Clinical Policy Title: Bariatric surgery for adults

Clinical Policy Number: CCP.1090

Effective Date:	**March 1, 2014**
Initial Review Date:	October 16, 2013
Most Recent Review Date:	August 30, 2018
Next Review Date:	September 2019

Policy contains:

- Bariatric surgery.
- Metabolic surgery.
- Obesity.
- Diabetes.

Related policies:

CCP.1054	Bariatric surgery for children and adolescents
CCP.1184	Cosmetic, plastic, and scar revision surgery
CCP.1061	Treatment for obstructive sleep apnea in adults
CCP.1195	Gastric electrical stimulation

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Coverage policy

AmeriHealth Caritas considers the use of bariatric surgery in adults to be clinically proven and, therefore, medically necessary when all of the following criteria are met (American Diabetes Association, 2018; American Society for Metabolic and Bariatric Surgery, 2013; Chalasani, 2012):

- Adult ages 18 years or older.
- Either:
  - Body mass index ≥ 40 kg/m^2 for at least the last two years prior to surgery.
  - Body mass index ≥ 35 kg/m^2 with at least one clinically significant obesity-related comorbidity, including type 2 diabetes, for at least the last two years prior to surgery.
  - Body mass index 30.0 to 34.9 kg/m^2 (27.5 kg/m^2 to 32.4 kg/m^2 in Asian Americans) in persons with type 2 diabetes whose hyperglycemia is inadequately controlled

(e.g., glycated hemoglobin A1C [or HbA1C] > 7 percent for most nonpregnant adults or individual target goals based on diabetes management needs and personal and lifestyle preferences) despite optimal treatment with either oral or injectable medications, and other cardiovascular risk factors are present (American Diabetes Association, 2018; Rubino, 2016).

- An acceptable operative risk is present.
- 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 (Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program, 2014).
- 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:
  - Active drug abuse.
  - Active suicidal ideation.
  - Borderline personality disorder.
  - Schizophrenia.
  - Psychotic disorder.
  - Uncontrolled depression.
  - Defined non-compliance with previous medical care.

AmeriHealth Caritas considers the following procedures covered services when the above medical necessity criteria are met (Institute of Health Economics, 2012; U.S. Food and Drug Administration, 2012):

- Open or laparoscopic Roux-en-Y gastric bypass (CPT codes 43644, 43645, 43846, 43847).
- Laparoscopic adjustable silicone gastric banding (CPT 43770).
- Open or laparoscopic sleeve gastrectomy 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).
- Open or laparoscopic vertical banded gastroplasty (CPT code 43842).
- 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.
- 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.
- Repair of a hiatal hernia during bariatric surgery for a preoperative diagnosis of hiatal hernia with clinical indications for surgical repair.

AmeriHealth Caritas considers surgery to correct complications that occur following the primary bariatric procedure (e.g., obstruction, stricture, erosion, or band slippage that cannot be corrected with band manipulation or adjustments) to be medically necessary.

AmeriHealth Caritas considers revision of a primary bariatric surgery procedure to be medically necessary when **all** of the following criteria are met:

- The member met the medical necessity criteria for his or her initial bariatric surgery.
- The member has been cleared for the revision procedure by a licensed mental health professional provider for presence of any mental health or substance abuse conditions, emotional readiness and ability to make and sustain lifestyle changes, and adequacy of the member's support system.
- The member has been compliant with a prescribed nutrition and exercise program following the primary bariatric procedure.
- For either indication:
  - Conversion to a sleeve gastrectomy or Roux-en-Y gastric bypass for members who failed 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 primary surgery.
  - Conversion from an adjustable band to a sleeve gastrectomy or Roux-en-Y gastric bypass for complications that cannot be corrected with band manipulation, adjustments, or replacement.

Limitations:

All other forms of bariatric surgery in adults are not medically necessary, including, but not limited to the mini-gastric bypass procedure (also called single anastomosis gastric bypass or omega gastric bypass) (Wang, 2017) or endoscopic bariatric therapies (e.g., intragastric balloons or duodenal-jejunal bypass liners) for temporary weight reduction (Jirapinyo, 2018; Thompson, 2017).

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 (Benarroch-Gampel, 2012).

The use of bariatric surgery in members with a body mass index < 30 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.

