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# *Clinical Coverage Guideline*



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## **Bariatric Surgery**

**Guideline Number: HS-006**

**Original Effective Date: 4/1/2007**

**Revision Date: 6/19/2008, 7/2/2009, 7/16/2009,  
8/18/2009**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

# Clinical Coverage Guideline HS-006

## Bariatric Surgery

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### DISCLAIMER

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### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### CLINICAL COVERAGE GUIDELINE

**Bariatric Surgery for the treatment of morbid obesity is considered medically necessary when the following criteria are met:**

1. Presence of morbid obesity that has persisted for at least 5 years, defined as either:
  - a. Body mass index (BMI)\* exceeding 40; **OR**,
  - b. BMI\* greater than 35 in conjunction with **ANY** of the following severe co-morbidities:
    - 1) Coronary heart disease; **OR**,
    - 2) Type 2 diabetes mellitus; **OR**,
    - 3) Clinically significant obstructive sleep apnea ( i.e., member meets the criteria for treatment of obstructive sleep apnea; **OR**,
    - 4) Medically refractory hypertension (blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite optimal medical management);

\* **NOTE:** BMI is calculated by dividing the patient's weight (in kilograms) by the height (in meters) squared: \*BMI = weight (kg) / [height (m)]<sup>2</sup> (To convert pounds to kilograms, multiply pounds by 0.45. To convert inches to meters, multiply inches by 0.0254)

**AND**

2. Member has completed growth (18 years of age or documentation of completion of bone growth);

**AND**

3. The member must concurrently participate in an organized multidisciplinary surgical preparatory regimen coordinated by a qualified bariatric surgeon in order to improve surgical outcomes, reduce the potential for

surgical complications, and establish the member's ability to comply with post-operative medical care and dietary restrictions.

**AND**

4. Member has participated in a physician-supervised nutrition and exercise program (including a low calorie diet, increased physical activity, and behavioral modification). This physician-supervised nutrition and exercise program must meet **ALL** of the following criteria:
  - a. Participation in nutrition and exercise program must be supervised and monitored by a physician; **AND**,
  - b. Nutrition and exercise program must be 6 months or longer in duration; **AND**,
  - c. Nutrition and exercise program must occur within the two years prior to surgery; **AND**,
  - d. Participation in physician-supervised nutrition and exercise program must be documented in the medical record by an attending physician who does not perform bariatric surgery. Note: A physician's summary letter is not sufficient documentation.

Programs such as Weight Watchers®, Jenny Craig® and Optifast® are acceptable alternatives if done in conjunction with physician supervision and detailed documentation of participation is available for review. However, physician-supervised programs consisting exclusively of pharmacological management are not sufficient to meet this requirement.

**AND**

5. Mental health evaluation by a psychiatrist or psychologist to determine any contraindications as listed below, 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 are:
  - a. Active drug abuse
  - b. Active suicidal ideation
  - c. Borderline personality disorder
  - d. Schizophrenia
  - e. Psychotic disorder
  - f. Uncontrolled depression
  - g. Defined non-compliance with previous medical care

***Procedures Covered***

**Only the following surgical procedures are covered:**

- a. Gastric segmentation along its vertical axis with a Roux-en-Y bypass with distal anastomosis placed in the jejunum (Open and Laparoscopic, CPT 43846 and 43644, respectively)
- b. Laparoscopic adjustable silicone gastric banding using the LAP-BAND (LASGB) (CPT 43770)
- c. Biliopancreatic Diversion with Duodenal Switch (Open and Laparoscopic, CPT 43847 and 43645, respectively)

***Non-Covered Procedures***

The following procedures are not covered due to being unsafe or not adequately studied:

- a. Open adjustable gastric banding
- b. Open and laparoscopic sleeve gastrectomy
- c. Open and laparoscopic vertical banded gastroplasty
- d. Gastric balloon
- e. Intestinal bypass

### **Repeat Surgery**

**Repeat surgery is considered medically necessary under the following condition ONLY:**

1. A complication has occurred associated with the original procedure

**NOTE:** Inadequate weight loss due to individual noncompliance with postoperative nutrition and exercise recommendations is **NOT** considered medically necessary for revision or conversion surgery.

