Clinical Guideline



Guideline Number: CG008, Ver. 5

Bariatric Surgery (Adults)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates, who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Morbid (clinically severe) obesity is a condition in which body fat accumulates to a level that can cause or inhibit the treatment of life-threatening medical comorbidities. Initial treatment steps include a regimented plan of diet and lifestyle changes, often designed and supervised by a team of healthcare professionals. Morbidly obese patients who have failed traditional treatment methods and are being treated for associated high-risk conditions including diabetes, hypertension, or obstructive sleep apnea, may be candidates for bariatric surgery. Bariatric surgery procedures attempt to reduce fat tissue accumulation through restrictive or malabsorptive approaches and can often be performed as open or laparoscopic surgery. Restrictive surgeries function by decreasing the effective size of the stomach, creating a sensation of early satiety and preventing the patient from intaking large meals. Malabsorptive procedures function by rearranging the flow of food through the digestive system to decrease overall digestion/absorption of calories. Some procedures combine restrictive and malabsorptive approaches. Additionally, a comprehensive post-operative plan of diet, exercise, and behavioral modification is critical in achieving durable weight loss outcomes, where success is defined as reduction in excess body weight by 50% and returning to within 30% of a patient's ideal body weight. Treatment plans and surgical options differ for adults and adolescents [see CG009: Bariatric Surgery (Adolescents)]. Bariatric surgery always requires prior authorization.

Definitions

"Body Mass Index (BMI)" relates body weight to height, defined as body mass divided by body height squared in units of kg/m² and is used to risk-stratify members.

"Class I Obesity" is defined as a BMI of 30 - 34.9.

"Class II Obesity" is defined as a BMI 35 - 39.9.

"Class III Obesity" is defined as a BMI ≥40.

"Bariatric" is a term referring to the treatment of obesity.

"Open Surgery" refers to a procedure where a large incision allows for direct visualization and access to intra-abdominal organs.

"Laparoscopic Surgery" or minimally invasive surgery refers to a procedure often consisting of multiple small incisions allowing the use a small camera (laparoscope) and several thin instruments.

"Bariatric Surgery" is surgery on the stomach and/or intestines to assist with weight loss in patients with severe or extreme obesity (Classes II and III). Bariatric surgery can be done via restrictive procedures, malabsorptive procedures, or a combination of the two.

- "Restrictive Procedures" decrease digestive capacity, promote early satiety, and decrease the speed at which food moves through the digestive system.
 - o "Adjustable Gastric Banding (AGB)" is where an adjustable band is placed around the outside of the stomach and can be tightened or loosened to achieve the desired effect. It functions by decreasing the stomach capacity and limiting the speed at which food can enter the lower part of the stomach. This procedure is often performed laparoscopically. A unique feature of the procedure is that it is reversible through removal of the band. Risks include developing band slippage and/or erosion through stomach wall in 2-5% of cases. Positioning is important and, if incorrect, can be ineffective and cause vomiting. The Lap-Band™ is an example AGB device.
 - o "Sleeve Gastrectomy (SG)" is where the greater curvature of the stomach is resected, resulting in a tube or sleeve-like shape to restrict capacity. This can be performed via open incision or laparoscopically. It can also be combined with malabsorptive surgery in a sequential 2-stage procedure or at a later date if adequate weight loss is not obtained.
- "Malabsorptive Procedures" reduce digestion and absorption of calories through re-arrangement of the digestive system:
 - "Gastric Bypass (Roux-en-Y Gastric Bypass [RYGB])" combines restrictive and malabsorptive features. The stomach is divided into either a horizontal or vertical plane similar to banded gastropathy (restrictive). The Roux-en-Y procedure then takes the small intestine and creates a "Y" shape, where the two legs of the "Y" allow a portion of food to pass through undigested while retaining a limited digestive capacity for the remaining food (malabsorptive). A gastric bypass can be performed via open incision or laparoscopically. Expected weight loss at two years is approximately 70%.
 - "Biliopancreatic Diversion (BPD [Scopinaro Surgery])" was originally proposed to alleviate the metabolic concerns of original bypass procedures. It consists of a subtotal

gastrectomy (similar to sleeve gastrectomy) and diversion of the biliopancreatic secretions. There is a high incidence of vitamin/nutrient deficiency and gallstones, and a prophylactic cholecystectomy is routinely performed at the time of procedure. Duodenal switch is also often performed, which preserves the pylorus, resulting in less metabolic complications. The BPD can be performed via open incision or laparoscopically.

