NOTE: Transmittal 1711, dated April 17, 2009, is being rescinded and replaced with Transmittal 1728, dated May 4, 2009, to note the appropriate responsibility in the Business Requirements per the POC review. All other material remains the same.

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 as defined in NCD Manual Pub. 100-03, section 100.1

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

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
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<tbody>
<tr>
<td>R</td>
<td>32/150.1/General</td>
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<tr>
<td>R</td>
<td>32/150.3/ICD-9 Procedure Codes for Bariatric Surgery (FIs Only)</td>
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<tr>
<td>R</td>
<td>32/150.6/Claims Guidance for Payment</td>
</tr>
<tr>
<td>R</td>
<td>32/150.7/Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes</td>
</tr>
</tbody>
</table>

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.
NOTE: Transmittal 1711, dated April 17, 2009, is being rescinded and replaced with Transmittal 1728, dated May 4, 2009, to note the appropriate responsibility in the Business Requirements per the POC review. All other material remains the same.

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) ≥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 ≥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

*“Shall” denotes a mandatory requirement*

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility (place an “X” in each applicable column)</th>
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| 6419.1 | Contractors shall continue to pay hospital inpatient bariatric surgery claims to approved facilities (see link above) for patients with a BMI ≥ 35. In other words, claims that contain the following:  
- covered ICD-9 procedure code (see Attachment 1, Section A), and  
- ICD-9 diagnosis code 278.01 as a primary diagnosis, and  
- ICD-9 diagnosis code indicating T2DM (see Attachment 2) as a secondary diagnosis; and  
- ICD-9 diagnosis code indicating a BMI ≥ 35 (see Attachment 1, Section C) as a secondary diagnosis. | X | X |
| 6419.1.1 | Effective for discharges on or after February 12, 2009, contractors shall reject inpatient bariatric surgeries for patients with a BMI < 35. In other words, claims that contain the following:  
- covered ICD-9 procedure code (see Attachment 1, Section A), and  
- ICD-9 diagnosis code 278.01 as a primary diagnosis, and  
- ICD-9 diagnosis code indicating T2DM (see Attachment 2) as a secondary diagnosis; but  
Do not contain an ICD-9 diagnosis code indicating a BMI ≥ 35 (see Attachment 1, Section C) as a secondary diagnosis. | X | X |
| 6419.2 | Contractors shall continue to pay practitioner bariatric surgery claims when performed in an approved facility for patients with a BMI ≥ 35. In other words, claims that contain the following:  
- covered HCPCS code (see Attachment 1, Section B), and  
- ICD-9 diagnosis code 278.01 as a primary diagnosis, and  
- ICD-9 diagnosis code indicating T2DM (see Attachment 2) as a secondary diagnosis; and | X | X |
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<th>Number</th>
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</table>
| 6419.2.1 | Effective for dates of service on or after February 12, 2009, contractors shall **deny** practitioner bariatric surgery claims for patients with a BMI < 35. In other words, claims that contain the following:  
• covered HCPCS code (see Attachment 1, Section B), and  
• ICD-9 diagnosis code 278.01 as the primary diagnosis, and  
• ICD-9 diagnosis code indicating T2DM (see Attachment 2) as a secondary diagnosis; but Do **not** contain an ICD-9 diagnosis code indicating a BMI ≥ 35 (see Attachment 1, Section C) as a secondary diagnosis. | X | X |       |       |   |   |   |   |                    |        |
| 6419.3 | Contractors shall use the following messages when rejecting/denying non-covered bariatric surgery claims:  
**Medicare Summary Notice:**  
15.4 – The information provided does not support the need for this service or item.  
**Claim Adjustment Reason Code:**  
167 – This (these) diagnosis(es) is (are) not covered.  
**Remittance Advice Remark Code:**  
N372 – Only reasonable and necessary maintenance/service charges are covered.  
**Group Code:**  
CO – Contractual Obligation | X | X | X |       |   |   |   |   |                    |        |
| 6419.4 | Contractors shall adjust previously processed (and paid) claims that meet the claim criteria outlined in 6419.1.1 and 6419.2.1 above. Contractors shall not search their files but shall adjust claims brought to their attention between the interim period February 12, 2009, and the implementation date of this CR. | X | X | X |       |   |   |   |   |                    |        |
| 6419.5 | Contractors shall refer to Pub. 100-04, chapter 32, section 150, for this update and existing claims processing instructions related to bariatric surgery for morbid obesity. | X | X | X |       |   |   |   |   |                    |        |
III. PROVIDER EDUCATION TABLE

<table>
<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
<th>Responsibility (place an “X” in each applicable column)</th>
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<tbody>
<tr>
<td>6419.6</td>
<td>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 &quot;MLN Matters&quot; 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. 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.</td>
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IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements: "Should" denotes a recommendation

<table>
<thead>
<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
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<tbody>
<tr>
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<td>See CR Attachments 1 and 2</td>
</tr>
</tbody>
</table>

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

V. CONTACTS

Pre-Implementation Contact(s): Joe Bryson (institutional claims), 410-7X86-2986, joseph.bryson@cms.hhs.gov, Yvette Cousar (practitioner claims), 410-786-2160, Yvette.cousar@cms.hhs.gov, Arthur Meltzer (coverage), 410-786-9974, Arthur.meltzer@cms.hhs.gov, Pat Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@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.

Attachments
A. Covered ICD-9 Procedure Codes for Bariatric Surgery

- 44.38 - Laparoscopic gastroenterostomy (laparoscopic Roux-en-Y), or
- 44.39 - Other gastroenterostomy (open Roux-en-Y), or
- 44.95 - Laparoscopic gastric restrictive procedure (laparoscopic adjustable gastric band and port insertion), or

To describe either laparoscopic or open BPD with DS, all three following codes must be on the claim:
  - 43.89 - Other partial gastrectomy, and
  - 45.51 - Isolation of segment of small intestine, and
  - 45.91 - Small to small intestinal anastomosis

B. Covered HCPCS Procedure Codes

- 43770 - Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
- 43644 - Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less).
- 43645 - Laparoscopy with gastric bypass and small intestine reconstruction to limit absorption. (Do not report 43645 in conjunction with 49320, 43847.)
- 43845 - Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
- 43846 - Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less Roux-en-Y gastroenterostomy. (For greater than 150 cm, use 43847.) (For laparoscopic procedure, use 43644.)
- 43847 - With small intestine reconstruction to limit absorption

C. ICD-9 Diagnosis Codes Indicating a BMI ≥ 35 (secondary diagnosis only)

- 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
Attachment 2

Type 2 Diabetes Mellitus ICD-9-CM Codes - FY 2009 (secondary diagnosis only)

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
250.10 Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled
250.12 Diabetes with ketoacidosis, type II or unspecified type, uncontrolled
250.20 Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled
250.22 Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled
250.30 Diabetes with other coma, type II or unspecified type, not stated as uncontrolled
250.32 Diabetes with other coma, type II or unspecified type, uncontrolled
250.40 Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled
250.42 Diabetes with renal manifestations, type II or unspecified type, uncontrolled
250.50 Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled
250.52 Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled
250.60 Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled
250.62 Diabetes with neurological manifestations, type II or unspecified type, uncontrolled
250.70 Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled
250.72 Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled
250.80 Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled
250.82 Diabetes with other specified manifestations, type II or unspecified type, uncontrolled
250.90 Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled
250.92 Diabetes with unspecified complication, type II or unspecified type, uncontrolled
A. Covered Bariatric Surgery Procedures

Effective for services on or after February 21, 2006, Medicare has determined that the following bariatric surgery procedures are reasonable and necessary under certain conditions for the treatment of morbid obesity. The patient must have a body-mass index (BMI) ≥35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. This medical information must be documented in the patient's medical record. 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/MedicareApprovedFacilities/BSF/list.asp#TopOfPage.

- Open Roux-en-Y gastric bypass (RYGBP).
- Laparoscopic adjustable gastric banding (LAGB).
- Open biliopancreatic diversion with duodenal switch (BPD/DS).
- Laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS).

B. Non-Covered Bariatric Surgery Procedures

Effective for services on or after February 21, 2006, Medicare has determined that the following bariatric surgery procedures are not reasonable and necessary for the treatment of morbid obesity.

- Open vertical banded gastroplasty.
- Laparoscopic vertical banded gastroplasty.
- Open sleeve gastrectomy.
- Laparoscopic sleeve gastrectomy.
- Open adjustable gastric banding.

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.

Complete coverage guidelines can be found in the National Coverage Determination Manual (Pub. 100-03), sections 40.5 and 100.1.

150.3 - ICD-9 Procedure Codes for Bariatric Surgery (FIs Only)
(Rev.1728, Issued: 05-04-09, Effective: 02-12-09, Implementation: 05-18-09)
A. Covered ICD-9 Procedure Codes

For services on or after February 21, 2006, the following ICD-9 procedure codes are covered for bariatric surgery:

- 44.38 - Laparoscopic gastroenterostomy (laparoscopic Roux-en-Y), or
- 44.39 - Other gastroenterostomy (open Roux-en-Y), or
- 44.95 - Laparoscopic gastric restrictive procedure (laparoscopic adjustable gastric band and port insertion), or

To describe either laparoscopic or open BPD with DS, all three following codes must be on the claim:

- 43.89 - Other partial gastrectomy, and
- 45.51 - Isolation of segment of small intestine, and
- 45.91 - Small to small intestinal anastomosis.

NOTE: There is no distinction between open and laparoscopic BPD with DS for the inpatient setting. For either approach, all three codes must appear on the claim to be covered.

B. Non-covered ICD-9 Procedure Codes

For services on or after February 21, 2006, the following ICD-9 procedure codes are non-covered for bariatric surgery:

- 44.68 - Laparoscopic gastroplasty (vertical banded gastroplasty).
- 44.69 - Other. Inversion of gastric diverticulum. Repair of stomach NOS.
- 43.89 - Other partial gastrectomy.

NOTE: 44.68 is non-covered when used to bill for open adjustable gastric banding and laparoscopic vertical banded gastroplasty. 44.69 is non-covered when used to bill for open vertical banded gastroplasty. 43.89 is non-covered when used to bill for open and laparoscopic sleeve gastrectomy.

150.6 - Claims Guidance for Payment

(Rev.1728, Issued: 05-04-09, Effective: 02-12-09, Implementation: 05-18-09)

A. Covered Bariatric Surgery Procedures

Contractors shall process covered bariatric surgery claims as follows:

1. Identify bariatric surgery claims.
• **Contractors identify inpatient** bariatric surgery claims by the presence of ICD-9-CM diagnosis code 278.01 *as the primary diagnosis* (for morbid obesity) and one of the covered ICD-9-CM procedure codes listed in §150.3.

• **Contractors identify practitioner** bariatric surgery claims by the presence of ICD-9-CM diagnosis code 278.01 *as the primary diagnosis* (for morbid obesity) and one of the covered HCPCS procedure codes listed in §150.2.

2. Perform facility certification validation for all bariatric surgery claims on a pre-pay basis.

• A list of approved facilities may be found at: [http://www.cms.hhs.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage](http://www.cms.hhs.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage).

3. **Review** bariatric surgery claims data and determine whether a pre- or post-pay sample of bariatric surgery claims need further review to assure that the beneficiary has a BMI ≥35 (V85.35 - V85.4), and at least one co-morbidity related to obesity.

• The carrier/FI/A/B MAC medical director may define the appropriate method for addressing the obesity-related co-morbid requirement.

**NOTE:** If ICD-9-CM diagnosis code 278.01 *is present, but a covered procedure code (listed in §150.2 or §150.3) is/are not present*, the claim is not for bariatric surgery and should be processed under normal procedures.

**B. Non-Covered Bariatric Surgery Procedures**

**Carriers, FIs and A/B MACs** are to process non-covered practitioner bariatric surgery claims according to the conditions outlined below:

1. Deny claims billed with HCPCS procedure code 43842 when used for:

• Open vertical banded gastroplasty.

2. Deny claims billed with HCPCS NOC code 43999 when used for:

• Laparoscopic vertical banded gastroplasty.
• Open sleeve gastrectomy.
• Laparoscopic sleeve gastrectomy.
• Open adjustable gastric banding.

**The FIs and A/B MACs** are to process non-covered inpatient bariatric surgery claims according to the conditions outlined below:

1. Reject claims billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 44.68 when used for:
• Open adjustable gastric banding.
• Laparoscopic vertical banded gastroplasty.

2. Reject claims billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 44.69 when used for:

• Open vertical banded gastroplasty.

3. Reject claims billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 43.89 when used for:

• Open sleeve gastrectomy.
• Laparoscopic sleeve gastrectomy.

NOTE: If ICD-9 procedure code 43.89 appears on the claim along with 45.51 and 45.91 to describe open or laparoscopic BPD/DS, process as a covered procedure according to §150.6.A.

150.7 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes
(Rev.1728, Issued: 05-04-09, Effective: 02-12-09, Implementation: 05-18-09)

When rejecting/denying claims because bariatric surgery procedures were performed in an unapproved facility use:

• MSN 16.2 - "This service cannot be paid when provided in this location/facility."

• Claim Adjustment Reason Code 58 - "Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."

When rejecting/denying claims for non-covered bariatric surgery procedures use:

• MSN16.10 - Medicare does not pay for this item or service.

• Claim Adjustment Reason Code 50 - "These are non-covered services because this is not deemed a “medical necessity” by the payer."

When rejecting/denying claims for covered bariatric surgery procedures because the patient did not meet the conditions for coverage use:

• MSN 15.4 - “The information provided does not support the need for this service or item.”
• Claim Adjustment Reason Code 167 - "This (these) diagnosis(es) is (are) not covered"

• Remittance Advice Remark Code N372 - “Only reasonable and necessary maintenance/service charges are covered.”

• Group Code CO – Contractual Obligation

In addition to the codes listed above, afford appeal rights to all *denied* parties.