



Medicare Part C Medical Coverage Policy

Morbid Obesity Surgery

Origination: June 30, 1988

Review Date: October 18, 2017

Next Review: October, 2019

DESCRIPTION OF PROCEDURE OR SERVICE

Bariatric surgery procedures are performed to treat comorbid conditions associated with morbid obesity, also referred to as “clinically severe obesity.” Two types of surgical procedures are employed. Malabsorption procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorptions of nutrients occur. Restrictive procedures restrict the size of the stomach and decrease intake. Some surgical techniques combine both types of procedures.

Extreme (morbid) obesity is a condition of persistent and uncontrollable weight gain that is a potential threat to life. It is characterized by a body mass index (BMI) equal to or greater than 35kg/m² (or a BMI of 35 or higher).

Obesity is further classified according to the National Institutes of Health (NIH):

- Class I Obesity = BMI 30.0-34.9 kg/m²
- Class II Obesity = BMI 35.0-39.9 kg/m²
- Class III (Extreme) Obesity = BMI ≥ 40.0 kg/m²

POLICY STATEMENT

Coverage will be provided for surgery for morbid obesity when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member’s individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

SURGICAL PROCEDURES COVERED:

CMS allows national coverage for the following bariatric surgical procedures for Class II and Class III obesity:

- A. Open and laparoscopic gastric bypass (Roux-en-Y, RYGBP): This procedure achieves weight loss by gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. **RYGBP procedures can be open or laparoscopic.**
- B. Laparoscopic adjustable gastric banding: (LAGB) The LAGB achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, **depending on the rate of a patient's weight loss. AGB procedures are laparoscopic only.**
- C. Open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) or BPD with gastric reduction duodenal switch (BPD/GRDS): The BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD/DS is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transaction of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis. **BPD/DS procedures can be open or laparoscopic.**
- D. Laparoscopic Sleeve Gastrectomy: The Sleeve gastrectomy (SG) is a surgical procedure that involves excision of the lateral aspect of the stomach, leaving a much reduced and lesser-curve based tubular stomach. The Laparoscopic procedure has become a stand-alone approach and has both short and longer term weight loss. **This technique is not reversible.**

INDICATIONS FOR COVERAGE

Preauthorization by the Plan Services is required.

Bariatric procedures A (Roux-en-y) and B (LAGB) and C (BPD-DS) are covered when Criteria A: 1 and 2 are met. The Laparoscopic Sleeve Gastrectomy is covered when Criteria B is met. See Criteria C for a Laparoscopic Sleeve Gastrectomy for members over 61 years of age.

- A. The member must be extremely obese as defined by **one** of the following:
 1. BMI >35 associated with one of the following life-threatening or disabling co-morbid conditions related to obesity.
 - a. Poorly controlled type I or II Diabetes Mellitus
 - b. Poorly controlled dyslipidemia

- c. Poorly controlled hypertension
- d. Severe cardiopulmonary disease (e.g., coronary artery disease, cardiomyopathy, CHF, COPD or pulmonary hypertension)
- e. Obstructive sleep apnea
- f. Severe arthropathy of weight-bearing joints
- g. Pseudotumor cerebri.