"Repair" refers to a procedure or operation performed to correct and/or treat a complication of a prior surgery.

"Conversion" is when a prior procedure is converted to a new one—for example, when there are complications or inadequate weight loss with the primary surgery. An example is sleeve gastrectomy conversion to Roux-en-Y gastric bypass.

"Revision" refers to a procedure or operation performed due to failure of desired outcome of prior surgery or to reverse/adjust a prior surgery. It does not result in a new procedure, unlike conversion.

Clinical Indications and Coverage

Covered Procedures & Length of Stay

Oscar covers the following procedures and settings for the treatment of morbid obesity in adults (age ≥18) when medical necessity criteria are met:

- Roux-en-Y gastric bypass (<150cm)
 - Open 2 days inpatient admission
 - Laparoscopic 1 day inpatient admission
- Adjustable gastric banding
 - Laparoscopic Ambulatory
- Sleeve gastrectomy
 - Open 1 day inpatient admission
 - Laparoscopic Ambulatory or 1 day inpatient admission
- Biliopancreatic diversion with duodenal switch
 - Open 2 days inpatient admission
 - Laparoscopic 1 day inpatient admission

Length of Stay (LOS) Extensions

Subject to medical necessity review, Oscar may cover extensions for hospital admission under the following circumstances:

- Patients >65 years old
- In the presence of complex comorbidities (COPD, renal disease, heart failure)
- Conversion from laparoscopic to open procedure
- Complications in the peri- or postoperative phases, such as anastomotic leak, thromboembolic disease (DVT or pulmonary embolism), wound infection, bleeding, pneumonia, respiratory failure, evisceration, or splenic injury

• Clear liquid diet not tolerated during the postoperative phase

Criteria for Covered Procedures

Covered procedures are considered medically necessary when ALL of the following criteria are met:

- 1. Informed consent with appropriate explanation of risks, benefits, and alternatives; and
- 2. Adult aged 18 years or older with documentation of:
 - a. Body mass index (BMI) ≥40; or
 - b. BMI greater ≥35 with ONE of the following severe obesity-related comorbidities:
 - i. Clinically significant cardio-pulmonary disease (e.g. severe obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS)); *or*
 - ii. Coronary artery disease, objectively documented via stress test,
 echocardiography, angiography, prior myocardial infarction, or similar; or
 - iii. Objectively documented cardiomyopathy; or
 - iv. Medically refractory hypertension (defined as > 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of 3 antihypertensive agents); *or*
 - v. Type 2 diabetes mellitus.
- 3. Failure to achieve and maintain successful long-term weight loss via non-surgical therapy; and
- 4. Participation and adherence to a clinically supervised weight loss program within 6 months of the planned bariatric surgery to include behavioral and dietary modification and an exercise regimen.
- 5. The proposed bariatric surgery includes a comprehensive pre- and post-operative plan to evaluate nutritional status, overall health, and any specific surgical risks:
 - a. Preoperative evaluation to rule out and treat any other reversible causes of weight gain/obesity, may include routine lab testing, screenings, and risk evaluations such as:
 - Fasting blood glucose, fasting lipid panel, complete blood count (CBC), lipid/kidney function testing (Complete Metabolic Panel), blood typing, coagulation studies (PT/PTT/INR)
 - ii. Nutrient deficiency screening (vitamin B12, iron, folate) and formal nutrition evaluation by a registered dietician or nutritionist
 - iii. Cardiopulmonary risk evaluation to assess as part of standard pre-operative clearance with EKG, Chest X-Ray, and echocardiogram as appropriate based on medical comorbidities
 - iv. GI evaluation H. pylori screening in high-risk populations and assessment for necessity of cholecystectomy concurrent with surgery, if indicated
 - v. Endocrine evaluation Hemoglobin A1c if diabetic, serum TSH if indicated at risk, and appropriate workup of endocrine abnormalities such as Cushing's disease for suspected reversible causes of obesity as part of history and physical
 - vi. Age appropriate cancer screening verified complete and up to date
 - vii. Smoking cessation counseling, if applicable
- 6. Psycho-social behavioral evaluation to determine ability to succeed and adhere to postoperative recommendations and long-term follow up and to identify any major mental health disorders

that would contraindicate surgery and/or negatively impact patient compliance with postoperative follow-up care and adherence to nutrition guidelines.

