Clinical Policy Title: Bariatric surgery for adults

Clinical Policy Number: 08.03.02

Effective Date: March 1, 2014
Initial Review Date: October 16, 2013
Most Recent Review Date: September 21, 2016
Next Review Date: September 2017

Related policies:
CP# 08.03.01 Bariatric surgery for children and adolescents
CP# 16.03.08 Cosmetic, plastic and scar revision surgery

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of bariatric surgery in adults to be clinically proven and, therefore, medically necessary when the following criteria are met:

<table>
<thead>
<tr>
<th>Medical necessity criteria (All criteria must be met)</th>
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<tbody>
<tr>
<td>Adult age 18 years or older.</td>
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<tr>
<td>Presence of severe obesity (for at least the last two years prior to surgery).</td>
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<tr>
<td>Severe obesity defined as a body mass index (BMI) ≥ 40 kg/m² or BMI ≥ 35 kg/m² with at least one clinically significant obesity-related comorbidity.</td>
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<tr>
<td>An acceptable operative risk is present.</td>
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</tbody>
</table>
### Medical necessity criteria
(All criteria must be met)

| Documentation of attempted medically managed weight loss within the last two years prior to surgery without successful long-term weight reduction. This must include evidence of active participation within the last 12 months in a weight-management program that is supervised either by a physician or a registered dietician, for a minimum of six consecutive months (i.e., ≥ 180 days). The weight management program must adhere to recognized protocols of pre-surgical management and post-surgical programs, where patient selection includes adherence to protocols and appointments (see Background, Table 1). |

<table>
<thead>
<tr>
<th>Clearance by a mental health provider to determine contraindications, mental competency and understanding of the nature, extent and possible complications of the surgery and ability to sustain dietary behavioral modifications needed to ensure a successful outcome of surgery. Contraindicated diagnoses may include any of the following:</th>
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<tbody>
<tr>
<td>• Active drug abuse.</td>
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<td>• Active suicidal ideation.</td>
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<tr>
<td>• Borderline personality disorder.</td>
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<tr>
<td>• Schizophrenia.</td>
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<td>• Psychotic disorder.</td>
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<tr>
<td>• Uncontrolled depression.</td>
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<tr>
<td>• Defined non-compliance with previous medical care.</td>
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### Covered services when medical necessity criteria are met

<table>
<thead>
<tr>
<th>Open or laparoscopic Roux-en-Y gastric bypass (LRYGB) (CPT codes 43644, 43645, 43846, 43847).</th>
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<tbody>
<tr>
<td>Laparoscopic adjustable silicone gastric banding (CPT 43770).</td>
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<tr>
<td>Open or laparoscopic sleeve gastrectomy (LSG) when used as a stand-alone procedure (i.e., not as part of staged procedure or part of failed attempt that moves to an open procedure) (CPT code 43775).</td>
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<tr>
<td>Open or laparoscopic vertical banded gastroplasty (VBG) (CPT code 43842).</td>
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<tr>
<td>Repeat bariatric surgery for members who met medical necessity criteria for their initial bariatric surgery, and who meet either of the following medical necessity criteria:</td>
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<tr>
<td>• Failure to achieve adequate weight loss (at least 50 percent of excess body weight or failure to achieve body weight to within 30 percent of ideal body weight at least two years following the original surgery), due to a technical failure within the first 30 days of the original bariatric surgical procedure, and the member has been compliant with a prescribed nutrition and exercise program following the procedure.</td>
</tr>
<tr>
<td>• Replacement of an adjustable band due to complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments.</td>
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<tr>
<td>Adjustment of a silicone gastric band to control the rate of weight loss and/or treat symptoms secondary to gastric restriction, following a medically necessary adjustable silicone gastric banding procedure.</td>
</tr>
<tr>
<td>Cholecystectomy when performed in concert with elective bariatric procedures for members with documented pre-operative clinical signs and symptoms suggestive of gallbladder disease, or who are at high risk of developing gallbladder related symptoms after the bariatric procedure.</td>
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</tbody>
</table>
Limitations:

- All other uses of bariatric surgery in adults are not medically necessary.
- Routine use of cholecystectomy, when performed in concert with elective bariatric procedures in the absence of symptoms suggestive of gallbladder disease prior to surgery, is not medically necessary.
- The use of bariatric surgery in members with a BMI < 35 kg/m$^2$ is not medically necessary.
- The use of repeat bariatric surgery in members who initially achieved successful weight loss, but overcame the weight loss with behavioral changes is not medically necessary, as there is insufficient evidence of effectiveness in this population.
- The use of endoscopic bariatric therapies (EBTs, e.g., intragastric balloons) for temporary weight reduction is not medically necessary (CPT code 43999).
- Upper gastrointestinal endoscopy performed concurrent with a bariatric surgery procedure to confirm a surgical anastomosis, or to establish anatomical landmarks, is an integral part of the more comprehensive surgical procedure and is not separately reimbursable.

For Medicare members only:

Medical necessity criteria:

- BMI > 35 kg/m$^2$.
- Have at least one co-morbidity related to obesity, including type 2 diabetes mellitus.
- Previously unsuccessful with medical treatment for obesity.

