abdomen, using laparoscopy (hollow surgical tube and instruments inserted through an abdominal incision). Electrodes from the IGS are then implanted into the wall of the stomach and imaging or endoscopy is used to check that no perforations of the stomach wall have resulted. After a 1-month wait for healing at the surgical site, the device is turned on to intermittently stimulate the stomach wall. The IGS is programmed externally using a controller that sends radiofrequency signals to the device.

IGS for the treatment of obesity has been evaluated in randomized controlled trials (RCTs). The Screened Health Assessment and Pacer Evaluation (SHAPE) trial by Shikora, et al. (2009) compared gastric stimulation therapy to a standard diet and behavioral therapy regimen in a group of obese patients. The difference in excess weight loss between the control group and the treatment group was not found to be statistically significant at 12 months of follow-up. These results suggest that this technology is not effective in achieving significant weight loss in severely obese individuals.

Shikora (2004a) reported an update of the two U.S. clinical trials for gastric stimulation in obesity. The first was an RCT in 2000 that included patient's age 18–50 who had a BMI of 40–55. No statistical difference in the weight loss between study and control groups was found at six-month follow-up.

The second trial, the Dual-Lead Implantable Gastric Electrical Stimulation Trial (DIGEST), was a non-randomized, open-label study of patients with a BMI 40–55 kg/m<sup>2</sup> or 35–39 kg/m<sup>2</sup> and one or more significant comorbidities. At the 12-month follow-up point, 71% of participants lost weight (54% lost > 10% of excess, and 29% lost > 20% excess). At the 16-month follow-up, mean EWL was 23%.

Currently there are no IGS systems approved by the Food and Drug Administration to date for obesity

treatment. The evidence is limited to 1 small randomized controlled trial (RCT), 1 double-blind, placebo-controlled RCT, and 5 case series. Overall, there is insufficient evidence to support the efficacy and safety of IGS therapy for promoting weight loss among patients with morbid obesity. There are no data from controlled clinical trials that proves that IGS reliably leads to weight loss or that it is safe and effective compared with standard therapies including diet and exercise, pharmacotherapy, or with more invasive types of bariatric surgery. In fact, the only controlled trial involving a substantial number of patients demonstrated no effect on weight at 6 months after implantation of the device.

There is insufficient evidence in the published scientific literature to support the use of gastric pacing for the treatment of morbid obesity.

**Vagus Nerve Blocking**

Vagus nerve blocking (VNB) or vagal blocking therapy (VBLOC) is also being investigated as a treatment for obesity. VNB uses high-frequency, low-energy electrical pulses to block vagus nerve signals in the abdominal region, inhibiting gastric motility and increasing satiety (feeling full). No VNB devices have yet received U.S. FDA approval. Early clinical trial results suggest that VNB may achieve excess weight loss (EWL) that is comparable to approximately half of that achievable by LAGB (ECRI, 2009).

In an open-label study, Camilleri and associates (2008) evaluated the effects of vagal blocking by means of a new medical device that uses high-frequency electrical algorithms to create intermittent vagal blocking (VBLOC therapy) on excess weight loss (EWL). Electrodes were implanted laparoscopically on both vagi near the esophago-gastric junction to provide electrical block. Patients (obese subjects with body mass index [BMI] of 35 to 50 kg/m<sup>2</sup>) were followed for 6 months. The authors concluded that VBLOC therapy is associated with significant EWL and a desirable safety profile. They noted that these findings have resulted in the design and implementation of a randomized, double-blind, prospective, multi-center trial in an obese subject population.

**Intragastric Balloon (IGB)**

The silicon intragastric balloon (IGB) has been developed as a temporary aid for obese people who have had unsatisfactory results in their treatment for obesity, and in super-obese patients who often have a high risk for surgery (Fernandes, 2007). The balloon, placed endoscopically, is designed to float freely inside the stomach to reduce the volume of the stomach and leading to a premature feeling of satiety.