### **Recommended Facilities and Providers**

1. Facilities should be limited to tertiary care centers equipped to perform pre and post surgical interventions. The facility should have the following qualifications:
  - a. Be accomplished in bariatric surgery with a demonstrated commitment to provide adequate facilities and equipment, as well as properly trained and funded appropriate bariatric surgery support staff.
  - b. Be under the direction of a qualified surgeon who is in charge of an experienced and comprehensive bariatric surgery team that should include experienced surgeons and physicians, skilled nurses, specialty-trained nutritionists, experienced anesthesiologists, and, as needed, cardiologists, pulmonologists, rehabilitation therapists, and psychiatric staff.
2. The bariatric surgeon should be board certified by the American Board of Surgery or in the process of certification within 5 years after completion of an accredited residency program in general or gastrointestinal surgery, and recertification has been obtained by the American Board Surgery on an every 10-year basis, if applicable. Minimal qualifications for a bariatric surgeon include either fellowship training or extended mentoring by an experienced surgeon, preferably by members of international/national bariatric societies, in all aspects of bariatric surgery, advanced laparoscopic techniques, and additional training in re-operative techniques.

### **BACKGROUND:**

Gastric bypass surgery and gastroplasty cause weight reduction in morbidly obese patients. Gastroplasty reduces the capacity of the stomach and the size of the gastric outlet. Gastric bypass reduces stomach capacity and diverts partially digested food past the duodenum to the jejunum. Morbid or clinically severe obesity correlates with a Body Mass Index (BMI) of 40 kg/m<sup>2</sup> or with being greater than or equal to 100 pounds over ideal body weight.

The Lap-Band Adjustable Gastric Banding System (LAGBS) received FDA approval in June 2001 and is currently available as a weight reduction surgery in obese patients. The system consists of a band with a sutureless locking mechanism. The band is placed via a laparoscopic approach around the upper part of the stomach to form a small pouch and is connected by tubing to an access port that is positioned in the upper abdomen directly under the skin. The surgeon adjusts the size of the band around the stomach by percutaneously injecting or removing saline as needed through the access port.

### **CODING**

#### **Covered CPT®\* Codes**

- 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 band (gastric band and subcutaneous port components) Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
- 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
- 43846** Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb(less than 100 cm) Roux-en-Y gastroenterostomy
- 43847** Gastric restrictive procedure, with gastric bypass for morbid obesity with small bowel reconstruction to limit absorption

**Gastric Band Adjustment, Outpatient  
Covered for Medicare when medically necessary**

- 43999** Unlisted procedure to be billed for Outpatient Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
- 76000** Fluoroscopy (separate procedure) up to 1 hour physician time
- 76705** Ultrasound, abdominal, limited (eg, single organ, quadrant, follow-up)

**HCPCS Code**

**Covered for Medicaid when medically necessary and Non-Covered for Medicare**

- S2083** Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline  
**NON COVERED FOR MEDICARE** – Refer to HCPCS Level II Temporary National Codes

**Covered ICD-9-CM Procedure Codes**

- 44.38** Laparoscopic Gastroenterostomy; Bypass
- 44.39** Other Gastroenterostomy, Bypass
- 44.68** Laparoscopic gastroplasty, Banding
  
- 250.00** Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled
- 250.02** Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled
- 278.01** Morbid obesity
- 327.23** Obstructive Sleep apnea (adult)
- 401.0 - 401.9** Essential hypertension
- 414.01** Coronary atherosclerosis of native coronary artery
- V85.35** Body Mass Index 35.0-35.9, adult
- V85.36** Body Mass Index 36.0-36.9, adult
- V85.37** Body Mass Index 37.0-37.9, adult
- V85.38** Body Mass Index 38.0-38.9, adult
- V85.39** Body Mass Index 39.0-39.9, adult
- V85.4** Body Mass Index 40 and over, adult

\*Current Procedural Terminology (CPT) 2009 American Medical Association: Chicago, IL.®©