Covered services when medical necessity criteria are met:

- Open and laparoscopic RYGB.
- Open and laparoscopic biliopancreatic diversion with duodenal switch.
- Laparoscopic adjustable gastric banding (LAGB).
- LSG performed on and after June 27, 2012. Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone LSG for the treatment of co-morbid conditions related to obesity.

The following services are not medically necessary:

- Open adjustable gastric banding.
- Open and LSG (prior to June 27, 2012).
- Open and laparoscopic VBG.
- Gastric Balloon (Section 100.11).
- Intestinal Bypass (Section 100.8).
  - L32619 only: mini-gastric bypass also not covered.
  - Silastic ring vertical gastric bypass (Fobi pouch).

Alternative covered services:

- Physician office visits.
- Behavioral health visits.
- Nutritional counseling.
Background

Overweight and obesity pose a major public health challenge. For the past 20 years, there has been a dramatic increase in obesity in the United States, and rates remain high; more than one-third of U.S. adults (35.7 percent) are obese (CDC 2013). Obesity is highest among non-Hispanic blacks (49.5 percent), compared with Mexican Americans (40.4 percent), all Hispanics (39.1 percent) and non-Hispanic whites (34.3 percent) (Flegal 2012). Obesity continues to impose an economic burden on both public and private payers in the United States. Per capita medical spending for the obese is $1,429 higher per year, or roughly 42 percent higher, than for someone of normal weight. Medicare and Medicaid spending is estimated to be 8.5 percent and 11.8 percent lower, respectively, in the absence of obesity (Finklestein 2009).

According to the National Heart, Lung and Blood Institute (NHLBI), the health risks associated with being overweight or obese include mechanical arthropathy (weight-related degenerative joint disease), type 2 diabetes, clinically uncontrolled hypertension, hyperlipidemia, coronary artery disease, lower extremity lymphatic or venous obstruction, severe obstructive sleep apnea, and obesity related pulmonary hypertension (NHLBI 1998). Overweight or obese adults are also at risk for certain cancers such as endometrial, breast, prostate and colon cancers. Higher body weights are associated with increases in all-cause mortality (NHLBI 1998).

Weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease (Sjostrom 2013, Vest 2012). The Swedish Obese Subjects (SOS) long-term, prospective, controlled trial found that bariatric surgery was associated with a sustainable reduction in overall mortality and decreased incidences of diabetes, cancer in women, myocardial infarction and stroke (Sjostrom 2013). High insulin and/or high glucose at baseline predicted favorable treatment effects, whereas high baseline BMI did not. These results suggest that consideration of metabolic variables is at least as important as BMI for identifying who is most likely to benefit from surgery (Sjostrom 2013).

The NHLBI recommends bariatric surgery as an option for carefully selected adult patients with clinically severe obesity, when less-invasive methods of weight loss have failed and the patient is at high risk for obesity associated morbidity or mortality (NHLBI 1998). Interest in offering bariatric surgery to some people with a BMI 30 – 35 kg/m² is increasing, particularly for persons whose diabetes cannot be adequately controlled by an optimal medical regimen, especially in the presence of other major cardiovascular disease risk factors (International Diabetes Federation [IDF] 2011).

Bariatric surgery procedures:

Bariatric procedures are classified as restrictive procedures that limit gastric volume, malabsorptive procedures that limit food intake and alter digestion or combinations of the two. More than 90 percent of bariatric procedures performed in the United States use a laparoscopic approach (Nguyen 2011). The most commonly used procedures are LRYGB, LSG, open RYGB and LAGB. (Nguyen 2013, Habermann 2012).

As a restrictive procedure, gastric banding, specifically LAGB, has largely replaced gastroplasty and VBG. LAGB uses an adjustable band placed around the stomach near its upper end, creating a small pouch and a narrow passage into the larger remainder of the stomach. Gastric banding avoids the problems associated with malabsorptive techniques. Contraindications to adjustable gastric banding procedures
include inflammatory diseases of the gastrointestinal tract, severe cardiopulmonary disease, portal hypertension and cirrhosis of the liver.

Currently, AGB devices approved for marketing in the United States include the Bioenterics® LAP-BAND® Adjustable Gastric Banding System (INAMED Health, Santa Barbara, California) and the REALIZE™ Adjustable Gastric Band (Ethicon Endo-Surgery, Inc., Cincinnati, Ohio). The LAP-BAND® is FDA-approved for patients with a BMI $\geq 40$ kg/m$^2$ or a BMI $30 - 40$ kg/m$^2$, in the presence of at least one serious weight related comorbidity, who have failed more conservative weight loss alternatives and who are committed to life long changes in their eating habits. FDA approved the REALIZE™ Adjustable Gastric Band for patients with a BMI $\geq 40$ kg/m$^2$ or a BMI $\geq 35$ kg/m$^2$, with one or more obesity-related comorbidity (FDA 2013). The AGB procedures are reversible.

Short-term and long-term complications associated with bariatric surgery are specific to the type of surgery. Procedures that include division or anastomosis of the gastrointestinal tract carry the risk of leakage and bleeding. Venous thrombotic events, cardiorespiratory events and wound infections are uncommon after laparoscopic bariatric surgery compared to open approaches. Malabsorptive procedures increase the risk of long-term vitamin and nutrient deficiencies, although they can occur with restrictive procedures. Slippage, erosion and port-site complications are associated with gastric banding. Nausea and vomiting, anastomotic ulcers, pouch outlet stenosis and bowel obstructions can be related to the procedure or the weight loss. Non-surgical complications of bariatric surgery include nutritional deficits, enterally administered drug malabsorption, increased incidence of psychosocial issues, increased reports of accidental death and suicide, and complications arising from excess, redundant tissue after significant weight loss.

