
CMS Manual System

Pub. 100-20 One-Time Notification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 131

Date: DECEMBER 17, 2004

CHANGE REQUEST 3548

SUBJECT: Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices

I. SUMMARY OF CHANGES: Section 731 (b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) authorizes Medicare to cover the routine costs of clinical trials involving IDE category A devices effective for routine costs incurred on or after January 1, 2005. This extension of coverage only refers to the routine services performed for such a trial. The Category A device itself remains non-covered.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 1, 2005

IMPLEMENTATION DATE: January 3, 2005

II. CHANGES IN MANUAL INSTRUCTIONS

(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification
	Recurring Update Notification

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

Attachment – One-Time Notification

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SUBJECT: Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices

I. GENERAL INFORMATION

A. Background: Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Centers for Medicare & Medicaid Services (CMS) limited coverage of clinical trials to Investigational Device Exemption (IDE) Category B trials (42 CFR Subpart B) and routine costs for qualifying clinical trials (Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, section 310.1). Section 731(b) of the MMA expands the ability of CMS to cover costs in clinical trials by authorizing coverage of routine costs in certain IDE Category A trials. New regulations have been established to implement this statute. 69 FR 66236, 66420 (November 15, 2004).

B. Policy: Section 731 (b) of the MMA authorizes Medicare to cover the routine costs of clinical trials involving IDE Category A devices effective for routine costs incurred on or after January 1, 2005. Category A (experimental/investigational) devices are innovative medical devices believed to be in Class III, for which “absolute risk” of the device has not been established (that is, initial questions of safety and effectiveness have not been resolved and the Food and Drug Administration (FDA) is unsure whether the device can be safe and effective). For a trial to qualify for payment of routine costs, it must meet certain criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards. In addition, the MMA established additional criteria for trials initiated before January 1, 2010, to ensure that the devices involved in these trials be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. As guidance in evaluating the immediately life-threatening requirement, contractors should use the following definition: “a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.”

CMS defines and provides examples for routine costs in the Medicare NCD Manual section 310.1.

It is the responsibility of the provider participating in the clinical trial to furnish all necessary information concerning the device, the clinical trial, and participating Medicare beneficiaries that the contractor deems necessary for a coverage determination and claims processing. The provider must contact their local Medicare contractor before billing for this service.

Physicians billing for routine costs in a clinical trial where a Category A device is used for a patient with a life-threatening condition, must place the IDE number of the Category A device on Form CMS-1500 paper claim in Item 23. Physicians who bill electronically must place the IDE number on the 2300 Investigational Device Exemption Number REF segment, data element REF02 (REF01=LX) of the 837p.

Hospitals must place the Category A IDE number on the 837i electronic claim format in 2300 Investigational Device Exemption Number REF Segment, data element REF02 (REF01=LX). If billing on Form CMS-1450 paper form, the IDE number must be in Form Locator 43.

NOTE: The Category A device itself remains non-covered. This extension of coverage effective on and after January 1, 2005, only pertains to the routine costs in a clinical trial that involves an IDE Category A device, and only when such device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3548.1	Contractors shall process claims for routine costs of clinical trials that involve IDE Category A devices effective for dates of service on and after January 1, 2005.	X		X						
3548.1.1	Contractors shall follow the same claims processing criteria for processing routine costs in a clinical trial associated with an IDE Category A device as is currently done for routine costs associated with an IDE Category B device. (For example, providers shall furnish certain information to the contractor prior to submission of a claim for payment, i.e., a copy of the FDA approval letter with the approved IDE code number, name of the device, etc.)	X		X						

Requirement Number	Requirements	Responsibility (place an "X" in the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CBF	
3548.2	<p>Contractors shall determine that the Category A device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.</p> <p>(Contractors should use the following definition as guidance in evaluating the immediately life-threatening requirement: "a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.")</p>	X		X						
3548.3	<p>Carriers shall accept the following on claims for routine costs in a clinical trial associated with an IDE Category A device:</p> <ul style="list-style-type: none"> • QV modifier • ICD-9 diagnosis code V70.7 			X						
3548.4	<p>FIs shall accept the following on claims for routine costs in a clinical trial associated with an IDE Category A device:</p> <ul style="list-style-type: none"> • Condition code 30 • ICD-9 diagnosis code V70.7 	X								
3548.5	<p>FIs shall accept the following on outpatient claims for routine costs in a clinical trial associated with an IDE Category A device:</p> <ul style="list-style-type: none"> • Revenue code 0624 • Condition code 30 • QV modifier • ICD-9 diagnosis code V70.7 	X								
3548.6	<p>Contractors shall continue to deny provider (RTP) claims submitted for IDE Category A devices themselves (as devices used in Category A clinical trials remain non-covered by Medicare).</p>	X		X						

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: CMS is working to obtain a modifier that will be required, in addition to the QV modifier, for providers to use when billing for routine costs of clinical trials involving IDE Category A devices used in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Information on this will be forthcoming in a future instruction.

X-Ref Requirement #	Instructions
3548.1.1	Contractors should look in the short descriptor field of the IDE database for the Category A designation.

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

<p>Effective Date*: January 1, 2005</p> <p>Implementation Date: January 3, 2005</p> <p>Pre-Implementation Contact(s): JoAnna Baldwin (coverage policy), 410-786-7205 jbaldwin@cms.hhs.gov</p> <p>Joe Bryson (Part A claims processing), 410-786-2986 jbryson2@cms.hhs.gov</p> <p>Vera Dillard, (Part B claims processing), 410-786-6149 vdillard@cms.hhs.gov</p> <p>Post-Implementation Contact(s): Regional Office</p>	<p>Medicare Contractors shall implement these instructions within their current operating budgets.</p>
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