In a Cochrane review by Fernandes et al. (2007), nine randomized controlled trials involving 395 patients comparing intragastric balloon with conventional weight loss management. Six out of 9 studies had a follow-up of less than one year with the longest study duration was 24 months. Compared with conventional management, IGB did not show convincing evidence of a greater weight loss. On the other hand, complications of intragastric balloon placement occurred, however few of a serious nature. The relative risks for minor complications like gastric ulcers and erosions were significantly raised.

Melissas, et al. (2007) studied 140 morbidly obese patients who underwent intragastric balloon placement. These patients refused bariatric surgery because of fear of complications and mortality and were followed over a 6- to 30-month period (mean 18.3 months) after balloon extraction. Of the 140 patients in the study, 100 patients lost > or = 25% of their excess weight on balloon extraction and were categorized as successes, while 40 patients did not achieve that weight loss and were categorized as failures. During the follow-up period, 44 of the originally successful patients (31.4%) regained weight and were categorized as recurrences, while the remaining 56 patients (40%) maintained their EWL of > or = 25% and were considered long-term successes. In addition, during follow-up, 45 patients (32.1%)

requested and underwent bariatric surgery for their morbid obesity (21 adjustable gastric band, 11 laparoscopic sleeve gastrectomy, 13 laparoscopic gastric bypasses). Of these, 13 (32.5%) were from the group of 40 patients categorized as failures upon intragastric balloon removal, 28 (63.6%) were from the group of 44 patients whose obesity recurred, and 4 (7.1%) were from the 56 patients who although they maintained successful weight loss requested further weight reduction. The authors concluded that use of the intragastric balloon served as a first step and a smooth introduction to bariatric surgery for morbidly obese patients who initially refused surgical intervention; however, the incidence of surgical intervention was double in patients who initially experienced the benefits of weight loss and then had obesity recurrence, compared with patients in whom the method failed.

Adverse effects associated with the intragastric balloon include gastric erosion, reflux, and obstruction (Fernandes, 2007).

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

**Gastrointestinal Liner**

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.

Verdam, et al (2012) stated that 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.

Schouten et al. (2010) conducted a randomized controlled trial of an endoscopically placed duodenal-jejunal bypass sleeve or EndoBarrier Gastrointestinal Liner in 30 patients. An additional 11 patients served as a diet control group with all patients following the same low-calorie diet during the study period. Twenty-six devices were successfully implanted. In 4 patients, implantation could not be achieved and the devices were explanted prior to the initial protocol end point because of migration (1), dislocation of the anchor (1), sleeve obstruction (1), and continuous epigastric pain (1). The remaining patients all completed the study. Mean excess weight loss after 3 months was 19.0% for device patients versus 6.9% for control patients. Of 8 patients with diabetes, 7 patients showed improvement at follow-up. The authors concluded that the EndoBarrier Gastrointestinal Liner was a safe noninvasive device with excellent short-term weight loss results; however, long-term randomized studies are necessary to determine the role of the device in the treatment of morbid obesity.

A prospective, randomized trial by Gersin, et al. (2010) compared 21 patients receiving the duodenojejunal bypass liner (DJBL) with 26 patients undergoing a sham procedure. Primary outcomes measured the difference in the percentage of excess weight loss (EWL) at week 12 between the 2 groups. Thirteen duodenojejunal bypass liner subjects and 24 sham subjects completed the 12-week study. The duodenojejunal bypass liner group had a EWL of 11.9% compared to 2.7% in the sham group. Eight patients in the duodenojejunal bypass liner group dropped out of the study early because of GI bleeding (n = 3), abdominal pain (n = 2), nausea and vomiting (n = 2), and an unrelated preexisting illness (n = 1). The authors concluded that duodenojejunal bypass liner promotes a more significant weight loss beyond a minimal sham effect in candidates for bariatric surgery. This study is limited by

small patient sample, short term follow-up and complication rates.

**Laparoscopic Greater Curvature Plication (LGCP)**

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

**Other Applications**

Kuruba, et al. (2007) prospectively studied 201 obese patients (body mass index  $48 + 7 \text{ kg/m}^2$ ), of which 65 reported urinary incontinence, to evaluate the effects of bariatric surgery to resolve urinary incontinence. Of the 45 patients that underwent bariatric surgery, 38 reported mild (4%), moderate (47%), or severe (49%) urinary incontinence preoperatively. Nineteen of the 38 patients (50%) demonstrated resolution of urinary incontinence and the other 19 reported residual slight-moderate (36%) or severe (13%) urinary incontinence. The authors concluded that bariatric surgery in obese patients with urinary incontinence improves or eliminates symptoms. The study is limited by small sample size and fact that patients with urinary incontinence undergoing bariatric surgery already had a diagnosis of morbid obesity.

