

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 198	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/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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Table of Contents
R	14/10/Coverage of Medical Devices
R	14/20/Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies
R	14/20.1/Medicare Requirements for Coverage of Items and Services in FDA-Approved Category A and B IDE Studies
R	14/20.2/Payment for Items and Services in Category A and B IDE Studies
R	14/20.3/FDA Withdrawal of IDE Approval or Change in Categorization
N	14/20.4/Confidentiality of IDE Information
N	14/20.5/Re-evaluation of FDA-approved IDE Device Categorization Decision
R	14/30/Hospital Institutional Review Board (IRB) Approved Non-significant Risk Devices
N	14/30.1/Payment for Hospital IRB Approved Non-significant Risk Devices
R	14/40/Services Related to and Required as a Result of Services Which are Not Covered Under Medicare

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
D	14/50/Coverage Requirements
D	14/60/Hospital Institutional Review Board (IRB) Approved IDE Devices
D	14/70/Payment for IDE Category B Devices
D	14/80/Services Related to and Required as a Result of Services Which are not Covered Under Medicare
D	14/90/FDA Withdrawal of IDE Approval
D	14/100/Confidentiality of IDE Information
D	14/110/Appeals Process for FDA IDE Categorization Decisions
R	16/10/General Exclusions from Coverage

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. 100-02	Transmittal: 198	Date: November 6, 2014	Change Request: 8921
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SUBJECT: Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies

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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 - 02.1	Effective on and after January 1, 2015, contractors shall be aware of changes to the Medicare coverage requirements and review procedures related to items	X	X						

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	and services in FDA-approved Category A and B Investigational Device Exemption (IDE) Studies 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	C E D I
		A	B	H H H		
8921 - 02.2	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 Benefit Policy Manual

Chapter 14 - Medical Devices

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10 - Coverage of Medical Devices

(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

The Food and Drug Administration (FDA) defines a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

For dates of service on or after November 1, 1995, Medicare may cover certain FDA-approved and Institutional Review Board (IRB)-approved investigational devices and services incident to, provided the investigational device meets *certain requirements, including:*

- The device or services associated with the use of a device were provided to the beneficiary within the start and end dates contained in the master file;
- There *are no regulations, national coverage policies, or manual instructions* that would otherwise prohibit Medicare coverage.

Devices that may be covered under Medicare include the following categories:

- Devices approved by the FDA through the Pre-Market Approval (PMA) process;
- Devices cleared by the FDA through the 510(k) process;
- FDA-approved *Investigational Device Exemption (IDE)* Category B devices; and
- Hospital IRB-approved *non-significant risk* devices.

NOTE: Study sponsors are not required to seek Medicare coverage in order to conduct their studies or trials.

20 – Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies

(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

NOTE: Throughout this section, the terms “study” and “trial” are used interchangeably.

The FDA assigns a special identifier number that corresponds to each device granted an IDE. For purposes of assisting *the Centers for Medicare & Medicaid Services (CMS)* in determining Medicare coverage *of items and services in IDE studies*, the FDA will place all approved IDE *devices* in one of two categories:

Category A (Experimental) device, which refers to a device for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective;

or

Category B (Non-experimental/investigational) device, which refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

The FDA notifies CMS when it notifies the IDE study sponsor (i.e. manufacturer) that the device is categorized as either Category A or Category B.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is not a national non-coverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the beneficiary were not enrolled in a clinical study.

20.1 – Medicare Requirements for Coverage of Items and Services in FDA-approved Category A and B IDE Studies

(Rev. 198, Issued: 11- 06-14, Effective: 01-01-15, Implementation: 01-05-15)

A. Category A IDE Studies

Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met (as described below).

B. Category B IDE Studies

Medicare may make payment for a Category B 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 the submission of the first related claim that the Medicare coverage IDE study criteria are met (as described below).