The American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS) created the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), the only nationwide accreditation and quality improvement program for metabolic and bariatric surgery (MBSAQIP 2014). MBSAQIP accreditation provides an objective and measurable means of demonstrating high quality multidisciplinary care.

Table 1. MBSAQIP requirements

<table>
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<tr>
<th>Each center must use the following perioperative care protocols outlining the process for evaluating the patient seeking metabolic and bariatric surgery that have been approved and endorsed by the center’s MBS Committee:</th>
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<tr>
<td>• Defined selection criteria process based on the resources and expertise of the center.</td>
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<td>• Psychosocial-behavioral evaluation.</td>
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<td>• Algorithms for preoperative system clearances.</td>
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<tr>
<td>• Preoperative and postoperative nutrition regimen.</td>
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<tr>
<th>Each practicing metabolic and bariatric surgeon in the center must use a standardized order-set, specific to each metabolic and bariatric procedure. This order-set must address:</th>
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<tr>
<td>• Dietary progression.</td>
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<td>• Deep vein thrombosis prophylaxis.</td>
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<td>• Respiratory care.</td>
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<td>• Physical activity.</td>
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<td>• Pain management.</td>
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<td>• Parameters for notifying the attending surgeon.</td>
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There must be a defined process for the early recognition and management of warning signs of complications including tachycardia, fever, shortness of breath and excessive abdominal pain.
Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 4, 2016. Search terms were: "Bariatric Surgery" (MeSH) and "Obesity/surgery" (Mesh).

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

The most common bariatric procedures in current practice are open and laparoscopic RYGB, sleeve gastrectomy, open and laparoscopic AGB, and BPD with/without DS. The few available large randomized clinical trials (RCTs) with long-term follow-up (7 – 10 years or more) and rapid innovation in the field hampers the ability to match the optimal bariatric surgery procedure to a surgical candidate. Knowledge regarding the risks and benefits of each procedure, along with patient preferences, are critical to making an informed decision concerning the best option.

For patients with a BMI at least 40 kg/m$^2$ or BMI at least 35 kg/m$^2$ with one or more serious weight related co-morbidities:

- Overall, bariatric surgery is effective for significant weight loss. Limited data suggest significant weight loss is sustained over the long term (at least 10 years).
- Compared to non-surgical care, bariatric surgery is associated with long-term reduction in overall mortality and decreases in the incidence of diabetes, cancer in women, myocardial infarction and stroke. Among patients who underwent an AGB procedure, its long-term effects on dyslipidemia and hypertension are inconclusive.
- Compared to non-surgical care, the cost-effectiveness of bariatric surgery appears favorable in patients with type 2 diabetes, primarily by reducing the incidence of type 2 diabetes and associated treatment costs over the long term.
- No definitive conclusions can be made regarding the relative cost-effectiveness of different bariatric procedures.
For patients with a BMI between 30 kg/m$^2$ and 35 kg/m$^2$ with type 2 diabetes, there is insufficient evidence regarding the effectiveness of bariatric surgery for controlling type 2 diabetes.

There is insufficient evidence to support the routine use of concurrent cholecystectomy during RYGB performed or morbid obesity, particularly in asymptomatic patients.

Adaptations of many bariatric procedures have been proposed or used to improve patient outcomes. Evidence fails to show equivalent or improved patient outcomes, relative to available alternatives. These adapted procedures include, but are not limited to:

- Fobi-Pouch.
- Intragastric balloons (IGBs).
- Mini-gastric bypass.
- Natural Orifice Transluminal Endoscopic Surgery™ (NOTES™), also referred to as endoscopic (oral)-assisted, endoluminal or transoral incisionless surgery, (e.g., ROSE, Stomaphyx™)/endoscopic oral-assisted procedures).
- Laparoscopic greater curvature plication.

Other adaptations such as transoral gastroplasty using the TOGA® system (Satiety Inc., Palo Alto, CA) and a duodenal-jejunal bypass liner using the EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Lexington, MA), have not been FDA-approved for bariatric weight loss.

The following professional societies have produced guidelines for bariatric surgery:

- **American Diabetes Association (2015):**
  - Bariatric surgery may be considered for adults with BMI > 35 kg/m$^2$ and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacologic therapy.
  - Patients with type 2 diabetes who have undergone bariatric surgery need lifelong 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 to 35 kg/m$^2$, there is currently insufficient evidence to generally recommend surgery in patients with BMI <35 kg/m$^2$.
  - The long-term benefits, cost-effectiveness and risks of bariatric surgery in individuals with type 2 diabetes should be studied in well-designed controlled trials, with optimal medical and lifestyle therapy as the comparator.