Kuruba et.al. (2007) also provided the following recommendations for evaluation in the preoperative period. In the perioperative period treatment of co-morbidities should be optimized. For patients with a history of type 2 diabetes mellitus, strict glycemic control should be instituted to maintain a blood glucose level  $<150$  or a hemoglobin A1c  $<7$ . Patients with OSA should be using CPAP or BiPAP at least 4-6 weeks prior to surgery in an effort to decrease hypercarbia, hypoxemia and pulmonary artery vasoconstriction. Patients with NASH may benefit from calorie restriction for a several weeks preoperatively to reduce the size of the liver, making surgery easier. Beta blockers may decrease the risk of intra-operative ischemia, infarction or dysrhythmia in patients with coronary artery disease; however its role has not been defined in bariatric surgery.

A 2010 guideline by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) states that due to concerns for higher failure rates after fundoplication in the morbidly obese patient (BMI  $>35 \text{ kg/m}^2$ ) and the inability of fundoplication to address the underlying problem (obesity) and its associated co-morbidities, gastric bypass should be the procedure of choice when treating GERD in this patient group. The benefits in patients with BMI  $>30$  is less clear and needs further study. (Stefanidis, et al., 2010)

**2. EXTERNAL SOURCES/ GROUPS POLICY:**

**The National Heart, Lung and Blood Institute (NHLBI):** The NHLBI published guidelines for all treatments for obesity in adults (including bariatric surgery) in 1998 (NHLBI, 1998). The guideline stated that "weight loss surgery is an option in carefully selected patients with clinically severe obesity (BMI of 40 or BMI of 35-39.9 with co-morbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality." It also stated that RYGBP and "vertical gastric banding" result in "substantial" weight loss. Further, it recommended that patients be followed by a multidisciplinary team of experts, including medical, behavioral, and nutritional experts. The National Heart, Lung and Blood Institute (NHLBI) also stated the following Practical Guide Identification, Evaluation, and Treatment of Overweight and Obesity in Adults statement: "Weight loss surgery is an option for weight reduction in patients with clinically severe obesity, i.e., a BMI  $\geq 40$ , or a BMI  $\geq 35$  with comorbid conditions". Weight loss surgery should be reserved for patient in whom other methods of treatment have failed and who have clinically severe obesity (once commonly referred to

as “morbid obesity”).

**The American Association of Clinical Endocrinologists, the Obesity Society, and American Society for Metabolic & Bariatric Surgery:** They published a guideline in 2008 on the selection criteria and exclusion factors for bariatric surgery. Patient selection criteria include the standard BMI restriction of  $>40\text{kg/m}^2$  with no co-morbidities and  $>35\text{kg/m}^2$  with obesity associated co-morbidity. Children and adolescents over the 95th percentile for weight based on age should be considered for a bariatric procedure in a specialized center when a severe co-morbidity is present and only after a very careful assessment of such patients and their parents. Additionally, patients must have failed previous nonsurgical attempts at weight reduction including nonprofessional programs (ex. Weight Watchers). There is an expectation that patient will adhere to postoperative care; have follow-up visits with physician(s) and team members; will adhere to recommended medical management, including the use of dietary supplements; and follow instructions regarding any recommended procedures or tests. Patients with reversible endocrine or other disorders that can cause obesity, current drug or alcohol abuse, uncontrolled, severe psychiatric illness, or lack of comprehension of risks, benefits, expected outcomes, alternatives and lifestyle changes required with bariatric surgery should be excluded.