C. Seeking CMS Approval of Category A and B IDE Studies for Purposes of Medicare Coverage

Effective for Category A and B IDE studies approved by the FDA on or after January 1, 2015, interested parties (i.e., study sponsors) that wish to seek Medicare coverage in Category A or B IDE studies must submit a request for review and approval via email to clinicalstudynotification@cms.hhs.gov or via hard copy to the following address:

*Centers for Medicare and Medicaid Services
Center for Clinical Standards and Quality
Director, Coverage and Analysis Group
ATTN: Clinical Study Certification
Mail Stop: S3-02-01
7500 Security Blvd.
Baltimore, MD 21244*

Interested parties do not need to submit both electronic and hard copies of requests.

Each request must include the following information:

- *A request letter that describes the scope and nature of the IDE study, discussing how the interested party believes that the IDE study meets each of the Medicare Coverage IDE Study Criteria (described below),*
- *FDA approval letter of the IDE,*
- *IDE study protocol,*
- *IRB approval letter (interested parties need only submit one IRB approval letter with their request),*
- *NCT number, and*
- *Supporting materials, as appropriate.*

For each Category A or B IDE study approved for purposes of Medicare coverage, CMS will post on the CMS Coverage Website the following information:

- *Study title,*
- *Sponsor name,*
- *NCT number,*
- *IDE number, and*
- *CMS approval date.*

Providers participating in and seeking Medicare reimbursement for items and services in Category A or B IDE studies, prior to submitting claims, are responsible for checking the CMS Coverage Website to identify whether CMS (or its designated entity) has approved the study for purposes of Medicare coverage.

NOTE: *For billing requirements for items and services in FDA-approved Category A and B IDE studies, see Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 68.*

Contractors must check the CMS Coverage Website list of approved Category A and B IDE studies prior to processing related claims for Medicare payment.

D. Medicare Coverage IDE Study Criteria

For purposes of Medicare coverage of items and services in Category A and B IDE studies, an IDE study must meet all of the following criteria:

1. *The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.*
2. *The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.*
3. *The study results are not anticipated to unjustifiably duplicate existing knowledge.*

4. *The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.*
5. *The study is sponsored by an organization or individual capable of successfully completing the study.*
6. *The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.*
7. *Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.*
8. *The study is registered with the National Institutes of Health's National Library of Medicine's ClinicalTrials.gov.*
9. *The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes, and that the release should be hastened if the study is terminated early.*
10. *The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.*

NOTE: *These requirements do not provide coverage for any devices or services that would otherwise not be covered by Medicare outside the study (e.g., statutorily excluded devices or items and services excluded from coverage through regulation or manual instructions).*

20.2 - Payment for Items and Services in Category A and B IDE Studies **(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)**

Payment for Category A and B IDE study routine care items and services, or Category B IDE devices, may not exceed what Medicare would have paid for comparable approved routine care items and services and devices.

20.3 - FDA Withdrawal of IDE Approval or Change in Categorization **(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)**

If the FDA becomes aware that a categorized device no longer meets certain requirements and a sponsor (e.g., a manufacturer) loses its Category B status, or violates relevant IDE requirements necessitating FDA's withdrawal of IDE approval, all payment for the device and related routine care items and services should cease. The CMS master file and CMS Coverage Website will be updated to reflect withdrawals of FDA IDE approvals and categorization changes, as appropriate.

20.4 – Confidentiality of IDE Information **(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)**

*Contractors may **not** release claims information or information received that is proprietary in nature to the sponsor (e.g., a manufacturer). Since the IDE number as well as other information will be necessary to process claims, the contractor must take appropriate action to ensure that the confidentiality of the information is*

protected. Because this information is proprietary in nature, the contractor may not release it under the Freedom of Information Act.

20.5 – Re-evaluation of an FDA-approved IDE Categorization Decision (Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

Any sponsor (i.e., manufacturer) that does not agree with the FDA decision that categorizes its device as Category A may submit a written request asking the FDA to reevaluate its categorization decision. The sponsor (i.e., a manufacturer) may send a written request to the FDA at any time asking for a reevaluation of its original categorization decision, submitting any additional evidence and information which it believes supports a re-categorization. The FDA notifies both CMS and the sponsor (i.e., manufacturer) of its reevaluation decision.