AND

- 2. All of the following criteria are satisfied:
 - a. The Member has been unsuccessful with medical treatment for obesity and has participated in a medically supervised exercise program for at least six consecutive months without meaningful weight loss.
 - b. The surgery is medically appropriate for the member.
 - c. Member has achieved full growth.
 - d. Correctable metabolic causes of obesity (e.g., adrenal, pituitary or thyroid disorders) have been evaluated and ruled out or if present have been/ are being clinically treated.
 - e. Surgery is part of a comprehensive pre-surgical, surgical and post-surgical program.
- B. Indications for the Laparoscopic Sleeve Gastrectomy (LSG) are covered only when **ALL** the following Criteria is met:
 - 1. The member has a BMI greater than or equal to 35kg/m² **AND**
 - 2. The member has at least one co-morbid condition related to obesity; **AND**
 - a. The member has demonstrated active participation in weight management program within the last 12 months prior to surgery with physician or other health care professional's supervision. (A program where the physician has only followed pharmacological management is not acceptable.)
 - b. The weight management program notes must document weight **AND**, current dietary regimen **AND** physical activity.
 - 3. A thorough multidisciplinary evaluation within the last 6 months to include **ALL** of the following:
 - a. An evaluation by a bariatric surgeon with recommended surgical treatment, including a description of the procedure,
 - b. Referral from a primary care provider,
 - c. Evaluation for bariatric surgery by a mental health provider including a statement involving motivation and the ability to follow up on post op requirements.
 - d. A nutritional evaluation by a physician or registered dietician.
 - 4. For dates of service prior to September 24, 2013, LSG shall be furnished in a CMS approve facility.
For dates of service on or after September 24, 2013, facility certification shall no longer be required for coverage of covered bariatric procedure.

C. FOR PATIENTS > 61 year old; in addition to the criteria above, the following are met

- a. In addition to the psychological evaluation, there must be “evidence” documented in the patient’s medical record that the patient is able to personally understand the nature and potential complications of surgery and has the capacity to follow the postoperative care and nutritional requirements
- b. Indications for this age group will include at least one of the following serious comorbidities:
 1. Diabetes Mellitus **OR**
 2. Hypertension not well controlled with a single medication **OR**
 3. Hyperlipidemia requiring more than one medication to manage **OR**
 4. Joint Disease requiring surgical intervention **OR**
 5. Gastroesophageal Reflux Disease (GERD) refractory to a 2 month trial of appropriate treatment and medications **OR**
 6. Obstructive Sleep Apnea requiring CPAP **OR**
 7. Potential organ transplant candidacy at UNOS- certified center whereby BMI \geq than or equal to 35.

WHEN COVERAGE WILL NOT BE APPROVED

A. Surgery for Morbid Obesity is not covered in the following situations:

1. When the preceding criteria for coverage are not met.
2. When the procedure is considered investigational, including:
 - a. Gastric wrapping – a surgical procedure in which the stomach is folded over on itself and a full stomach wrap (polypropylene mesh) is applied. The outcome is to limit gastric volume.
 - b. Open adjustable gastric banding- an open surgical procedure to place adjustable gastric band around the exterior of the stomach.
 - c. Open sleeve gastrectomy- the greater curvature of the stomach is resected from the angle of HIS to the distal antrum, resulting in a stomach remnant shaped like a tube or a “sleeve.”
 - d. Laparoscopic sleeve gastrectomy prior to June 27th, 2012.
 - e. Open and Laparoscopic vertical banded gastroplasty.
 - f. Stomach Intestinal Pylorus Sparing Surgery (SIPS)
3. When one or more of the following contraindications are present:
 - a. Active peptic ulcer disease,
 - b. Alcohol or drug abuse,
 - c. Significant psychiatric disorders, severe depression or mental retardation resulting in failure of the individual to comprehend the nature and intent of surgery. These individuals must get psychiatric clearance.
4. Contraindications for the Lap Sleeve Gastrectomy are:
 - a. Dementia to the extent that self care is precluded
 - b. Required home oxygen;
 - c. Organ failure unless the patient is a transplant candidate.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

Applicable codes: 43644, 43645, 43770, 43771, 43772, 43773, 43774, 43775, 43845, 43846, 43847, 43848, 43842, 43843, 43886, 43887, 43888, 43999, and 43659 (when member has a diagnosis of Morbid Obesity)

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

An adequate preoperative evaluation for bariatric surgical procedures must include all the following:

