

# **CMS Manual System**

## **Pub 100-03 Medicare National Coverage Determinations**

**Transmittal 54**

**Department of Health & Human Services (DHHS)**

**Centers for Medicare & Medicaid Services (CMS)**

**Date: APRIL 28, 2006**

**Change Request 5013**

**SUBJECT: Bariatric Surgery for Treatment of Morbid Obesity**

**I. SUMMARY OF CHANGES:** Section 40.5 - Revised to include reference to covered surgical procedures. Section 100.1 - Effective for services on or after February 21, 2006, Medicare will cover open and laparoscopic Roux-en Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB) and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) if certain criteria are met and the procedure is performed in an approved facility. In addition, effective for services performed on or after February 21, 2006, Medicare has decided that open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy and open adjustable gastric banding are nationally non-covered for Medicare. These revisions to sections 40.5 and 100.1 of Pub. 100-03 are national coverage determinations (NCDs) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR 405.1064, effective May 1, 2005). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See 1869(f)(1)(A)(i) of the Social Security Act.

### **NEW/REVISED MATERIAL**

**EFFECTIVE DATE: February 21, 2006**

**IMPLEMENTATION DATE: May 30, 2006 for physician claims billed to the carrier, and October 2, 2006 for hospital claims billed to the FI.**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:**

**R = REVISED, N = NEW, D = DELETED**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/Table of Contents
<b>R</b>	1/40.5/Treatment of Obesity (Effective February 21, 2006)
<b>R</b>	1/Table of Contents
<b>R</b>	1/100.1/Bariatric Surgery for Treatment of Morbid Obesity (Effective February 21, 2006)

**III. FUNDING:**

**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

**IV. ATTACHMENTS:**

Manual Instruction

*\*Unless otherwise specified, the effective date is the date of service.*

# **Medicare National Coverage Determinations Manual**

## **Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations**

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### **Table of Contents** *(Rev.54, 04-28-06)*

40.5 - Treatment of Obesity *(Effective February 21, 2006)*

## **40.5 – Treatment of Obesity**

*(Rev.54, Issued: 04-28-06, Effective: 02-21-06, Implementation: 05-30-06 Carrier/10-02-06 FI)*

### **A. General**

Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. *Non-surgical* services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions. *Certain designated surgical services for the treatment of obesity are covered for Medicare beneficiaries who have a BMI  $\geq 35$ , have at least one co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity.*

In addition, supplemented fasting is a type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins, and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein.

### **B. Nationally Covered Indications**

*Certain designated surgical services for the treatment of obesity are covered for Medicare beneficiaries who have a BMI  $\geq 35$ , have at least one co-morbidity related to obesity and have been previously unsuccessful with the medical treatment of obesity. See §100.1.*

### **C. Nationally Noncovered Indications**

*1. Treatments for obesity alone remain non-covered.*

2. Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).

### **D. Other**

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for *coverage on a case-by-case basis or pursuant to a local coverage determination*. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

(This NCD last reviewed *February 2006*.)

See §§100.1, 100.8, and 100.11.

# **Medicare National Coverage Determinations Manual**

## **Chapter 1, Part 2 (Sections 90 – 160.25) Coverage Determinations**

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### **Table of Contents (Rev.54, 04-28-06)**

100.1 - *Bariatric Surgery for Morbid Obesity (Effective 21, 2006)*

## **100.1 - Bariatric Surgery for Treatment of Morbid Obesity**

**(Rev.54, Issued: 04-28-06, Effective: 02-21-06, Implementation: 05-30-06 Carrier/10-02-06 FI)**

### **A. General**

*Bariatric surgery procedures are performed to treat comorbid conditions associated with morbid obesity. Two types of surgical procedures are employed. Malabsorptive procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur. Restrictive procedures restrict the size of the stomach and decrease intake. Surgery can combine both types of procedures.*

*The following are descriptions of bariatric surgery procedures:*

#### **a. Roux-en-Y Gastric Bypass (RYGBP)**

*The RYGBP 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. Biliopancreatic Diversion with Duodenal Switch (BPD/DS)**

*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 with duodenal switch is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection 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.*

#### **c. Adjustable Gastric Banding (AGB)**

*AGB 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. ABG procedures are laparoscopic only.*

#### **d. Sleeve Gastrectomy**

*Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP. Sleeve gastrectomy procedures can be open or laparoscopic.*

*e. Vertical Gastric Banding (VGB)*

*VGB achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less.*

***B. Nationally Covered Indications***

*Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index  $\geq 35$ , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. These procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006).*

*A list of approved facilities and their approval dates are listed and maintained on the CMS Coverage Web site at <http://www.cms.hhs.gov/center/coverage.asp>, and published in the Federal Register.*

***C. Nationally Non-covered Indications***

*The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:*

- Open adjustable gastric banding*
- Open and laparoscopic sleeve gastrectomy; and*
- Open and laparoscopic vertical banded gastroplasty.*

*The two previously non-coverage determinations remain unchanged - Gastric Balloon (Section 100.11) and Intestinal Bypass (Section 100.8).*

***D. Other***



*NA.*

*(This NCD last reviewed February 2006.)*

*See §§40.5, 100.8, and 100.11.*