**REFERENCES**

1. Centers for Medicare and Medicaid Services National Coverage Determination. Bariatric Surgery for the Treatment of Morbid Obesity (100.1). Feb 12, 2009.
2. National Institutes of Health Consensus Development Conference Statement. Gastrointestinal Surgery for Severe

- Obesity. *Ann Intern Med.* 1991;115:956-961
3. Mun EC, Blackburn GL, Matthews JB. Current Status of Medical and Surgical Therapy for Obesity. *Gastroenterology.* 2001;120(3):669-681
  4. Gentileschi P, Kini S, Catarci M, Gagner M. Evidence-Based Medicine: Open and Laparoscopic Bariatric Surgery. *Surg Endosc.* 2002;16(5):736-744
  5. Guidelines for Laparoscopic and Conventional Surgical Treatment of Morbid Obesity. *Surg Endosc.* 2001;15(10):1251-1251
  6. Nguyen NT, Goldman C, Rosenquist Cj, et al. Laparoscopic Versus Open Gastric Bypass: A Randomized Study of Outcomes, Quality of Life, and Costs. *Ann Surg.* 2001;234(3):279-291
  7. Westling A, Gustavsson S. Laparoscopic vs Open Roux-en-Y Gastric Bypass: A Prospective, Randomized Trial. *Obes Surg.* 2001;11(3):284-292
  8. Weiner R, Bockhorn H, Rosenthal R, et al. A Prospective Randomized Trial of Different Laparoscopic Gastric Banding Techniques for Morbid Obesity. *Surg Endosc.* 2001;15(1):63-68
  9. Azagra Js, Goergen M, Ansay J, et al. Laparoscopic Gastric Reduction Surgery. Preliminary Results of a Randomized, Prospective Trial of Laparoscopic vs Open Vertical Banded Gastroplasty. *Surg Endosc.* 1999;13(6):555-558
  10. Colquitt J, Clegg A, Sidhy M, Royle P. Surgery for Morbid Obesity (Protocol for a Cochrane Review ). The Cochrane Library, issue 2, 2002. Oxford, UK: Updated Software
  11. U.S. Food and Drug Administration . Lap-Band Adjustable Gastric Banding (LABG) System Summary of Safety and Effectiveness Data. PMA No. p000008. Issues June 5, 2001. Rockville MD: FDA; June 3 2002. <http://www.fda.gov/cdrh/pdf/p000008.html>
  12. Melissas J, Christodaoulakis M, Spyridakis M, et al. Disorders Associated with Clinically Severe Obesity: Significant Improvement after Surgical Weight Reduction. *South Med J.* 1998;91(12):1143-1148.
  13. Clegg AJ, Colquitt J, Sidhu MK, et al. The Clinical Effectiveness and Cost-Effectiveness of Surgery for People with Morbid Obesity: A Systematic Review and Economic Evaluation. *Health Techno Assess.* 2002;6(12):1-153
  13. van de Weijgert EJHM, Ruseler CH, Elte JWF. Long-term Follow up After Gastric Surgery for Morbid Obesity: Preoperative Weight Loss Improves the Long-term Control of Morbid Obesity after Vertical Banded Gastroplasty. *Obes Surg.* 1999;9:4262-43 American Dietetic Association. Weight Management – Position of ADA. *J Am Diet Asso*1997;97:71-74.
  14. National Academy of Science, Institute of Medicine, Committee to Develop Criteria for Evaluating The Outcomes of Approaches to Prevent and Treat Obesity. *Weighing the Options: Criteria for Evaluation Weight-Management Programs.* PR Thomas, ed. Washington, D.C. National Academy Press; 1995.
  15. Clegg A, Sidhy MK, Colquitt MJ, et al. Clinical and Cost-Effectiveness of Surgery for People with Morbid Obesity. Southhampton,UK: Southampton Health Technology Assessments Centre, Wessex Institute for Health Research and Development. December 2001. Ren CJ, Patterson E, Gagnier M. Early Results of Laparoscopic Biliopancreatic Eversion with Duodenal Switch: A Case Series of 40 Consecutive Patients. *Obes Surg.* 2000;10(6):514-524