- **American Association for the Study of Liver Diseases, American College of Gastroenterology and the American Gastroenterological Association (Chalasani 2012):**
  - Foregut bariatric surgery is not contraindicated in otherwise eligible obese individuals with non-alcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), but without established cirrhosis.
  - The type, safety and efficacy of foregut bariatric surgery in otherwise eligible obese individuals with established cirrhosis due to NAFLD is not established.
  - It is premature to consider foregut bariatric surgery as an established option to specifically treat NASH.
  - Bariatric surgery may be considered in patients who fail lifestyle interventions and who have a BMI of ≥ 35 with comorbidities, such as poorly controlled diabetes, who are expected to improve with weight reduction.

- **American Heart Association (Poirier 2011):**
o Currently, bariatric surgery should be reserved for patients who have severe obesity, in whom efforts at medical therapy have failed, with an acceptable operative risk, and who demonstrate motivation and understanding of surgery and the commitment required afterwards.

o Care by an interdisciplinary team is imperative for best management.

o Relative contraindications to surgery: severe heart failure, end-stage lung disease, active malignancy, cirrhosis with portal hypertension, uncontrolled drug or alcohol dependency, and impaired intellectual capacity, whereby the patient cannot understand the lifestyle changes necessary after surgery. Anatomic limitations such as severe intra-abdominal adhesions, giant ventral hernias, large liver and physiological intolerance of pneumoperitoneum, may make a laparoscopic approach impossible and require traditional open laparotomy for access to surgery. These features associated with a given patient should always be evaluated carefully in experienced centers to properly evaluate the risk/benefit ratio of a given surgical procedure.

- American Society for Metabolic and Bariatric Surgery (2013):
  o Patients with a BMI ≥ 40 kg/m\(^2\) without coexisting medical problems and acceptable surgical risk should be eligible for one of the procedures.
  o Patients with a BMI ≥ 35 kg/m\(^2\) and one or more severe obesity-related co-morbidities.
  o Patients with BMI of 30 – 34.9 kg/m\(^2\) with diabetes or metabolic syndrome may be offered a bariatric procedure, although current evidence is limited.
  o Insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone or cardiovascular disease risk reduction alone, independent of BMI criteria.
  o Best choice for any bariatric procedure depends on the individualized goals of therapy (e.g., weight loss and/or metabolic [glycemic] control), available local/regional expertise (surgeon and institution), patient preferences and personalized risk.
  o There is insufficient evidence to generalize in favor of one bariatric surgical procedure for the severely obese population. In general, laparoscopic bariatric procedures are preferred over open bariatric procedures, due to lower early postoperative morbidity and mortality.
  o Preoperative evaluation must include a comprehensive medical history, psychosocial history, physical examination and appropriate laboratory testing to assess surgical risk.
  o The medical necessity for bariatric surgery should be documented.
  o Because informed consent is a dynamic process, there should be a thorough discussion with the patient regarding the risks and benefits, procedural options, choices of surgeon and medical institution, and the need for long-term follow-up and vitamin supplementation, (including costs required to maintain appropriate follow-up).
  o Preoperative weight loss is encouraged as it can reduce liver volume and may help improve the technical aspects of surgery in patients with an enlarged liver or fatty liver disease. Preoperative weight loss or medical nutritional therapy may improve co-morbidities in selected cases, such as reasonable preoperative glycemic targets.
  o Candidates for bariatric surgery should avoid pregnancy preoperatively, and for 12 – 18 months postoperatively.

Policy updates:

For the September 2014 update, we included two meta-analyses and one systematic review. The results of both meta-analyses suggest bariatric surgery is more effective than non-surgical treatment of type 2
diabetes and the control of metabolic syndrome, in the short term. High-quality RCTs with large sample sizes and long follow-up periods are needed to provide more reliable evidence (Li 2013, Gloy 2013). A systematic review by Cirocchi (2013) found insufficient evidence of additional benefit of using robotic technology in bariatric surgery. The results of these analyses do not alter the initial policy.

For the September 2015 update, we identified no new information that would materially change the initial policy.

In 2016, we added two systematic reviews/meta-analyses and three evidence-based professional guidelines for this policy. The new information addresses the evolving role EBTs in obesity management and the presurgical psychosocial evaluation of bariatric surgical candidates.

FDA has approved two EBT devices for use in the United States: The ReShape Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, California) and the Orbera IGB (Apollo Endosurgery, Inc., Austin, Texas) (FDA 2016a and 2016b). Both IGBs are approved as a temporary aid (6 months) for obese patients who have had unsatisfactory results in their clinical treatment for obesity and for super obese patients with higher surgical risk. They are intended to reduce gastric capacity, cause satiety and make it easier for patients to take smaller amounts of food. FDA cited pivotal trial evidence that IGB was safe with rare serious complications and provided statistically significant, greater short-term weight loss than diet alone.

The ASGE and ASMBS confirmed the IGB as an effective tool for short-term weight loss (Abu Dayyeh 2015, ASMBS 2015). The rationale for use is to provide a therapeutic option for patients who either: 1) may meet medical necessity for bariatric surgery but choose not to have surgery, or; 2) may not qualify as surgical candidates on the basis of existing criteria or surgeon assessment. Such devices should be considered adjunctive therapy and complement current obesity therapy options (Abu Dayyeh 2015, ASMBS 2015). However, data on the durability of the results are lacking, and the benefit of such temporary weight reduction is unclear.