**The Society of American Gastrointestinal Endoscopic Surgeons and the American Society for Bariatric Surgery (SAGES/ASBS):** SAGES/ASBS published a guideline in 2000 specifically focused on bariatric surgery. Patient selection criteria include the standard BMI restriction and the ability to show that dietary attempts at weight control have been ineffective. The guideline describes RYGBP, VBG, BPD, and various gastric banding procedures but does not discuss their relative efficacies. It notes that advanced skills are required to perform bariatric surgical procedures laparoscopically.

**The American Society for Metabolic & Bariatric Surgery (ASMBS):** The ASMBS published position statements on sleeve gastrectomy as a bariatric procedure in 2007 and 2009. The sleeve gastrectomy procedure has been utilized as a first-stage bariatric procedure to reduce surgical risk in high-risk patients by induction of weight loss and this may be its most useful application at the present time. Sleeve gastrectomy appears to be a technically easier and/or faster laparoscopic procedure than Roux-en-Y gastric bypass or malabsorptive procedures in complex or high risk patients including the super-super-obese patient ( $\text{BMI} > 60\text{kg/m}^2$ ). Long-term ( $> 5\text{yr}$ ) weight loss and co-morbidity resolution data for sleeve gastrectomy is limited at this time. Weight regains or a desire for further weight loss in a super-super-obese patient may require the procedure to be revised to a gastric bypass or biliopancreatic diversion with duodenal switch. Detailed informed consent including information about the possibility of long-term weight regain and the potential need for subsequent conversion to another procedure is suggested before the sleeve gastrectomy is planned for an individual patient. Decisions to perform this procedure should also be in compliance with ethical guidelines published by the ASMBS.

The ASMBS recognizes performance of sleeve gastrectomy may be an option for carefully selected patients undergoing bariatric surgical treatment, particularly those who are high risk or super-super-obese, and that the concept of staged bariatric surgery may have value as a risk reduction strategy in high-risk patient populations. It is suggested that surgeons performing sleeve gastrectomy prospectively collect and report outcome data for this procedure in the scientific literature. In addition, it is suggested that surgeons performing sleeve gastrectomy inform patients regarding the lack of published evidence for sustained weight loss beyond 5 years and provide them with information regarding alternative procedures with published long-term (5 years) data confirming sustained weight loss and co-morbidity resolution based upon available literature at this time.

**The American Gastroenterological Association:** The AGA published a guideline in 2002 on all treatments for obesity, including bariatric surgery. Patient selection criteria for bariatric surgery include the standard BMI restriction, inability to achieve weight loss without surgery, the presence of acceptable operative risks, and ability to comply with long-term follow-up. The guideline states that weight loss is greater after RYGBP than after VBG and that perioperative outcomes are better after laparoscopic procedures than after open procedures. Further, the guideline recommends that malabsorptive procedures such as distal RYGBP and BPD/DS "should be considered as potential options for very obese patients (BMI >50 kg/m<sup>2</sup>)."

**National Institute for Health and Clinical Excellence (NICE):** In December 2006, NICE published a clinical guideline that focused on the prevention, identification, assessment, and management of overweight and obesity in adults and children. As regards adults, it stated that bariatric surgery is appropriate to recommend as a first-line option for adults with a BMI > 50 kg/m<sup>2</sup> in whom surgical intervention is deemed appropriate. The multidisciplinary bariatric surgical team should provide:

- Preoperative assessment to detect any psychological or clinical factors that may affect adherence to postoperative care requirements. The assessment should include a risk-benefit analysis, centered on preventing complications of obesity, and specialist assessment for eating disorder(s).
- Information on the various surgery types, including potential weight loss and consequent risks.
- Regular postoperative follow-up by a dietetic specialist and surgeon.
- Manage the patient's co-morbidities.
- Psychological support before and after surgery.
- Information about plastic surgery (such as apronectomy) where appropriate.
- Access to suitable equipment, including scales, theater tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses, and seating suitable for patients undergoing bariatric surgery, and staff trained in how to use them.

Due to increased complication and mortality risks, revisional surgery should be undertaken only in specialist centers by surgeons with extensive experience.

**American Academy of Sleep Medicine (AASM):** In Practice Parameters for the Medical Therapy of Obstructive Sleep Apnea, the AASM states that there is consensus among members of the Task Force and the Standards of Practice Committee that bariatric surgery may play a role in the treatment of obstructive sleep apnea patients who are morbidly obese, as an adjunct to less invasive and rapidly active first-line therapies (Morgenthaler, et al., 2006).