1. Evaluation of the member's understanding of the procedure to be performed, including the procedure's risks and benefits, length of stay in the hospital, behavioral changes required prior to and after the surgical procedure (including dietary and exercise requirements), follow up requirements with the performing surgeon, and anticipated psychological changes.
2. Evaluation of the member's family/caregiver's support and understanding of the information described in number 1 above.
3. Nutritional/dietary assessment by a nutritionist/dietician, as well as specific follow up plans.
4. Psychological assessment of the member's ability to understand and adhere to the program by a mental health professional to include: levels of depression, eating behaviors, stress management, cognitive abilities, social functioning, self-esteem, personality factors or other mental health diagnoses that may affect treatment, readiness and ability to adhere to required lifestyle modifications and have follow up social support.
5. History and physical examination by the requesting surgeon.
6. The Centers for Medicare and Medicaid (CMS) has recognized the importance of screening and treating obesity and recently provided Medicare coverage for intensive behavioral therapy for obesity.

References:

1. Medicare Local Coverage Determination for Laparoscopic Sleeve Gastrectomy for Severe Obesity – Palmetto GBA Part A/B (L34576); Effective Date 10/01/2015, accessed via <http://www.cms.gov/medicare-coverage-database/> 10/18/17.
2. National Coverage Determination for Bariatric Surgery for Treatment of Morbid Obesity 100.1, Effective Date 9/24/2013. Accessed via www.cms.gov on 10/18/17.

Policy Implementation/Update Information:

Revision Dates: July 31, 1992; October 27, 1997; May 19, 2004; June 9, 2004; August 24, 2005

Revision Date: May 16, 2007- Added b, f, & g as surgical procedures not covered.

September 2009: No changes proposed to the review criteria. Formatting and minor wording changes only.

Revision Date: October 15, 2010: Updated language under "Indications for Coverage" to reflect current CMS policy and removed codes 43659 and 43999.

Revision Date: December 15, 2010: Removed item a. under #1 for Indications for Coverage as it is redundant per current item b.

Updated section; when Coverage Will Not Be approved, to reflect NCD language and, listed the subsets of Intestinal Bypass surgery. Added statement regarding NCD/LCD is currently silent as it pertains to gastric wrapping since there is not a specific code for gastric wrapping.

Revision Date: 04/17/2013; All procedure descriptions edited to mirror NCD; Criteria added for Lap sleeve gastrectomy per LCD;

Updated language for Non-Covered procedures per the NCD; Edited contraindications; Deleted Special Note regarding Gastric Wrapping. Minor edits for clarification.

Revision Date: October 16, 2013 to include NCD update regarding the removal of the certification facility requirement.

Revision Date: November 16, 2013 to include changes to the LCD criteria for Lap Sleeve.

Revision Date: January 17, 2014; Added Palmetto LCD revision to mirror CMS statement regarding bariatric facilities.

Revision Date: Revised to strike criteria under C.c. that the patient must sign the informed consent personally. It was determined that the member should be appropriately educated and informed after completing the other criteria. Date for next review moved to 2015.

Revision Date: July 15, 2015: Added obesity classification to Procedure/Service description and Surgical Procedures Covered sections, per LCD for clarification; removed language referencing Medicare approved bariatric centers as criteria for coverage per CMS guidance (CAG-00250R3), under When Coverage Will Not Be Approved, added item f, per Medical Director request; removed Medicare Approved Facilities website as a reference. October 29, 2015 updated LCD due to ICD-10 update only.

Revision Date: July 12, 2017- Annual Review, No CMS Updates. Minor Revisions Only. Coding Section: Added "43659 (when member has a diagnosis of Morbid Obesity)

Revision Date: October 18, 2017-Indications for Coverage: Section B. 2. a) Revised to read: "The member has demonstrated active participation in a weight management program **within** the last 12 months prior to surgery with physician or other health care professional's supervision. (A program where the physician has only followed pharmacological management is not acceptable.)"

Approval Dates:

Medical Coverage Policy Committee: October 18, 2017

Policy Owner: Carolyn Wisecarver, RN, BSN
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