Results of a recent meta-analysis indicate severely obese patients with depression may gain psychological benefits in addition to the physical benefits already associated with surgery (Dawes 2016). An ASMBS guideline statement reinforced the importance of psychosocial evaluation in the multidisciplinary treatment of the bariatric patient (Sogg 2016). Central to this is identifying factors that may pose challenges to optimal surgical outcome and providing recommendations to the patient and bariatric team on how to address these issues. The new information would not alter the original policy; therefore no changes are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Dawes (2016)</td>
<td>Key points:</td>
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<tr>
<td>Mental health conditions and bariatric surgery</td>
<td>- Systematic review and meta-analysis of 59 studies (65,363 total patients) reporting on prevalence of preoperative mental health conditions and 27 studies (50,182 total patients) reporting on associations between preoperative mental health conditions and postoperative outcomes.</td>
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<td></td>
<td>- Among patients seeking and undergoing bariatric surgery, most common mental health conditions were depression (19%, 95% confidence interval [CI] 14% to 25%) and binge eating disorder (17%, 95% CI 13% to 21%).</td>
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| Abu Dayyeh (2015) for the ASGE | • Unclear association between preoperative mental health conditions and postoperative weight loss.  
• Bariatric surgery was consistently associated with postoperative decreases in the prevalence of depression (7 studies; 8%-74% decrease) and the severity of depressive symptoms (6 studies; 40%-70% decrease), but inconclusive causal relationship. |
| Endoscopic bariatric therapies (EBT) (Orbera and EndoBarrier) | **Key points:**  
• Systematic review of 82 studies and meta-analysis of 17 studies (1,683 total patients) to assess performance based on ASGE Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) efficacy thresholds for clinical adoption.  
• Orbera IGB meets PIVI thresholds for both primary and nonprimary bridge obesity therapy (mean %EWL = 25% at 1 year).  
• EndoBarrier not FDA-approved.  
• EBT should be performed as part of a comprehensive, multidisciplinary treatment program by providers appropriately trained and skilled in EBT techniques and technologies. |
| Li (2013)                      | **Key points:**  
• Meta-analysis of five RCTs (196 total patients in LRYGB group, 200 in LSG group).  
• Overall quality: moderate to high.  
• LRYGB had a higher remission rate of type 2 diabetes, greater weight loss and lower low-density lipoprotein, triglycerides, homeostasis model assessment index and insulin levels.  
• No difference in the reoperation rate between groups.  
• LRYGB had higher incidence of complications; more effective than LSG for treatment of type 2 diabetes and control of metabolic syndrome in the short term (< 3 yrs).  
• Longer follow-up data are needed. |
| Gloy (2013)                    | **Key points:**  
• Meta-analysis of 11 RCTs (796 total patients) with BMI mostly > 40.  
• Overall quality: moderate to high, but small studies.  
• Greater body weight loss and higher remission rates of type 2 diabetes and metabolic syndrome with bariatric surgery up to two years of follow-up. |
| Cirocchi (2013)                | **Key points:**  
• Systematic review of one RCT, nine clinical controlled trials (CCT) and 12 case series.  
• Overall quality: low to moderate; small sample size with moderate to high risk of bias.  
• Insufficient evidence to support the superiority of robotic surgery in complex cases; may facilitate some of the surgical steps. |
| Sjostrom (2013)                | **Key points:**  
• Long-term, prospective, match-controlled trial of 2,010 subjects (BMI ≥ 34 kg/m² in men, ≥ 38 kg/m² in women) who underwent bariatric surgery (GBP [13%], banding [19%] and VBG [68%]) and 2,037 contemporaneously matched control subjects receiving usual care; follow-up periods varied from 10 to 20 years.  
• Incidence of type 2 diabetes: no significant differences among surgical types.  
• Bariatric surgery associated with a long-term reduction in overall mortality v. usual care (adjusted hazard ratio [HR] = 0.71, 95% CI 0.54 to 0.92; P = 0.01); decreased incidences of diabetes (adjusted HR = 0.17; P < 0.001); myocardial infarction (adjusted HR = 0.71; P = 0.02); stroke (adjusted HR = 0.66; P = 0.008) and cancer (women: adjusted HR = 0.58; P = 0.0008; men: n.s.).  
• Diabetes remission rate increased several fold at two years (adjusted odds ratio [OR] = 8.42; P < 0.001) and 10 years (adjusted OR = 3.45; P < 0.001).  
• Authors’ conclusions: high insulin and/or high glucose at baseline predicted favorable treatment effects; high baseline BMI did not, indicating that current selection criteria for bariatric surgery need to be revised.
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<tr>
<td><strong>FDA (2012)</strong>&lt;br&gt;Impact of Weight Loss from AGB</td>
<td><strong>Key points:</strong>&lt;br&gt;• Systematic review of 17 studies (one RCT, 16 observational studies); used linear or logistic regression modeling. BMI range not reported.&lt;br&gt;• Diabetes: significant correlations between weight loss and improvement/remission.&lt;br&gt;• Dyslipidemia: mixed results.&lt;br&gt;• Hypertension: weight loss not correlated with improvements in hypertension.&lt;br&gt;• Limited data on long-term effectiveness of LAGB.&lt;br&gt;• Limited reporting of post-operative complications and adverse events: most common were band displacements, stomach prolapse/enlargement, wound complications (including infections), port repositioning, band erosions, recurrent band slippage, and tube leaks.</td>
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<tr>
<td><strong>IHE (2012)</strong>&lt;br&gt;Long-term outcomes of bariatric surgery</td>
<td><strong>Key points:</strong>&lt;br&gt;• Systematic review of 31 RCTs (surgery vs. another surgery or standard care [diet/exercise], eight RCTs (laparoscopic surgery vs. open surgery), two systematic reviews (Klarenbach 2010; Colquitt 2009) and three prospective cohort studies, including the SOS study, that reported on long-term outcomes. BMI ≥ 40 kg/m² or a BMI ≥ 35 kg/m² with comorbidity.&lt;br&gt;• Reducing BMI:&lt;br&gt;  o One year follow-up, from most to least efficacious: jejunoileal bypass (JB), loop gastric bypass, mini-gastric bypass, BPD, SG, RYGB, horizontal gastroplasty (HG), VBG, AGB, and standard care (15 RCTs). Small but significantly greater decrease in BMI with laparoscopic surgery v. open surgery (five RCTs).&lt;br&gt;  o At two year follow-up, significantly greater after RYGB than VBG and AGB. No data available for other options (10 RCTs).&lt;br&gt;  o At two to three year follow-up, significantly greater after LAGB than non-surgical treatment (two RCTs).&lt;br&gt;  o At three to five year follow-up, results similar to ranking at one and two years. No difference between open and laparoscopic surgery (seven RCTs).&lt;br&gt;• Other outcomes: compared to RYGB, AGB had shorter hospital stays, fewer late ulcers, lower levels of late stenosis, late hernia and early wound infection, but had more late failed surgeries and higher risks of late slippage or dilatation.&lt;br&gt;• Limited safety data for SG.&lt;br&gt;• Resolution of or improvements in comorbidities (six RCTs); significantly &gt; resolution of diabetes with open v. laparoscopic surgery (one small study); significantly &gt; resolution of dyslipidemia with laparoscopic v. open surgery (one small study).&lt;br&gt;• HrQoL: Various measures used across studies. At one year follow-up, no significant differences between AGB and RYGB. Limited data showed improved physical functioning, social functioning and mental health with laparoscopic v. open surgery, better QoL with RYGB v. VBG, but no difference between mini-gastric bypass v. RYGB.&lt;br&gt;• Mortality: similar results at five years across any pair of surgical intervention (23 RCTs); at 10 year follow-up, improved with bariatric surgery v. conventional treatment. Unknown if survival effect of bariatric surgery is explained by weight loss or by other beneficial effects of the surgical procedures.</td>
</tr>
<tr>
<td><strong>BCBSA TEC (2012a)</strong>&lt;br&gt;Bariatric surgery in patients with diabetes and BMI &lt; 35 kg/m²</td>
<td><strong>Key points:</strong>&lt;br&gt;• Systematic review of one RCT and 15 case series of GBP, SG, ileal interposition, gastric banding, BPD, duodenal-jejunal exclusion.&lt;br&gt;• Diabetes remission rates at ≥ 1 year follow-up (nine total studies): between 48% and 100% for GBP, 93% with gastric bypass, 47% for sleeve gastrectomy.&lt;br&gt;• Insufficient evidence for all other bariatric procedures.</td>
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</table>
| **BCBSA TEC (2012b)** | **Key points:**<br>• Systematic review of one small RCT, one nonrandomized comparative database study and five
## Citation, Methods, Recommendations

