

<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 100</b>	<b>Date: April 17, 2009</b>
	<b>Change Request 6419</b>

**SUBJECT: Surgery for Diabetes**

**I. SUMMARY OF CHANGES:** Effective for services performed on and after February 12, 2009, CMS determines that 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 Medicare beneficiaries who have type 2 diabetes mellitus (T2DM) and a BMI less than 35 are not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act, and therefore are not covered. Additionally, effective for services performed on and after February 12, 2009, CMS determines that open and laparoscopic RYGBP, LAGB, and open and laparoscopic BPD/DS in Medicare beneficiaries who have T2DM and a BMI greater or equal to 35 improves health outcomes. Thus, type 2 diabetes mellitus is a comorbid condition related to obesity. This revision is an NCD. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405, 1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

**NEW / REVISED MATERIAL**

**EFFECTIVE DATE: FEBRUARY 12, 2009**

**IMPLEMENTATION DATE: May 18, 2009**

*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**

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
<b>R</b>	1/Table of Contents
<b>R</b>	1/100.1/Bariatric Surgery for Treatment of Morbid Obesity (Various Effective Dates Below)
<b>N</b>	1/100.14/Surgery for Diabetes (Effective February 12, 2009)

**III. FUNDING:**

**SECTION A: For Fiscal Intermediaries and Carriers:**

No additional funding will be provided by CMS; contractor activities are to be carried out within 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 does 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.

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

**Business Requirements  
Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 100	Date: April 17, 2009	Change Request: 6419
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**SUBJECT: Surgery for Diabetes**

**Effective Date: February 12, 2009**

**Implementation Date: May 18, 2009**

## I. GENERAL INFORMATION

**A. Background:** Currently, the Centers for Medicare & Medicaid Services (CMS) has a specific national coverage determination (NCD) for certain types of bariatric surgery for morbidly obese persons (body mass index (BMI)  $\geq 35$ ) having one or more comorbidities, including diabetes, associated with obesity, and have been previously unsuccessful with medical treatments. NCD at Pub 100-03, section 100.1 (Bariatric Surgery for Morbid Obesity), does not restrict surgery for diabetes alone, leaving the coverage decision to local contractor discretion. Subsequently, CMS assessed the evidence for the ability of various gastric and intestinal bypass procedures to improve diabetes status among obese, overweight, and non-overweight diabetics regardless of that procedure's coverage under NCD 100.1, and to clarify the Agency's coverage policy for these surgical procedures among Medicare beneficiaries in respective weight categories.

**B. Policy:** Effective for services performed on and after February 12, 2009, CMS determines that 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 Medicare beneficiaries who have type 2 diabetes mellitus (T2DM) and a BMI  $< 35$  are not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act, and therefore are not covered. See NCD Manual Pub. 100-03, section 100.14.

Additionally, effective for services performed on and after February 12, 2009, CMS determines that open and laparoscopic RYGBP, LAGB, and open and laparoscopic BPD/DS in Medicare beneficiaries who have T2DM and a BMI  $\geq 35$  improves health outcomes. Thus, type 2 diabetes mellitus is a comorbid condition related to obesity as defined in NCD Manual Pub. 100-03, section 100.1

In addition, the procedure must be performed at an approved facility. A list of approved facilities may be found at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage>.

**NOTE:** This NCD does not change related NCDs at Pub. 100-03, sections 40.5 (Obesity), 100.8 (Intestinal Bypass Surgery), or 100.11 (Gastric Balloon for Treatment of Obesity). In addition, treatments for obesity alone remain non-covered, as does use of the open or laparoscopic sleeve gastrectomy, open adjustable gastric banding, and open and laparoscopic vertical banded gastroplasty procedures, regardless of the patient's BMI or comorbidity status.

## II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				O T H E R
							F I S S	M C S	V M S	C W F	
6419.1	Effective for claims with dates of service on and after February 12, 2009, contractors shall process claims for bariatric surgeries for patients with T2DM according to the NCDs at Pub. 100-03, sections 100.1, 100.14, the claims processing instructions at Pub. 100-04, chapter 32, sections 150.1, 150.6, 150.7, and the BRs at Pub. 100-04 attached to CR 6419.	X		X	X						

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				O T H E R
							F I S S	M C S	V M S	C W F	
6419.2	<p>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 site 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 your next regularly scheduled bulletin.</p> <p>Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X		X	X						

## IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements:**

*"Should" denotes a recommendation*

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

**Section B: For all other recommendations and supporting information, use this space:**

## V. CONTACTS

**Pre-Implementation Contact(s):** Joe Bryson (institutional claims), 410-786-2986, [joseph.bryson@cms.hhs.gov](mailto:joseph.bryson@cms.hhs.gov), Valeri Ritter (institutional claims), 410-786-8652, [Valeri.ritter@cms.hhs.gov](mailto:Valeri.ritter@cms.hhs.gov), Yvette Cousar (practitioner claims), 410-786-2160, [Yvette.cousar@cms.hhs.gov](mailto:Yvette.cousar@cms.hhs.gov), Arthur Meltzer (coverage), 410-786-9974, [Arthur.meltzer@cms.hhs.gov](mailto:Arthur.meltzer@cms.hhs.gov), Pat Brocato-Simons (coverage), 410-786-0261, [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov).

**Post-Implementation Contact(s):** Regional office

## VI. FUNDING

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

No additional funding will be provided by CMS; contractor activities are to be carried out within 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 does 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

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### Table of Contents *(Rev. 100, 04-17-09)*

100.1 – Bariatric Surgery for Treatment of Morbid Obesity *(Various Effective Dates Below)*

*100.14 – Surgery for Diabetes (Effective for February 12, 2009)*

**100.1 - Bariatric Surgery for Treatment of Morbid Obesity (*Various Effective Dates Below*)**  
(*Rev. 100; Issued: 04-17-09; Effective Date: 02-12-09; Implementation Date: 05-18-09*)

**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. It may be the first step in a two-stage procedure when performing RYGBP. 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 and laparoscopic sleeve gastrectomy; and,
- 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**

*N/A*

**(This NCD last reviewed February 2009.)**

## **100.14 - Surgery for Diabetes (Effective February 12, 2009)**

**(Rev. 100; Issued: 04-17-09; Effective Date: 02-12-09; Implementation Date: 05-18-09)**

### **A. General**

*Medicare currently covers bariatric surgery for persons with type 2 diabetes mellitus (T2DM) and a body mass index (BMI)  $\geq$  35. Surgical procedures that are used in this context are discussed in section 100.1. It was proposed that these same procedures may be beneficial for beneficiaries with T2DM who do not meet the criteria for treatment of morbid obesity. The Centers for Medicare & Medicaid Services (CMS) specifically evaluated the evidence associated with surgery among persons with T2DM to assess the effectiveness of such procedures in reducing the signs and symptoms of this disease in Medicare beneficiaries with a BMI  $<$  35.*

### **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 BMI  $\geq$  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, CMS determines that T2DM is a co-morbidity for purposes of section 100.1.*

*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**

*Effective for services performed on and after February 12, 2009, open and laparoscopic RYGBP, open and laparoscopic BPD/DS, and LAGB are non-covered for Medicare beneficiaries who have a BMI  $<$  35 and T2DM.*

### **D. Other**

*N/A*

***(This NCD last reviewed February 2009.)***