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.

Repair of a hiatal hernia is not medically necessary when diagnosed at the time of bariatric surgery, or in the absence of preoperative clinical indications for surgical repair.

Routine liver biopsy during obesity surgery is not medically necessary in the absence of preoperative clinical suspicion of liver disease.

For Medicare members only:

AmeriHealth Caritas considers bariatric surgery to be clinically proven and, therefore, medically necessary when performed in accordance with: National Coverage Determination 100.1; Local Coverage Articles A52447, A53026, A53028, A53444, and A54923; and Local Coverage Determinations L35022, L34576, and L33411.

Medical necessity criteria:

- Body mass index > 35 kg/m^2.
- 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 Roux-en-Y gastric bypass.
- Open and laparoscopic biliopancreatic diversion with duodenal switch.
- Laparoscopic adjustable gastric banding.
- Laparoscopic sleeve gastrectomy performed on and after June 27, 2012. Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy for the treatment of co-morbid conditions related to obesity.

The following services are not medically necessary:

- Open adjustable gastric banding.
- Open and laparoscopic sleeve gastrectomy (prior to June 27, 2012).
- Open and laparoscopic vertical banded gastroplasty.
- Gastric balloon.
- Other bypass procedures (L33411, L35022):

- Intestinal Bypass.
- Mini-gastric bypass.
- Silastic ring vertical gastric bypass (Fobi pouch).

Alternative covered services:

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

Background

Overweight (body mass index 25 – 29.9 kg/m^2) and obesity (body mass index > 30 kg/m^2) 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 (Centers for Disease Control and Prevention, 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).

According to the National Heart, Lung and Blood Institute (1998), the health risks associated with being overweight or obese include mechanical arthropathy (weight-related degenerative joint disease), metabolic dysfunction, cardiovascular disease, severe obstructive sleep apnea, obesity-related pulmonary hypertension, and increases in all-cause mortality. Weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease, and improves obesity-associated gonadal dysfunction and thyroid function (Escobar-Morreale, 2017; Guan, 2017; Sjostrom, 2013; Vest, 2012).

The National Heart, Lung and Blood Institute (1998) 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. Interest in offering bariatric surgery to some people with a body mass index 30 to 35 kg/m^2 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 (Dixon, 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.

Currently, the U.S. Food and Drug Administration (2018) has approved four devices for treating obesity:

- The LAP-BAND® Adjustable Gastric Banding System (Apollo Endosurgery, Inc., Austin, Texas) is the only adjustable gastric banding device approved for marketing in the United States.

The LAP-BAND is approved for patients with a body mass index ≥ 40 kg/m^2 or a body mass index 30 – 39.9 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 lifelong changes in their eating habits. The adjustable gastric banding procedure is reversible.

- Three endoscopic bariatric therapies (specifically intragastric balloons) are approved as a temporary aid (six months) for obese patients who have failed to lose weight through diet and exercise 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. They are:
  - Orbera® intragastric balloon (Apollo Endosurgery, Inc., Austin, Texas).
  - ReShape® Integrated Dual Balloon System (ReShape Medical Inc., San Clemente, California).
  - Obalon® Balloon System (Obalon Therapeutics, Inc., Carlsbad, California).
- One gastric emptying system (AspireAssist®, Aspire Bariatrics, Inc., King of Prussia, Pennsylvania) is approved for adults ≥ 22 years old with a body mass index of 35.0 to 55.0 kg/m^2 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist tube is inserted between the stomach and outside of abdomen to drain food after eating. It is intended for long-term use in conjunction with lifestyle therapy (to help patients develop healthier eating habits and reduce caloric intake) and continuous medical monitoring.

Searches

AmeriHealth Caritas 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.

We conducted searches on July 11, 2018. 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

More than 90 percent of bariatric procedures performed in the United States use a laparoscopic approach (Nguyen, 2011). The most commonly used procedures are laparoscopic Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy, open Roux-en-Y gastric bypass, and laparoscopic adjustable gastric band (Nguyen, 2013; Habermann, 2012). As a restrictive procedure, gastric banding, specifically laparoscopic adjustable gastric banding, has largely replaced gastroplasty and vertical banded gastroplasty. Gastric banding avoids the problems associated with malabsorptive techniques. The few available large randomized clinical trials 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.