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</table>
| LAGB in persons with BMI < 35 kg/m² with weight-related co-morbidity | case series.  
- Overall quality: moderate for weight loss and low for all other outcomes, including mortality, weight-related comorbidities and quality of life.  
- At two years, excess weight loss significantly greater for LAGB than medical programs (87.2% vs. 21.8%, p < 0.001); decrease in BMI significantly greater for the LAGB group (-7.3 vs. -2.0, p < 0.001).  
- Short-term complication rate is low, but long-term complication rate is higher and not well defined, particularly for the population of patients with non-morbid obesity.  
- The effect of weight loss on health outcomes is unclear. Advantages of LAGB v. established alternatives in non-morbidly obese patients inconclusive. |
| Picot (2012) Weight loss surgery for mild to moderate obesity | Key points:  
- Systematic review of two RCTs and cost-effectiveness analysis.  
- Overall quality: low to moderate. Limited length of follow-up and modest size of RCTs.  
- Class I BMI 30 to 34.99 or Class II BMI 35 to 39.99  
- Statistically significant benefit from LAGB v. non-surgical comparator for weight loss and obesity-related comorbidity.  
- Both interventions associated with adverse events.  
- Maintenance of benefits over longer period unclear. Adverse events possibly underestimated. |
| Cost-effectiveness analyses |  |
| Benaroch-Gampel (2012) Cholecystectomy during RYGB for morbid obesity | Key points:  
- Decision model to evaluate cost-effectiveness of current strategies: routine concurrent cholecystectomy, RYGB alone with or without postoperative ursodiol therapy, and selective cholecystectomy based on preoperative ultrasonography (US).  
- Most cost-effective strategy was RYGB alone without pre-op US with an average cost (over RYGB costs) of $537 per patient, followed by RYGB with concurrent cholecystectomy and selective cholecystectomy based on pre-op US.  
- Recommend against routine cholecystectomy during RYGB in asymptomatic patients. |
| Padwal (2011) Bariatric surgery for severe obesity | Key points:  
- Systematic review of seven small RCTs of clinical and economic evidence.  
- Procedure-specific differences in efficacy and risks exist.  
- Higher surgical volumes associated with better outcomes.  
- Bariatric surgery more efficacious vs. non-surgical care in reducing weight, with acceptable cost-effectiveness.  
- Surgery resulted in long-term incremental cost-utility ratios of < $1,000 – $40,000 (2009 USD) per quality-adjusted life year (QALY) v. non-surgical treatment.  
- No definitive conclusions regarding the relative cost-effectiveness, but bariatric surgery appears favorable in patients with type 2 diabetes. |
| Picot (2012) Weight loss surgery for mild to moderate obesity | Key points:  
- Conclusions: at willingness to pay thresholds of £20,000 per QALY and £30,000 per QALY, bariatric surgery appears to be clinically effective and cost-effective for people with class I or II obesity and type 2 diabetes, but less likely to be cost-effective for people with class I obesity only. |

