Medicare Learning Network
MLN Matters
CMS CENTERS for MEDICARE & MEDICAID SERVICES
Information for Medicare Fee-for-Service Health Care Professionals

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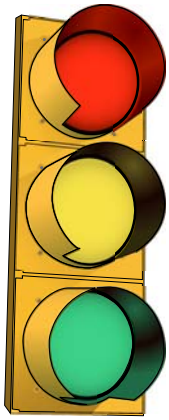
MMA - Coverage of Routine Costs of Clinical Trials Involving Investigational Device Exemption (IDE) Category A Devices

Note: This article was revised to contain web addresses that conform to the new CMS web site and to show they are now MLN Matters articles. All other information remains the same.

Provider Types Affected

Physicians and providers

Provider Action Needed



STOP – Impact to You

Effective for routine costs incurred on or after January 1, 2005, Medicare will cover the routine costs of clinical trials involving Investigational Device Exemption (IDE) Category A devices (used in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition).

CAUTION – What You Need to Know

This extension of coverage refers to the routine services performed for such clinical trials. The Category A device itself remains non-covered.

GO – What You Need to Do

This extension of coverage refers to the routine services performed for such clinical trials. The Category A device itself remains non-covered.

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:

- IDE Category B trials (21 CFR 405.201); and
- Routine costs for qualifying clinical trials (National Coverage Determinations (NCD) Manual 310.1).

The MMA (Section 731(b)) expands the ability of CMS to cover costs in clinical trials by authorizing coverage of routine costs in certain clinical trials involving IDE Category A devices effective for routine costs incurred on or after January 1, 2005.

This extension of coverage refers to the routine services performed for such a trial, and the Category A device itself remains non-covered.

Category A (experimental/investigational) devices are innovative medical devices about which the Food and Drug Administration (FDA) has major questions regarding safety and effectiveness. For a trial to qualify for payment of routine costs, it must meet certain criteria established by the Secretary of the Department of Health and Human Services 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:

1) Diagnosis;

2) Monitoring; or

3) Treatment of an immediately life-threatening disease or condition ("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).

Providers participating in the clinical trial are responsible for furnishing all information the Medicare contractor (carrier or fiscal intermediary) deems necessary for coverage determination and claims processing regarding:

- The device;
- The clinical trial; and
- The participating Medicare beneficiaries.

Also, the provider must contact their local Medicare carrier or intermediary before billing for this service.

Billing Instructions

For routine services performed in a clinical trial where a Category A device is used for a patient with a life-threatening condition:

- Physicians billing with the CMS Form 1500 must place the IDE number of the Category A device in Item 23;
- Physicians billing electronically must place the IDE number on the 2300 Investigational Device Exemption Number REF segment, data element REF02 (REF01=LX) of the 837p; and
- 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 the CMS-1450 paper form, the IDE number must be in Form Locator 43.
- All providers should place the QV modifier on the claim to reflect routine costs in a clinical trial associated with an IDE Category A device. Note, however, that CMS is working to obtain another

modifier that will be required in addition to the QV modifier. Further news will be provided on that modifier once CMS receives it.

- All providers should also note that Medicare will continue to deny claims submitted for the IDE Category A device itself.

Implementation

The implementation date for this instruction is January 3, 2005.

Additional Information

For complete details, please see the official instruction issued to your carrier/intermediary regarding this change. That instruction may be viewed by going to http://www.cms.hhs.gov/transmittals/Downloads/R131OTN.pdf on the CMS web site.

If you have any questions, please contact your carrier/intermediary at their toll-free number, which may be found at http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip on the CMS web site.