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 thrombolic 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. Contraindications to adjustable gastric banding procedures include inflammatory diseases of the gastrointestinal tract, severe cardiopulmonary disease, portal hypertension, and cirrhosis of the liver.

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.

For patients with a body mass index at least 40 kg/m^2 or a body mass index at least 35 kg/m^2 with one or more serious weight related co-morbidities (Institute of Health Economics, 2012; Paswal, 2012; U.S. Food and Drug Administration, 2012):

- 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 adjustable gastric banding 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 body mass index 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 (Picot, 2012).

There is insufficient evidence to support the routine use of concurrent cholecystectomy during Roux-en-Y gastric bypass performed for severe obesity, particularly in asymptomatic patients (Benarroch-Gampel, 2012).

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 established alternatives. These adapted procedures include, but are not limited to (Dixon, 2012):

- Fobi-Pouch.
- Intragastric balloons.
- 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, California) and a duodenal-jejunal bypass liner using the EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Lexington, Massachusetts), have not been U.S. Food and Drug Administration-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 body mass index >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 body mass index of 30 to 35 kg/m^2, there is currently insufficient evidence to generally recommend surgery in patients with body mass index < 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 or nonalcoholic steatohepatitis, but without established cirrhosis.
  - The type, safety, and efficacy of foregut bariatric surgery in otherwise eligible obese individuals with established cirrhosis due to non-alcoholic fatty liver disease are not established.
  - It is premature to consider foregut bariatric surgery as an established option to specifically treat nonalcoholic steatohepatitis.
  - Bariatric surgery may be considered in patients who fail lifestyle interventions and who have a body mass index of ≥ 35 kg/m^2 with comorbidities, such as poorly controlled diabetes, who are expected to improve with weight reduction.
- American Heart Association (Poirier, 2011):
  - 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.
  - Care by an interdisciplinary team is imperative for best management.
  - 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):
  - Patients with either a body mass index ≥ 40 kg/m^2 without coexisting medical problems or a body mass index ≥ 35 kg/m^2 and one or more severe obesity-related co-morbidities and acceptable surgical risk should be eligible for one of the procedures.
  - Patients with body mass index of 30 – 34.9 kg/m^2 with type 2 diabetes or metabolic syndrome may be offered a bariatric procedure, although current evidence is limited.

- There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of body mass index criteria.
- 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.
- 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.
- Preoperative evaluation must include a comprehensive medical history, psychosocial history, physical examination, and appropriate laboratory testing to assess surgical risk.
- The medical necessity for bariatric surgery should be documented.
- 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).
- 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.
- Candidates for bariatric surgery should avoid pregnancy preoperatively, and for 12 to 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 randomized controlled trials with large sample sizes and long follow-up periods are needed to provide more reliable evidence (Gloy, 2013; Li, 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 of endoscopic bariatric

treatments in obesity management and the presurgical psychosocial evaluation of bariatric surgical candidates. The American Society for Gastrointestinal Endoscopy (Abu Dayyeh, 2015) and American Society for Metabolic and Bariatric Surgery (2015) confirmed the intragastric balloon as an effective adjunctive tool for short-term weight loss. 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. 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 American Society for Metabolic and Bariatric Surgery 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.

In 2017, new evidence for the safety and effectiveness of intragastric balloons as a temporary weight loss option and the AspireAssist gastric emptying system is encouraging but still insufficient to change policy recommendations at this time (Abu Dayyeh, 2017; Thompson, 2017). There is sufficient evidence from randomized controlled trials demonstrating consistent, superior efficacy of bariatric/metabolic surgery (primarily Roux-en-Y gastric bypass and sleeve gastrectomy) for reducing weight and lowering glycemia compared with a variety of medical/ lifestyle interventions in persons with type 2 diabetes and a body mass index < 35 kg/m^2 (range 25 to 35 kg/m^2) (Cohen, 2017).

