

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 150</b>	<b>Date: January 29, 2013</b>
	<b>Change Request 8028</b>

Transmittal 148, dated November 9, 2012 is rescinded and replaced by Transmittal 150, dated January 29, 2013. The Business Requirement 8028.1 has been updated to include the correct responsibility FI that was previously omitted. All other information remains the same.

**SUBJECT: Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG)**

**I. SUMMARY OF CHANGES:** Effective for claims with dates of service on or after June 27, 2012, Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a-c are satisfied.

- a. The beneficiary has a body-mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>,
- b. The beneficiary has at least one co-morbidity related to obesity, and,
- c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

**EFFECTIVE DATE: June 27, 2012**

**IMPLEMENTATION DATE: February 28, 2013**

*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:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/100.1/Bariatric Surgery for Treatment of Morbid Obesity

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

#### **IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 150	Date: January 29, 2013	Change Request: 8028
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**SUBJECT: Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG)**

**EFFECTIVE DATE: June 27, 2012**

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## I. GENERAL INFORMATION

**A. Background:** In 2006, the Centers for Medicare & Medicaid Services (CMS) released a final National Coverage Determination (NCD) on Bariatric Surgery for the Treatment of Morbid Obesity (NCD Manual Section 100.1 [http://www.cms.gov/manuals/downloads/ncd103c1\\_Part2.pdf](http://www.cms.gov/manuals/downloads/ncd103c1_Part2.pdf)). For Medicare beneficiaries who have a BMI  $\geq 35$ , at least one co-morbidity related to obesity, and who have been previously unsuccessful with medical treatment for obesity, the following procedures were determined to be reasonable and necessary:

- 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).

In addition, the NCD stipulates that the above bariatric procedures be covered only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (BSCOE) (Program Standards and requirements in effect on February 15, 2006). Due to lack of evidence at the time, the 2006 NCD specifically non-covered open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy (LSG), and open adjustable gastric banding. In 2009, CMS updated the NCD to include type 2 diabetes mellitus as a co-morbidity.

In September 2011, CMS re-opened the NCD to determine whether new and emerging evidence supported inclusion of LSG as a reasonable and necessary bariatric surgery under sections 1862 (a)(1)(A) and/or 1862 (a)(1)(E) of the Act. Open sleeve gastrectomy was not considered and remains non-covered.

**B. Policy:** Effective for claims with dates on or after June 27, 2012, Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of stand-alone LSG for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a-c are satisfied.

- a. The beneficiary has a body-mass index (BMI)  $\geq 35$  kg/m<sup>2</sup>,
- b. The beneficiary has at least one co-morbidity related to obesity, and,
- c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement.*

Number	Requirement	Responsibility										
		A/B MAC		D M E  M A C	F I	C A R R I E R	R H I	Shared- System Maintainers				O t h e r
		P a r t  A	P a r t  B					F I S S	M C S	V M S	C W F	
8028.1	<p>Effective for claims with dates of service on or after June 27, 2012, MACs acting within their respective jurisdictions may determine coverage of stand-alone LSG for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a-c are satisfied.</p> <p>a. The beneficiary has a body-mass index (BMI) <math>\geq 35</math> kg/m<sup>2</sup> <input type="checkbox"/>,</p> <p>b. The beneficiary has at least one co-morbidity related to obesity, and,</p> <p>c. The beneficiary has been previously unsuccessful with medical treatment for obesity.</p>	X	X		X	X						

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility									
		A/B MAC		D M E  M A C	F I	C A R R I E R	R H I	Other			
		P a r t  A	P a r t  B								
8028.2	<p>MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized</p>	X	X		X	X					

Number	Requirement	Responsibility					
		A/B MAC	D M E	F I	C A R R I E R	R H H I	Other
		P a r t  A	P a r t  B	M A C			
	information that would benefit their provider community in billing and administering the Medicare program correctly.						

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**  
*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Deirdre O'Connor, 410-786-3263 or Deirdre.oconnor@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage) , Shauntari Cheely, 410-786-1818 or Shauntari.Cheely@cms.hhs.gov , Chanelle Jones, 410-786-9668 or Chanelle.jones@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

**VI. FUNDING**

**Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

**Section B: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**Medicare National Coverage Determinations Manual**  
**Chapter 1, Part 2 (Sections 90 – 160.26)**  
**Coverage Determinations**

*Rev. 150, Issued: 01-29-13, Effective: 06-27-12, Implementation: 02-28-13)*

*100.1 - Bariatric Surgery for Treatment of Morbid Obesity*

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

**(Rev. 150, Issued: 01-29-13, Effective: 06-27-12, Implementation: 02-28-13)**

### **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:

#### **1. 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.

#### **2. Biliopancreatic Diversion with Duodenal Switch (BPD/DS)**

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 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.

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

The 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. AGB procedures are laparoscopic only.

#### **4. 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. *In the past, sleeve gastrectomy was the first step in a two-stage procedure when performing RYGBP, but more recently has been offered as a stand-alone surgery.* Sleeve gastrectomy procedures can be open or laparoscopic.

#### **5. Vertical Gastric Banding (VGB)**

The 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. VGB procedures are essentially no longer performed.

## **B. Nationally Covered Indications**

Effective for services performed on and after February 21, 2006, 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).

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determines that Type 2 diabetes mellitus is a co-morbidity for purposes of this NCD.

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 sleeve gastrectomy*; and,

Laparoscopic sleeve gastrectomy (*prior to June 27, 2012*)

Open and laparoscopic vertical banded gastroplasty.

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

## **D. Other**

*Effective for services performed on and after June 27, 2012, Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied.*

- a. The beneficiary has a body-mass index (BMI)  $\geq 35$  kg/m<sup>2</sup> □,*
- b. The beneficiary has at least one co-morbidity related to obesity, and,*
- c. The beneficiary has been previously unsuccessful with medical treatment for obesity.*

**(This NCD last reviewed *June 2012*.)**