- a. No current substance abuse has been identified; and
- b. Members who have any of the following conditions MUST have formal, documented preoperative psychological clearance:
 - i. A history of schizophrenia, borderline personality disorder, suicidal ideation, severe depression
 - ii. Who are currently under the care of a psychologist/psychiatrist
 - iii. Who are on psychotropic medications, as necessary in order to exclude members who are unable to provide informed consent or who are unable to comply with the pre- and postoperative regimen

Members with a BMI 30-34.9

A recent joint statement by international diabetes organizations concluded that the current scientific evidence supports a benefit to metabolic surgery in some patients with Class I obesity (BMI 30 - 34.9) who have poorly controlled type 2 diabetes despite optimal medical therapy. However, they also acknowledge continued knowledge limitations related to this population, in particular (a) the relatively modest number of these patients represented in randomized controlled trials to date, (b) the absence of head to head trials comparing the effectiveness of different types of procedures in this population, and (c) the lack of clear definition of what constitutes failure of optimal medical therapy. As a result, Oscar will consider the medical necessity of bariatric surgery in members with a BMI of 30 - 34.9 who continue to have poorly controlled type 2 diabetes despite adherence to optimal medical therapy on a case-by-case basis.

Repair, Replacement, Removal, Revision, or Conversion

- 1. Repair is considered medically necessary when there is documentation of a surgical complication related to the original surgery, including:
 - 1. Fistula
 - 2. Erosion
 - 3. Leakage of suture/staple line
 - 4. Herniated band
 - 5. Obstruction
 - 6. Enlargement of the pouch due to complications of vomiting
 - a. Note: Enlargement of pouch (stretching) is NOT covered if due to overeating, as this is not a surgical complication and is therefore not considered medically necessary.
- 2. Replacement of an adjustable gastric band is considered medically necessary only if there are complications (e.g., port leakage, slippage) that cannot be corrected with band manipulation or adjustments.
- 3. Removal of an adjustable gastric band may be considered medically necessary when recommended by the member's physician.

- 4. Revision of a primary bariatric surgery is considered medically necessary when ALL of the following criteria are met:
 - a. The procedure has failed due to dilated gastrojejunal stoma, dilation of the anastomosis site, or dilation of the gastric pouch; *and*
 - b. The initial surgery successfully resulted in weight loss; and
 - c. The member has been compliant with the postoperative plan of diet, exercise, and behavioral modification.
- 5. Conversion surgery is performed in cases of inadequate weight loss when unrelated to surgical complications.
 - a. Oscar considers conversion of an adjustable gastric band to a sleeve gastrectomy, RYGB or BPD/DS medically necessary if there are complications that cannot be corrected with band manipulation or adjustments.
 - b. Oscar considers conversion to a sleeve gastrectomy, RYGB or BPD/DS medically necessary when ALL of the following criteria are met:
 - i. Meets all medical necessity criteria for bariatric surgery as defined above; and
 - ii. Documented compliance with postoperative plan of diet, exercise, and behavioral modification; *and*
 - iii. A minimum of 2 years following original surgery with:
 - 1. Weight loss of less than 50% of preoperative excess body weight; and
 - 2. Remains >30% over ideal body weight.

Coverage Exclusions

Non-Covered Procedures

Oscar considers the following procedures to be experimental, investigational or unproven as they have either not demonstrated long-term benefit, have unnecessary risks, or have demonstrated inferior outcomes to safer, more appropriate techniques:

- Gastroplasty (stomach stapling)
- Intragastric balloon
- Gastric plication (Laparoscopic)
- Vagal blockade
- Mini gastric bypass/Billroth II
- Aspiration therapy procedures
- Jejunoileal bypass
- BPD without duodenal switch
- >150cm long limb gastric bypass (except for BPD with DS)
- Vertical Banded Gastroplasty (VBG)
- Natural orifice transoral surgery (NOTES)
- Silastic ring (Fobi pouch)
- Open adjustable gastric banding
- Prophylactic mesh placement to prevent incisional hernia after open bariatric surgery

Skin Removal Surgery

Excess skin is common after a successful bariatric surgery. Unless MCG criteria is met, skin removal by abdominoplasty and/or panniculectomy is considered a cosmetic and elective procedure that is not medically necessary by Oscar.