International diabetes organizations (American Diabetes Association, 2018; Rubino, 2016) support extending metabolic surgery as a treatment option to persons with a body mass index 30.0 to 34.9 kg/m^2 whose hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications, who have cardiovascular risk factors, and who are an acceptable surgical risk. The American Society for Metabolic and Bariatric Surgery (2012) also supports bariatric surgery for this patient cohort, stating that: *"The existing cut-off of body mass index which excludes those with Class 1 obesity was established arbitrarily nearly 20 years ago. There is no current justification on grounds of evidence of clinical effectiveness, cost-effectiveness, ethics, or equity that this group should be excluded from life-saving treatment."* The policy limitation for this obesity group was modified accordingly.

In 2018, we added a systematic review (Cohen, 2017) on the effectiveness of Rou-en-Y gastric bypass in patients with Class 1 obesity and type 2 diabetes mellitus, a systematic review (Popov, 2017) on the impact of intragastric balloons on obesity-related co-morbidities, and a systematic review (Wang, 2017) comparing the safety and effectiveness of laparoscopic mini-gastric bypass and laparoscopic sleeve gastrectomy procedures. The results are consistent with previous findings, and no policy changes are warranted.

Policy ID changed from CP# 08.03.02 to CCP.1090.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Abu Dayyeh (2017) Best practice advice: endoscopic bariatric therapies	**Key points:** • Consider endoscopic bariatric therapies in patients with obesity who have been unsuccessful in losing or maintaining weight loss with lifestyle interventions. • Consider endoscopic bariatric therapies in patients with severe obesity as a bridge to traditional bariatric surgery or as a bridge to allow unrelated interventions that are unable to be performed because of weight limits (i.e., orthopedic surgery, organ transplantation). • Use endoscopic bariatric therapies as part of a structured weight loss program that includes dietary intervention, exercise therapy, and behavior modification, in both the active weight loss phase and the long-term maintenance phase.
Cohen (2017) Roux-en-Y gastric bypass in type 2 diabetes patients with mild obesity	**Key points:** • Systematic review and meta-analysis of five randomized controlled trials comparing Roux-en-Y gastric bypass to medical care in persons with a body mass index 30 - 40 kg/m^2; 43.3% < 35 kg/m^2. • The studies included a larger proportion of women, and the average time of duration with type 2 diabetes ranged between six and 10 years. • Despite randomization, the baseline demographics such as age, HbA1C, and duration of diabetes were often less favorable in the surgical group. • At the longest follow-up, Roux-en-Y gastric bypass significantly improved: total type 2 remission odds ratio (OR) 17.48 (95% confidence interval [CI] 4.28 to 71.35); partial type 2 remission OR 20.71 (95% CI 5.16 to 83.12); and HbA1C at longest follow-up in the surgery group (OR - 1.83 (95% CI - 2.14 to - 1.51). • Roux-en-Y gastric bypass improves metabolic outcomes for at least five years in patients with class I obesity.
Popov (2017) The impact of intragastric balloons on obesity-related co-morbidities	**Key points:** • Systematic review and meta-analysis of 10 randomized controlled trials and 30 observational studies (5,668 total subjects). • Overall quality: moderate. • Evidence from randomized controlled trials suggested improvement in most metabolic parameters in subjects receiving intragastric balloon therapy versus conventional non-surgical therapy, reported as mean difference, 95% CI: – Fasting glucose change: -12.7 mg/dl, -21.5 to -4. – Triglycerides: -19 mg/dl, -42 to 3.5. – Waist circumference: -4.1 cm, -6.9 to -1.4. – Diastolic blood pressure: -2.9 mm Hg, -4.1 to -1.8. • The odds ratio for diabetes resolution after intragastric balloon therapy=1.4 (95% CI 1.3 to 1.6). • Serious adverse events=1.3%.