If the FDA reconfirms its original decision on the categorization of the device, the sponsor (e.g., a manufacturer) may seek a review by the CMS Central Office. The device sponsor (e.g., a manufacturer) must submit its request in writing, and must include all materials submitted with its reevaluation request to the FDA. Review requests must be addressed to:

*Centers for Medicare & Medicaid Services
Attn: IDE Categorization Review
Mail Stop: S3-02-01
Coverage and Analysis Group,
Center for Clinical Standards and Quality,
7500 Security Blvd.
Baltimore, MD 21244-1850*

The CMS staff will review this information to determine whether to change the categorization of the device and will issue a written decision notifying both the device sponsor (e.g., a manufacturer) and the FDA of its decision. In evaluating a manufacturer's request for re-categorization, CMS will review only that information submitted to the FDA. Information not submitted to the FDA for its consideration will not be reviewed by CMS.

To the extent that CMS relies on confidential commercial or trade secret information in any judicial proceeding, CMS will maintain confidentiality of the information in accordance with Federal law.

No reviews of a categorization decision other than those described above are available to a sponsor (e.g., a manufacturer). Neither the FDA original categorization decision or reevaluation, nor CMS' review constitutes an initial determination for purposes of the Medicare appeals processes under part 405, subpart G or subpart H or parts 417, 473, or 498 of title 42 of the Code of Federal Regulations.

30 - Hospital Institutional Review Board (IRB) Approved Non-significant Risk Devices (Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

Clinical trials for non-significant risk devices (devices which do not require an FDA-approved IDE) are the responsibility of the hospital's IRB. While these devices do not require an FDA-approved IDE, many of the FDA-approved IDE requirements apply to these non-significant risk devices (e.g., they may not be legally marketed). Medicare contractors are responsible for making the coverage determinations on non-significant devices that are the responsibility of the hospital's IRB. Contractors should apply the same coverage criteria, where appropriate, to these devices as are applied to FDA-approved IDE Category A and B IDE devices.

***30.1 – Payment for Hospital IRB Approved Non-significant Risk Devices
(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)***

Payment for an IRB approved device (provided to a non-hospital patient) and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.

***40 - Services Related to and Required as a Result of Services Which are Not Covered Under Medicare
(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)***

Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered under Medicare. These non-covered services include all services furnished in preparation for the use of a non-covered device, services furnished contemporaneously with, and necessary to the use of, a non-covered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related non-covered services.

Refer to Pub. 100-02, Medicare Benefit Policy Manual, Chapter 16, “General Exclusions from Coverage,” §180 - “Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.”

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Chapter 16 - General Exclusions From Coverage
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10 – General Exclusions *from* Coverage

10 - General Exclusions *from* Coverage

(Rev. 198, Issued: 11-06-14, Effective: 01-01-15, Implementation: 01-05-15)

No payment can be made under either the hospital insurance or supplementary medical insurance program for certain items and services, when the following conditions exist:

- Not reasonable and necessary (§20);
- No legal obligation to pay for or provide (§40);
- Paid for by a governmental entity (§50);
- Not provided within United States (§60);
- Resulting from war (§70);
- Personal comfort (§80);
- Routine services and appliances (§90);
- Custodial care (§110);
- Cosmetic surgery (§120);
- Charges by immediate relatives or members of household (§130);
- Dental services (§140);
- Paid or expected to be paid under workers' compensation (§150);
- Non-physician services provided to a hospital inpatient that were not provided directly or arranged for by the hospital (§170);
- Services Related to and Required as a Result of Services Which are not Covered Under Medicare (§180);
- Excluded foot care services and supportive devices for feet (§30); or,

Excluded investigational devices (See Chapter 14).