Relative Contraindications

General

- Medically correctable cause of obesity
- Severe or unstable cardiovascular disease
- Severe coagulopathy
- Severe pulmonary disease
- Cirrhosis with portal hypertension
- Ongoing substance abuse or substance abuse in preceding 12 months
- Severe or poorly controlled psychiatric disorder or mental illness
- Medical, psychological, psychosocial, or cognitive condition that prevents adherence to post-op dietary and medical requirements or impairs decision capacity
- Non-compliance with dietary restrictions
- Bulimia nervosa
- Current or planned pregnancy within 12-18 months
- Advanced stage neoplastic disease

Laparoscopic Adjustable Gastric Banding

- Inflammatory bowel disease
- Potential upper GI bleeding such as esophageal or gastric varices
- Congenital or acquired malformations of the GI tract such as stenoses or atresias
- Intra-operative gastric injury during the implantation procedure
- Chronic pancreatitis
- Cirrhosis
- Portal hypertension
- Any infection, bacteremia, or sepsis
- Chronic, long-term use of steroids
- Systemic inflammatory or autoimmune condition such as scleroderma and systemic lupus erythematosus

Malabsorptive Procedures (Roux-en-Y and Biliopancreatic Bypass with Duodenal Switch)

- Inflammatory bowel disease
- Critical need to maintain drug levels, such as in seizure or psychiatric illness, where malabsorption or changes in drug metabolism may result in serious consequences

Applicable Billing Codes (HCPCS & CPT Codes)

Codes covered if clinical criteria are met:

Code	Description
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
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
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components) [not covered if history of prior Roux-en-Y gastric bypass or sleeve gastrectomy] [not covered with gastric plication]
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)
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43850	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy

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	
47562 - 47620	Cholecystectomy	
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline	
S9449	Weight management classes, non-physician provider, per session	
S9451	Exercise classes, non-physician provider, per session	
S9452	Nutrition classes, non-physician provider, per session	
ICD-10 codes covered if criteria are met:		
Code	Description	
E66.01	Morbid (severe) obesity due to excess calories	
E66.2	Morbid (severe) obesity with alveolar hypoventilation	
Z68.35	Body mass index (BMI) 35.0-35.9, adult	
Z68.36	Body mass index (BMI) 36.0-36.9, adult	
Z68.37	Body mass index (BMI) 37.0-37.9, adult	
Z68.38	Body mass index (BMI) 38.0-38.9, adult	
Z68.39	Body mass index (BMI) 39.0-39.9, adult	
Z68.41	Body mass index (BMI) 40.0-44.9, adult	
Z68.42	Body mass index (BMI) 45.0-49.9, adult	
Z68.43	Body mass index (BMI) 50-59.9, adult	
Z68.44	Body mass index (BMI) 60.0-69.9, adult	
Z68.45	Body mass index (BMI) 70 or greater, adult	
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Codes <u>not covered</u> for indications listed in this Guideline:

Code	Description
15876 - 15879	Suction assisted lipectomy; head and neck, trunk, upper/lower extremities

0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
43620	Gastrectomy, total; with esophagoenterostomy
43621	Gastrectomy, total; with Roux-en-Y reconstruction
43622	Gastrectomy, total; with formation of intestinal pouch, any type
43631	Gastrectomy, partial, distal; with gastroduodenostomy
43632	Gastrectomy, partial distal; with gastrojejunostomy (Billroth II) [when specified as bariatric surgery]
43633	Gastrectomy, partial, distal; with Roux-en-Y reconstruction
43634	Gastrectomy, partial, distal; with formation of intestinal pouch
43635	Vagotomy when performed with partial distal gastrectomy (List separately in addition to code(s) for primary procedure)
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach [when specified as gastric plication (laparoscopic greater curvature plication [LGCP]) with or without gastric banding, or mini-gastric bypass procedure]
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
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open

43999	Unlisted procedure, stomach [when specified as endoluminal gastric restrictive surgery or placement of intragastric balloon device]
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43855	Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy

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Clinical Guideline Revision/History Information

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Signed:	Sean Martin, MD, Medical Director