BARIATRIC SURGERY

Policy Number: 2014M0067A Effective Date: October 1, 2014

Table of Contents:

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
<th>Cross Reference Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>POLICY DESCRIPTION</td>
<td>2</td>
<td>Gastric Electrical Stimulation for Gastroesophageal Reflux Disease (GERD), 2013M0030A</td>
</tr>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td>Gastroparesis, 2013M0015A</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>8</td>
<td>Endoscopic Procedures for Gastroesophageal Reflux Disease (GERD), 2013M0030A</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>REFERENCES</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>17</td>
<td></td>
</tr>
</tbody>
</table>

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.”
**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. Individuals who may be considered as candidates for gastrointestinal surgery include those with a BMI above 35 who suffer from Type II diabetes or life-threatening cardiopulmonary problems such as severe sleep apnea or obesity-related heart disease. 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/m² (Class III obesity), OR
   B. Patients with BMI = 35-39.9 kg/m² who also have one or more of the following high-risk medical co-morbid 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, 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. 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 gastroplasty [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.

• Intragastric balloon. Further studies are needed to determine the safety and efficacy of intragastric 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.

Clinical Considerations:

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/m2 - Normal
3. 25-29.9 kg/m2 - Overweight
4. 30-34.9 kg/m2 - Obesity Class I
5. 35-39.9 kg/m2 - Obesity Class II
6. > 40 kg/m2 –Extreme Obesity Class III

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 ≥ 40) or a BMI ≥ 35 and serious comorbid conditions.

• 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:** 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.

- **Preoperative Psychological/Psychiatric Evaluation documentation:** An objective examination by a mental health professional (psychiatrist or psychologist) 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:**
  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.

**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) ≥ 30 kilograms per square meter (kg/m²), morbid obesity as a BMI ≥ 40 kg/m², super-obesity as a BMI ≥ 50 kg/m², and super super-obesity as a BMI ≥ 60 kg/m². 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):

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI</th>
</tr>
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<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5 kg/m²</td>
</tr>
<tr>
<td>Normal weight</td>
<td>18.5–24.9 kg/m²</td>
</tr>
<tr>
<td>Overweight</td>
<td>25–29.9 kg/m²</td>
</tr>
<tr>
<td>Obesity (Class 1)</td>
<td>30–34.9 kg/m²</td>
</tr>
<tr>
<td>Obesity (Class 2)</td>
<td>35–39.9 kg/m²</td>
</tr>
<tr>
<td>Extreme Obesity (Class 3)</td>
<td>≥ 40 k/m²</td>
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BMI is a calculated number devised by using the formula - weight in kilograms divided by height in meters squared (kg/m²). 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/m² 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.

5. **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.

6. **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.

7. **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.

8. **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. Accessed July 6, 2014.

- 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/m² or less obese patients who have at least a body mass index (BMI) of 30 kg/m² 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. Accessed July 6, 2014. 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. Accessed July 6, 2014.

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 July 6, 2014.

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 July 6, 2014.

- 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. Accessed July 6, 2014.

- 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 February 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/MedicareApprovedFacilities/Bariatric-Surgery.html](http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/Bariatric-Surgery.html), and published in the Federal Register for services provided up to and including date of service September 23, 2013.

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/m²,
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:**

**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.

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.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tr>
<td>ICD-9 Codes</td>
<td>Description</td>
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<tr>
<td>278.00</td>
<td>Obesity</td>
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<td>278.01</td>
<td>Morbid obesity</td>
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<tr>
<td>ICD-10 Codes</td>
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<td>E66.0</td>
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<td>E66.8</td>
<td>Morbid obesity</td>
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<td>CPT® Codes</td>
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<tr>
<td>43644</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)</td>
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<tr>
<td>43645</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption</td>
</tr>
<tr>
<td>43770</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)</td>
</tr>
<tr>
<td>43771</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only</td>
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<tr>
<td>43772</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only</td>
</tr>
<tr>
<td>43773</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only</td>
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<tr>
<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components</td>
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<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (e.g., sleeve gastrectomy)</td>
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<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded</td>
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<td>Code</td>
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<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty</td>
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<tr>
<td>43845</td>
<td>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)</td>
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<td>43846</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy</td>
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<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption</td>
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<tr>
<td>43848</td>
<td>Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)</td>
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<tr>
<td>43886</td>
<td>Gastric restrictive procedure, open; revision of subcutaneous port component only</td>
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<tr>
<td>43887</td>
<td>Gastric restrictive procedure, open; removal of subcutaneous port component only</td>
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<tr>
<td>43888</td>
<td>Gastric restrictive procedure, open; removal/replacement of subcutaneous port component only</td>
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<tr>
<td>43999</td>
<td>Unlisted procedure, stomach (e.g., Laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, open adjustable gastric banding, laparoscopic sleeve gastrectomy)</td>
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</table>

CPT® is a registered trademark of the American Medical Association.

**REFERENCES:**


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<td>08/28/2014</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Committee (QIACC).</td>
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<tr>
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