Citation	Content, Methods, Recommendations
Wang (2017) Comparison of safety and effectiveness between laparoscopic mini-gastric bypass and laparoscopic sleeve gastrectomy	**Key points:** • Systematic review of two randomized controlled trials and 12 non-randomized controlled trials (1,998 patients in mini-gastric bypass group, 1,864 patients in sleeve gastrectomy group). • Overall quality: moderate, limited by selection bias, heterogeneous baseline characteristics, small sample sizes. • Compared to sleeve gastrectomy, mini-gastric bypass was associated with: higher 1-year percentage excess weight loss; higher 5-year percentage excess weight loss; higher remission rates for type 2 diabetes mellitus, hypertension, and obstructive sleep apnea; lower rates of osteoarthritis remission, leakage, and overall late complications; higher ulcer rate; lower gastroesophageal reflux disease rate; shorter hospital stay; lower revision rate; but no statistically significant differences in overall complication rates (early complications, bleed, vomiting, and anemia) or operation time. • Due to study limitations, large multicenter randomized controlled trials are needed to compare the short-term and long-term effectiveness and safety of mini-gastric bypass and sleeve gastrectomy.
Dawes (2016) Mental health conditions and bariatric surgery	**Key points:** • 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. • Among patients seeking and undergoing bariatric surgery, most common mental health conditions were depression (19%, 95% CI 14% to 25%) and binge eating disorder (17%, 95% CI 13% to 21%). • Unclear association between preoperative mental health conditions and postoperative weight loss. • Bariatric surgery was consistently associated with postoperative decreases in the prevalence of depression (seven studies; 8% to 74% decrease) and the severity of depressive symptoms (six studies; 40% to 70% decrease), but inconclusive causal relationship.
Rubino (2016) for the 2nd Diabetes Surgery Summit Joint statement by international diabetes organizations	**Key points:** • Numerous randomized controlled trials of mostly short/intermediate duration demonstrate excellent glycemic control and reduced cardiovascular risk factors with metabolic surgery. • Recommend metabolic surgery to treat type 2 diabetes in patients with: – Body mass index ≥40 kg/m^2, regardless of the level of glycemic control or complexity of glucose lowering regimens. – Body mass index ≥35.0 to 39.9 kg/m^2 when hyperglycemia is inadequately controlled by lifestyle and optimal medical therapy. • Consider metabolic surgery to treat type 2 diabetes if body mass index 30.0 to 34.9 kg/m^2 and hyperglycemia is inadequately controlled despite optimal treatment with either oral or injectable medications. • Body mass index thresholds should be reduced by 2.5 kg/m^2 for Asian patients.
Abu Dayyeh (2015) for the American Society for Gastrointestinal	**Key points:** • Systematic review of 82 studies and meta-analysis of 17 studies (1,683 total patients) to assess performance based on American Society for Gastrointestinal Endoscopy Preservation and Incorporation of Valuable endoscopic Innovations efficacy thresholds for clinical adoption.

Citation	Content, Methods, Recommendations
Endoscopy Endoscopic bariatric therapies (Orbera and EndoBarrier)	• Orbera intragastric balloon meets efficacy thresholds for both primary and nonprimary bridge obesity therapy (mean percentage excess weight loss = 25% at 1 year). • EndoBarrier not U.S. Food and Drug Administration-approved. • Endoscopic bariatric therapies should be performed as part of a comprehensive, multidisciplinary treatment program by providers appropriately trained and skilled in Endoscopic bariatric therapies techniques and technologies.
Cirocchi (2013) Robotic bariatric surgery	**Key points:** • Systematic review of one randomized controlled trial, nine clinical controlled trials, 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.
U.S. Food and Drug Administration (2012) Impact of weight loss from adjustable gastric banding	**Key points:** • Systematic review of 17 studies (one randomized controlled trial, 16 observational studies); used linear or logistic regression modeling. Body mass index range not reported. • Diabetes: significant correlations between weight loss and improvement/remission. • Dyslipidemia: mixed results. • Hypertension: weight loss not correlated with improvements in hypertension. • Limited data on long-term effectiveness of laparoscopic adjustable gastric banding. • 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.
Institute of Health Economics (2012) Long-term outcomes of bariatric surgery	**Key points:** • Systematic review of 31 randomized controlled trials (surgery versus another surgery or standard care [diet/exercise], eight randomized controlled trials (laparoscopic surgery versus open surgery), two systematic reviews (Klarenbach, 2010; Colquitt, 2009) and three prospective cohort studies that reported on long-term outcomes. body mass index ≥ 40 kg/m^2 or a body mass index ≥ 35 kg/m^2 with comorbidity. • Reducing body mass index: – One year follow-up, from most to least efficacious: jejunoileal bypass, loop gastric bypass, mini-gastric bypass, biliopancreatic diversion, sleeve gastrectomy, Roux-en-Y gastric bypass, horizontal gastroplasty, vertical banded gastroplasty, adjustable gastric banding, and standard care (15 randomized controlled trials). Small but significantly greater decrease in body mass index with laparoscopic surgery versus open surgery (five randomized controlled trials). – At two year follow-up, significantly greater after Roux-en-Y gastric bypass than vertical banded gastroplasty and adjustable gastric banding. No data available for other options (10 randomized controlled trials). – At two to three year follow-up, significantly greater after laparoscopic adjustable gastric banding than non-surgical treatment (two randomized controlled trials). – At three to five year follow-up, results similar to ranking at one and two years. No difference between open and laparoscopic surgery (seven randomized controlled trials).

