CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 158	**Date: December 23, 2013**
	Change Request 8484

Transmittal 157, dated November 15, 2013, is being rescinded and replaced by Transmittal 158, dates December 23, 2013 to add omitted ICD codes in section 150.5.1, Pub. 100-04 Claims Processing Manual, and to make technical corrections in sections 40.5, 100.8, 100.11 & 100.14, Pub. 100-03 NCD Manual. All other information remains the same.

SUBJECT: Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity

I. SUMMARY OF CHANGES: Effective for dates of service on and after September 24, 2013, facility certification shall no longer be required for coverage of covered bariatric surgery procedures.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, 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.)

EFFECTIVE DATE: September 24, 2013
IMPLEMENTATION DATE: December 17, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/100.1/Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (Effective September 24, 2013)
R	1/40.5/Treatment of Obesity
R	1/100.8/Intestinal Bypass Surgery
R	1/100.11/Gastric Balloon for Treatment of Obesity
R	1/100.14/Surgery for Diabetes

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: 158	Date: December 23, 2013	Change Request: 8484

Transmittal 157, dated November 15, 2013, is being rescinded and replaced by Transmittal 158, dates December 23, 2013 to add omitted ICD codes in section 150.5.1, Pub. 100-04 Claims Processing Manual, and to make technical corrections in sections 40.5, 100.8, 100.11 & 100.14, Pub. 100-03 NCD Manual. All other information remains the same.

SUBJECT: Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity

EFFECTIVE DATE: September 24, 2013

IMPLEMENTATION DATE: December 17, 2013

I. GENERAL INFORMATION

A. Background: This change request is due to a reconsideration of section 100.1 of the National Coverage Determination (NCD) Manual titled Bariatric Surgery for Treatment of Morbid Obesity. On January 24, 2013 the Centers for Medicare & Medicaid Services (CMS) initiated a national coverage analysis (NCA) for the reconsideration of the requirement that covered bariatric surgery procedures are only covered when performed in facilities that are certified. In addition, we decided to make some additional changes to the NCD which are defined in section B.

In 2006, CMS established a National Coverage Determination (NCD) on Bariatric Surgery for the Treatment of Morbid Obesity (NCD Manual Section 100.1). For Medicare beneficiaries who have a BMI $\geq$ 35, have 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) or gastric reduction duodenal switch (BPD/GRDS).

In addition, the NCD stipulates that these bariatric procedures are 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 (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (Program Standards and requirements in effect on February 15, 2006). The 2006 NCD specifically non-covered open vertical banded gastroplasty, laparoscopic vertical banded gastroplasty, open sleeve gastrectomy, laparoscopic sleeve gastrectomy, and open adjustable gastric banding because there was a paucity of evidence to support claims of improved health outcomes from those procedures.

This NCA specifically addressed the need for the continuation of the requirement for facility certification by ACS or the AABS) currently the American Society for Metabolic and Bariatric Surgery (ASMBS).

B. Policy: The CMS has determined that the evidence is sufficient to conclude that continuing the requirement for certification for bariatric surgery facilities would not improve health outcomes for Medicare beneficiaries. Therefore, CMS will remove this certification requirement.

CMS has determined that no changes be made to the bariatric surgery procedures that are deemed covered in section 100.1 of the National Coverage Determination (NCD) Manual.

CMS plans to change the title to better reflect the scope of the NCD and to make it clear in the manual that under the existing policy the local Medicare Administrative Contractors have the authority to make coverage decisions for any bariatric surgery procedures not specifically identified as covered or non-covered by an NCD.

In addition, to the proposed decision above, CMS is renumbering and consolidating its manual for section 100.1. This is an administrative change only to make it easier for the public to read and understand the NCD manual. There is no change in coverage because of the renumbering and consolidation.

- The additional NCDs related to bariatric surgery will be consolidated and subsumed into section 100.1 of the NCD Manual. These include sections 40.5, 100.8, 100.11 and 100.14.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
8484-03.1	Effective for dates of service on and after September 24, 2013, facility certification shall no longer be required for coverage of covered bariatric surgery procedures.	X	X										
8484-03.2	Effective on September 24, 2013, the title of section 100.1 in the NCD manual will be changed to "Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity".	X	X										
8484-03.3	A clarifying statement will be added to the section 100.1 of the NCD manual that states the following: The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-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, is left to the local Medicare Administrative Contractor.	X	X										
8484-03.4	Effective on September 24, 2013 , the following sections of the NCD manual related to bariatric surgery will be subsumed under	X	X										

Number	Requirement	Responsibility											
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				Other
		A	B	HHH					FISS	MCS	VMS	CWF	
	section 100.1: Sections 40.5, 100.8, 100.11 and 100.14.												

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility							
		A/B MAC			DME MAC	FI	CARRIER	RHHI	Other
		A	B	HHH					
8484-03.5	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ 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 information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X						

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes 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, wanda.belle@cms.hhs.gov (Coverage), Yvette Cousar, 410-786-2160, yvette.cousar@cms.hhs.gov (Practitioner Part B), Patricia Brocato-Simons, 410-786-0261, patricia.brocatosimons@cms.hhs.gov (Coverage), Chanelle Jones, 410-786-9668, chanelle.jones@cms.hhs.gov (Practitioner Part B), Shauntari Cheely, 410-786-7818, shauntari.cheely@cms.hhs.gov (Institutional Claims), Deirdre O'Connor, 410-786-3263, Deirdre.Oconnor@cms.hhs.gov (Coverage)

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 10 – 80.12 and 90 – 160.25)

Coverage Determinations

Table of Contents

(Rev.158, 12-23-13)

100.1. – Bariatric Surgery for Treatment of Co-morbid Conditions Related to Morbid Obesity (Effective September 24, 2013)

100.1 - Bariatric Surgery for Treatment *of Co-Morbid Conditions Related to* Morbid Obesity

(Rev.158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note, sections 40.5, 100.8, 100.11, and 100.14 have been removed from the National Coverage Determination (NCD) Manual and incorporated into NCD 100.1

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.

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.

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) *or 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 *or BPD/GRDS* 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 *or BPD/GRDS* 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) *or Gastric Reduction Duodenal Switch (BPD/GRDS)*, and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

Effective for dates of service on and after February 21, 2006, 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 dates of service on and after September 24, 2013, facilities are no longer required to be certified.*

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determine*s* 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.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Bariatric-Surgery.html , and published in the Federal Register *for services provided up to and including date of service September 23, 2013.*

C. Nationally Non-Covered Indications

Treatments for obesity alone remain non-covered.

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

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

Open adjustable gastric banding;

Open sleeve gastrectomy;

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

Open and laparoscopic vertical banded gastroplasty;

Intestinal bypass surgery; and,

Gastric balloon for treatment of obesity.

D. Other

Effective for services performed on and after June 27, 2012, Medicare Administrative Contractors *(MACs)* 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^2,

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.

The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-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, is left to the local MACs.

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.

40.5 – Treatment of Obesity

(Rev.158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note section 40.5 has been removed from the NCD Manual and incorporated into NCD 100.1.

100.8 – Intestinal Bypass Surgery

(Rev.158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note section 100.8 has been removed from the NCD Manual and incorporated into NCD 100.1.

100.11 – Gastric Balloon for Treatment of Obesity

(Rev.158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note section 100.11 has been removed from the NCD Manual and incorporated into NCD 100.1.

100.14 – Surgery for Diabetes

(Rev.158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note section 100.14 has been removed from the NCD Manual and incorporated into NCD 100.1.