## Glossary
ASGE Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) efficacy thresholds —
Criteria that define a threshold of efficacy balanced with the risks of endoscopic bariatric therapies (EBTs):

EBT as primary obesity intervention with BMI >35 kg/m$^2$ should achieve ≥ mean 25% EWL measured at 12 months and 15% statistically significant mean EWL difference between a “primary” EBT and control groups.  
EBT as non-primary obesity intervention (e.g., early intervention, bridging, or metabolic therapy) should achieve ≥ 5% of the total body weight lost.  
≤ 5% incidence of serious adverse events.  
If low-risk EBT has a significant impact on ≥ 1 obesity-related comorbidities, the threshold for intervention may extend to individuals with BMI 30-35 kg/m$^2$.

Body mass index (BMI) — Calculated as weight (kg)/height squared (m$^2$) or weight [pounds]/height squared [inches$^2$]) x 703. Used to classify overweight and obesity, estimate relative risk of disease compared to normal weight, monitor weight loss and gauge therapeutic efficacy (NHLBI 1998):

- Overweight = BMI 25 – 29.9 kg/m$^2$.
- Obese = BMI > 30 kg/m$^2$.
- Clinically severe or morbid obesity = BMI ≥ 40 kg/m$^2$ or a BMI 35 – 39.9 kg/m$^2$ with comorbidies.

Dumping syndrome — Occurs when a large amount of undigested food passes rapidly from the stomach into the small intestine and is characterized by abdominal pain, nausea, vomiting and weakness.

Duodenal-jejunal bypass liner, endoscopic — An endoscopically placed and removable intestinal liner.  
As an example, the EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Lexington, MA) is described as a non-surgical, physical barrier that enables food to bypass portions of the intestine. This device is proposed for bariatric preoperative weight loss, but has not been FDA-approved.

Duodenum — The shortest segment and first part of the small intestine, which receives partially digested food from the stomach and begins the absorption of nutrients.

Fobi-Pouch — See Silastic ring vertical gastric bypass.

Gastrectomy — Surgical removal of all or part of the stomach.

Gastric banding — Uses an adjustable band placed around the stomach near its upper end, creating a small pouch and a narrow passage into the larger remainder of the stomach. Gastric banding avoids the problems associated with malabsorptive techniques and is technically reversible.

Gastric bypass — Combines the creation of a small stomach pouch to restrict food intake, and construction of a bypass of the duodenum and other segments of the small intestine to produce malabsorption.

Gastroplasty — Also referred to as stomach stapling. Involves the stapling of the upper portion of the stomach horizontally. A small opening is left for food to pass through to the lower portion. The outlet of the pouch is restricted by a band, which slows emptying, allowing the person to feel full after only a few bites of food.
**Ileum** — The final and longest segment of the small intestine. It is specifically responsible for the absorption of vitamin B12 and the reabsorption of conjugated bile salts.

**Intragastric balloon (IGB)** — Allows the reduction of the gastric reservoir capacity, causing a premature sensation of satiety that facilitates the consumption of smaller amounts of food. Used as a temporary aid for obese patients who have had unsatisfactory results in their clinical treatment for obesity, and for super-obese patients with higher surgical risk.

**Jejunoileal bypass** — The proximal jejunum is joined to the distal ileum, bypassing a large segment of the small bowel.

**Jejunum** — The middle part of the small intestine, connecting the duodenum and the ileum.

**Loop gastric bypass** — Involves the creation of a gastric pouch in the shape of a tube, by dividing the stomach at the junction of the body and the antrum, parallel to the lesser curve.

**Mini-gastric bypass** — Is performed laparoscopically and is similar to the RYGB technique except that, after the division of the stomach, a jejunal loop is created and anastomosed to the gastric pouch.

**Natural orifice transluminal endoscopic surgery (NOTES)** — Also referred to as endoscopic (oral) assisted, endoluminal or transoral incisionless surgery. Involves the use of natural orifice access (e.g., mouth, anus) to perform a surgical procedure that potentially reduces or eliminates the trauma of access incisions.

**Restorative obesity surgery, endoluminal (ROSE)** — An endoscopic–assisted procedure that is being investigated for the treatment of weight regain following gastric bypass surgery, which is caused by a gradual expansion of the gastric pouch. The stomach is accessed orally via an endoscope and the stomach pouch is reduced in size, using a device such as the StomaphyX™ endoluminal fastener and delivery system (EndoGastric Solutions, Inc., Redmond, WA).