Citation	Content, Methods, Recommendations
	• Other outcomes: compared to Roux-en-Y gastric bypass, adjustable gastric banding 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. • Limited safety data for sleeve gastrectomy. • Resolution of or improvements in comorbidities (six randomized controlled trials); significantly > resolution of diabetes with open versus laparoscopic surgery (one small study); significantly > resolution of dyslipidemia with laparoscopic versus open surgery (one small study). • Health-related quality of life: Various measures used across studies. At one year follow-up, no significant differences between adjustable gastric banding and Roux-en-Y gastric bypass. Limited data showed improved physical functioning, social functioning and mental health with laparoscopic versus open surgery, better health-related quality of life with Roux-en-Y gastric bypass versus vertical banded gastroplasty, but no difference between mini-gastric bypass versus Roux-en-Y gastric bypass. • Mortality: similar results at five years across any pair of surgical intervention (23 randomized controlled trials); at 10 year follow-up, improved with bariatric surgery versus conventional treatment. Unknown if survival effect of bariatric surgery is explained by weight loss or by other beneficial effects of the surgical procedures.

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Centers for Medicare & Medicaid Services National Coverage Determinations:

100.1 Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity.

A53028 Bariatric Surgery Coverage.

A53026 Bariatric Surgery Coverage.

A54923 Bariatric Surgery for Treatment of Co-Morbidities Conditions Related to Morbid Obesity.

A52447 Laparoscopic Sleeve Gastrectomy (LSG) – Medical Policy Article.

A53444 Periodic Adjustment of Gastric Restrictive Device after the Global Period: Coding and Billing Instructions.

Local Coverage Determinations:

L35022 Bariatric Surgical Management of Morbid Obesity.

L34576 Laparoscopic Sleeve Gastrectomy for Severe Obesity.

L33411 Surgical Management of Morbid Obesity.

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.

CPT Code	Description	Comments
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less).	
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption.	
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components).	
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only.	
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only.	
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only.	
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components.	
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)	
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty.	
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty.	
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch).	
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) roux-en-y gastroenterostomy.	
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption.	
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)	
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only.	
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only.	
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only.	

ICD-10 Code	Description	Comments
E66.01	Morbid (severe) obesity due to excess calories.	
E66.09	Other obesity due to excess calories.	
E66.1	Drug-induced obesity .	
E66.8	Other obesity.	
E66.9	Obesity, unspecified.	
K95.01	Infection due to gastric band procedure.	
K95.09	Other complications of gastric band procedure.	
K95.81	Infection due to other bariatric procedure.	
K95.89	Other complications of other bariatric procedure.	
Z46.51	Encounter for fitting and adjustment of gastric lap band	

ICD-10 Code	Description	Comments
Z68.35	Body mass index (body mass index) 35.0-35.9, adult.	
Z68.36	Body mass index (body mass index) 36.0-36.9, adult.	
Z68.37	Body mass index (body mass index) 37.0-37.9, adult.	
Z68.38	Body mass index (body mass index) 38.0-38.9, adult.	
Z68.39	Body mass index (body mass index) 39.0-39.9, adult.	
Z68.41	Body mass index (body mass index) 40.0-44.9, adult.	
Z68.42	Body mass index (body mass index) 45.0-49.9, adult.	
Z68.43	Body mass index (body mass index) 50-59.9 , adult.	
Z68.44	Body mass index (body mass index) 60.0-69.9, adult.	
Z68.45	Body mass index (body mass index) 70 or greater, adult.	
Z98.84	Bariatric Surgery Status	

HCPCS Level II Code	Description	Comments
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline	