

| | |
|--|---|
| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 3105 | Date: November 6, 2014 |
| | Change Request 8921 |

SUBJECT: Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies

I. SUMMARY OF CHANGES: The purpose of this CR is to update the manual instructions for Medicare coverage requirements and to review procedures related to items and services in FDA-approved Category A and B Investigational Device Exemptions in order to reflect current policy.

EFFECTIVE DATE: January 1, 2015

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

IMPLEMENTATION DATE: January 5, 2015

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/revise 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

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| R | Table of Contents |
| R | 32/68/Investigational Device Exemption (IDE) Studies |
| R | 32/68.1/Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies |
| R | 32/68.2/Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies |
| D | 32/68.3/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE. |
| D | 32/68.4/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE |
| D | 32/68.5/Contractor Review of Category B IDEs |

III. FUNDING:

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

Attachment - Business Requirements

| | | | |
|--------------------|--------------------------|-------------------------------|-----------------------------|
| Pub. 100-04 | Transmittal: 3105 | Date: November 6, 2014 | Change Request: 8921 |
|--------------------|--------------------------|-------------------------------|-----------------------------|

SUBJECT: Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies

EFFECTIVE DATE: January 1, 2015

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

IMPLEMENTATION DATE: January 5, 2015

I. GENERAL INFORMATION

A. Background: Section 1862(m) of the Social Security Act (and implementing regulations at 42 CFR 405 Subpart B) allows for payment of routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE studies conform to appropriate scientific and ethical standards. Additionally, the implementing regulations allowed Medicare contractors to make coverage decisions for Category B IDE devices and routine care services, in their review of claims for payment for these items and services.

B. Policy: As part of the Calendar Year (CY) 2014 Physician Fee Schedule rule, CMS modified 42 CFR 405 Subpart B of its regulations related to Medicare coverage of routine care items and services in Category A IDE studies and Medicare coverage of Category B IDE devices and routine care items and services. These regulatory modifications define Medicare coverage IDE study criteria for Category A and B IDE studies, and establish a centralized review process for approval of Category A and B IDE study protocols, for purposes of Medicare coverage. Specifically:

- Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria described in regulations are met.
- Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to submission of the first claim that the Medicare coverage IDE study criteria described in regulations are met.

II. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Responsibility | | | | | | | |
|-------------|--|----------------|---|----------------------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | D M E M A C | Shared- System Maintainers | | | | Other |
| | | A | B | | F I S S | M C S | V M S | C W F | |
| 8921 - 04.1 | Effective on and after January 1, 2015, contractors shall be aware of changes to Medicare coverage requirements and review procedures related to | X | X | | | | | | |

| Number | Requirement | Responsibility | | | | | | | |
|--------|---|----------------|---|----------------------------|----------------------------------|------------------|-------------|-------------|-------|
| | | A/B MAC | | D M E M A C | Shared- System Maintainers | | | | Other |
| | | A | B | | H H H | F I S S | M C S | V M S | |
| | items and services in FDA-approved Category A and B Investigational Device Exemptions in Pub. 100-02, Medicare Benefit Policy Manual, chapter 14, and chapter 16, section 10; and Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 68. | | | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|-------------|--|----------------|---|-------------|----------------------------|------------------|
| | | A/B MAC | | | D M E M A C | C E D I |
| | | A | B | H H H | | |
| 8921 - 04.2 | 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): Jamie Hermansen, 410-786-2064 or Jamie.Hermansen@cms.hhs.gov (Coverage), Rosemarie Hakim, 410-786-3934 or Rosemarie.Hakim@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage), Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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: 0

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents *(Rev. 3105, Issued: 11-06-14)*

68 - *Investigational Device Exemption (IDE) Studies*

68.1 - *Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies*

68.2 - *Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies*

68 – Investigational Device Exemption (IDE) Studies
(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 14 for complete Medicare coverage requirements for items and services in Category A and B IDE studies, related to these billing requirements.

NOTE: For information regarding Medicare coverage related to IDEs in Medicare Advantage plans, refer to Pub. 100-16, Medicare Managed Care Manual, chapter 4, section 10.7.2.

68.1 – Billing Requirements for Providers Billing for Routine Care Items and Services in Category A IDE Studies
(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

A. Institutional Inpatient and Outpatient Billing in Category A IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims only for routine care items and services in Category A IDE device studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection C (“General Billing Requirements”). The Category A IDE device shall not be reported on institutional claims since Category A IDE devices are not eligible for payment under Medicare.

B. Practitioner Billing in Category A IDE Studies

Routine Care Items and Services

Practitioners shall submit claims for the routine care items and services in Category A IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection C (“General Billing Requirements”). The Category A IDE device shall not be reported on practitioner claims since Category A IDE devices are not eligible for payment under Medicare.

C. General Billing Requirements

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study’s page and is always preceded by the letters “NCT.” Contractors verify the validity of a trial/study/registry by consulting CMS’s Coverage Website at: <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp>. Providers report the 8-digit number on the following claims locators:

CMS-1500 paper form-place in Field 19 (preceded by ‘CT’); or
837 P—Loop 2300, REF02, REF01=P4 (do not use ‘CT’ on the electronic claim)

In addition to the clinical trial number, claims shall include:

ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)

HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”

RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

Group Code - Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter O) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

| | | |
|---------------------|------------------------|---|
| <i>Data</i> | <i>CMS-1500</i> | <i>837i and 837p</i> |
| <i>IDE #</i> | <i>Item 23</i> | <i>Segment 2300, REF02(REF01=LX)</i> |

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services.”

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

68.2 – Billing Requirements for Providers Billing for Category B IDE Devices and Routine Care Items and Services in Category B IDE Studies

(Rev. 3105, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.

A. Institutional Inpatient Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in §69.6 of this chapter, and as described below under subsection D (“General Billing Requirements”).

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

B. Institutional Outpatient Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Institutional providers shall submit claims for the routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in section 69.6 of this chapter, and as described below under subsection D (“General Billing Requirements”).

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- *Category B IDE device HCPCS code, if applicable*
- *Appropriate HCPCS modifier:*
 - *Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or*
 - *Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or,*
 - *QA modifier for claims with dates of service prior to January 1, 2008.*
- *Category B IDE number*
- *Charges for the device billed as covered charges*

NOTE: *If the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier – FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing ‘no cost items’ under the OPSS, refer to chapter 4, §§20.6.9 and 61.3.1 of this manual.*

C. Practitioner Billing for Items and Services in Category B IDE Studies

Routine Care Items and Services

Practitioners shall submit claims for routine care items and services in Category B IDE studies approved by CMS (or its designated entity) and listed on the CMS Coverage Website, by billing according to the clinical trial billing instructions found in section 69.6 of this chapter, and as described below under subsection D (“General Billing Requirements”).

Category B Device

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

| Data | CMS-1450 | CMS-1500 | 837i and 837p |
|--------------|-----------------|-----------------|--|
| IDE # | FL 43 | Item 23 | Segment 2300, REF02(REF01=LX) |

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services.”

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.”

D. General Billing Requirements

Effective for claims with dates of service on or after January 1, 2014, it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. This is the number assigned by the NLM ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study’s page and is always preceded by the letters “NCT.” Contractors verify the validity of a trial/study/registry by consulting CMS’s Coverage Website at: <http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp>. Providers report the 8-digit number on the following claims locators:

- CMS-1500 paper form—place in Field 19 (preceded by ‘CT’); or
- 837 P—Loop 2300, REF02, REF01=P4 (do not use ‘CT’ on the electronic claim).

In addition to the clinical trial number, claims shall include:

- *ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)*
- *HCPCS modifier Q0 or Q1 as appropriate*

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

- *CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”*
- *RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”*
- *RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”*
- *Group Code-Contractual Obligation (CO)*