**Roux-en-Y gastric bypass (RYGB)** — The most commonly performed gastric bypass procedure. A small stomach pouch is created by stapling or by vertical banding to restrict food intake.

**Sleeve gastrectomy** — Also known as partial or vertical gastrectomy, is a restrictive procedure involving resection of the greater curvature of the stomach. May be used as the first procedure in a staged surgical approach or as a stand-alone procedure. Can be open or laparoscopic, but is not reversible.

**Silastic® ring vertical gastric bypass** — Involves a small (less than 25 ml) vertical banded pouch, a Silastic® ring around the stomach creating a stoma, and a gastroenterostomy to a Roux-en-Y limb.

**Transoral gastroplasty** — Also known as vertical sutured gastroplasty or endoluminal vertical. Involves the use of endoscopically guided staplers that create a stapled restrictive pouch along the lesser curvature of the stomach.

**Vertical banded gastroplasty (VBG)** — A restrictive procedure that uses both a band and staples to create a small stomach pouch. The pouch limits the amount of food that can be eaten at one time and slows passage of the food into the remainder of the stomach and gastrointestinal tract.
References

Professional society guidelines/others:


Peer-reviewed references:


Systematic Literature Review on the Impact of Weight Loss from Adjustable Gastric Banding on Diabetes, Hypertension, and Dyslipidemia. 2012. FDA website. 


**Clinical trials:**

Searched ClinicalTrials.gov on August 8, 2016 using terms: bariatric surgery | Open Studies | Adult, Senior | United States. 10 studies found, seven relevant.


Randomized Controlled Trial of Laparoscopic Gastric Bypass Plus Omentectomy Versus Laparoscopic Gastric Bypass Alone in Improving Diabetic Indices. ClinicalTrials.gov website. 


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<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>
</tr>
<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 (eg, 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>
</tr>
<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>
</tr>
<tr>
<td>43774</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components.</td>
</tr>
<tr>
<td>43775</td>
<td>Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)</td>
</tr>
<tr>
<td>43842</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty.</td>
</tr>
<tr>
<td>43843</td>
<td>Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty.</td>
</tr>
<tr>
<td>43845</td>
<td>Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoleiostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch).</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>43847</td>
<td>Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption.</td>
</tr>
<tr>
<td>CPT Code</td>
<td>Description</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>
</tr>
<tr>
<td>43886</td>
<td>Gastric restrictive procedure, open; revision of subcutaneous port component only.</td>
</tr>
<tr>
<td>43887</td>
<td>Gastric restrictive procedure, open; removal of subcutaneous port component only.</td>
</tr>
<tr>
<td>43888</td>
<td>Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only.</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E66.01</td>
<td>Morbid (severe) obesity due to excess calories.</td>
</tr>
<tr>
<td>E66.09</td>
<td>Other obesity due to excess calories.</td>
</tr>
<tr>
<td>E66.1</td>
<td>Drug-induced obesity.</td>
</tr>
<tr>
<td>E66.8</td>
<td>Other obesity.</td>
</tr>
<tr>
<td>E66.9</td>
<td>Obesity, unspecified.</td>
</tr>
<tr>
<td>K95.01</td>
<td>Infection due to gastric band procedure.</td>
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<tr>
<td>K95.09</td>
<td>Other complications of gastric band procedure.</td>
</tr>
<tr>
<td>K95.81</td>
<td>Infection due to other bariatric procedure.</td>
</tr>
<tr>
<td>K95.89</td>
<td>Other complications of other bariatric procedure.</td>
</tr>
<tr>
<td>Z46.51</td>
<td>Encounter for fitting and adjustment of gastric lap band</td>
</tr>
<tr>
<td>Z68.35</td>
<td>Body mass index (BMI) 35.0-35.9, adult.</td>
</tr>
<tr>
<td>Z68.36</td>
<td>Body mass index (BMI) 36.0-36.9, adult.</td>
</tr>
<tr>
<td>Z68.37</td>
<td>Body mass index (BMI) 37.0-37.9, adult.</td>
</tr>
<tr>
<td>Z68.38</td>
<td>Body mass index (BMI) 38.0-38.9, adult.</td>
</tr>
<tr>
<td>Z68.39</td>
<td>Body mass index (BMI) 39.0-39.9, adult.</td>
</tr>
<tr>
<td>Z68.41</td>
<td>Body mass index (BMI) 40.0-44.9, adult.</td>
</tr>
<tr>
<td>Z68.42</td>
<td>Body mass index (BMI) 45.0-49.9, adult.</td>
</tr>
<tr>
<td>Z68.43</td>
<td>Body mass index (BMI) 50-59.9, adult.</td>
</tr>
<tr>
<td>Z68.44</td>
<td>Body mass index (BMI) 60.0-69.9, adult.</td>
</tr>
<tr>
<td>Z68.45</td>
<td>Body mass index (BMI) 70 or greater, adult.</td>
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<tr>
<td>Z9884</td>
<td>Bariatric Surgery Status</td>
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<tr>
<th>HCPCS Level II</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2083</td>
<td>Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline</td>
</tr>
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