**American Diabetes Association (ADA):** A 2009 guideline on the standards of care states:

- Bariatric surgery should be considered for adults with BMI > 35 kg/m<sup>2</sup> and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy.
- Patients with type 2 diabetes who have undergone bariatric surgery need life-long lifestyle support and medical monitoring.
- Although small trials have shown glycemic benefit of bariatric surgery in patients with type 2 diabetes and BMI of 30-35 kg/m<sup>2</sup>, there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m<sup>2</sup> outside of a research protocol.

The long-term benefits, cost-effectiveness, and risks of bariatric surgery in individuals with type 2

diabetes should be studied in well-designed randomized controlled trials with optimal medical and lifestyle therapy as the comparator.

**3. EXPERT OPINION:** Not requested.

**SUMMARY:**

Bariatric surgery procedures are performed to treat morbid obesity and comorbid conditions associated with morbid obesity. Two types of surgical procedures are employed. Malabsorptive procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur. Restrictive procedures restrict the size of the stomach and decrease intake. Surgery can combine both types of procedures.

Severe obesity is known to aggravate numerous medical conditions. The comorbid conditions for which bariatric surgery might be considered medically necessary have been described in the [COVERAGE RATIONALE/CLINICAL CONSIDERATIONS](#) section. Though the conditions listed in this section need not be immediately life-threatening, the condition must not be trivial or easily controlled with non-invasive means (such as medication) and must be of sufficient severity as to pose considerable short- or long-term risk to function and/or survival. Consideration of the risk-benefit for each individual patient must be used to determine that surgery for obesity is the best option for treatment for that patient and no contraindications to bariatric surgery may exist.

Repeat bariatric surgery is generally not reasonable and necessary.

**COST ANALYSIS:**

These costs for gastric bypass surgery range approximately \$20,000 to \$29,000 in the United States (NIDDK, 2012; Pleatman, 2012); however, the average cost of \$25,000 for gastric bypass surgery increases to just over \$36,500 when considering complications from the first 6 months post-surgery, and to approximately \$65,000 should hospital readmission be required (Saunders, 2007). In many cases, patients will also undergo second-stage bariatric procedures at a base cost of approximately \$25,000.

**CLAIMS AND CUSTOMER SERVICE INSTRUCTIONS:**

**UNDER DEVELOPMENT:** This section will host claim payment and billing instructions to be used by Claims and Customer Service staff. Content in this section is to be developed cooperatively by multiple departments, and reviewed by the Medical Policy Group.

*Note: The contents of this section are confidential and are not to be shared externally. When printing a copy of a policy for external distribution, this section should be excluded.*

**APPLICABLE CODES:**

*The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims*



payment. Other medical policies and coverage determination guidelines may apply.

HCPCS Codes	Description
ICD-9 Codes	Description
278.00	Obesity
278.01	Morbid obesity
ICD-10 Codes	Description
E66.0	Obesity
E66.8	Morbid obesity
CPT® Codes	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (e.g., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
43888	Gastric restrictive procedure, open; removal/replacement of subcutaneous port component only
42659	Unlisted laparoscopy procedure, stomach
43999	Unlisted procedure, stomach (e.g., Laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, open adjustable gastric banding, laparoscopic sleeve gastrectomy)
64590	When used for weigh loss - Insertion or replacement of peripheral or gastric neurostimulator pulse

	generator or receiver, direct or inductive coupling (Note – this code may be covered for indications other than for weight loss).
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POLICY HISTORY:	
DATE	ACTION/DESCRIPTION
08/11/2014	New policy number 2014M0067A. Reviewed and approved by the Interim Medical Policy Committee.
08/28/2014	Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).
09/01/2014	Published to ucare.org
8/09/2016	Policy updated and approved by the Medical Policy Committee. Policy number updated to 2016M0067B
9/01/2016	Published to ucare.org

QUESTIONS AND ANSWERS:
Q1:
A1:

ATTACHMENTS: