

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



Revised product from the Medicare Learning Network® (MLN)

- [“Medicare Disproportionate Share Hospital”](#) Fact Sheet (ICN 006741)

MLN Matters® Number: MM8921

Related Change Request (CR) #: CR 8921

Related CR Release Date: November 6, 2014

Effective Date: January 1, 2015

Related CR Transmittal #: R3105CP and R198BP

Implementation Date: January 5, 2015

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

Provider Types Affected

This MLN Matters® Article is intended for providers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8921, which announces changes effective on and after January 1, 2015, to Medicare coverage requirements and review procedures related to items and services in Food and Drug Administration (FDA) approved Category A and B IDE studies. CR8921 makes changes to the following Medicare manuals:

- “Medicare Benefit Policy Manual,” Chapter 14;
- “Medicare Benefit Policy Manual,” Chapter 16, Section 10; and
- “Medicare Claims Processing Manual,” Chapter 32, Section 68.

Make sure that your billing staffs are aware of these changes.

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Background

Section 1862(m) of the Social Security Act and regulations at 42 CFR 405 Subpart B allows for payment of routine costs of care furnished to Medicare beneficiaries in Category A IDE studies and authorizes the Secretary to establish criteria to ensure that Category A IDE studies conform to appropriate scientific and ethical standards. Additionally, the 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.

Category A (Experimental) device 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.

Category B (Non-experimental/investigational) device 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 the Centers for Medicare & Medicaid Services (CMS) when it notifies the IDE study sponsor (i.e. manufacturer) that the device is categorized as either Category A or Category B.

As part of the Calendar Year (CY) 2014 Physician Fee Schedule rule, CMS modified its regulations at 42 CFR 405 Subpart B, related to Medicare coverage of routine care items and services in Category A and B IDE studies and Medicare coverage of Category B IDE devices, effective January 1, 2015. For purposes of Medicare coverage in Category A and B IDE studies, these regulatory modifications define Medicare coverage requirements, Medicare coverage IDE study criteria, and establish a centralized review process for approval of Category A and B IDE studies.

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 must submit a request for review and approval to CMS. Revised Chapter 14 of the “Medicare Benefit Policy Manual” contains detailed instructions on seeking CMS approval of Category A and B IDE studies for purposes of Medicare coverage. Additional information regarding submission of Category A and B IDE study review requests, along with the list of CMS-approved studies is available on the CMS Coverage Website at

<http://www.cms.gov/Medicare/Coverage/IDE/index.html>.

Medicare claims for routine care items and services related to Category A or B IDE studies and Category B IDE devices should be submitted to MACs that will identify routine costs for which Medicare payment is made for each related claim.

NOTE: IDE studies approved by MACs prior to January 1, 2015, will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study

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sponsors should continue to follow the process established by the MAC for any site additions or protocol changes.

Additional Information

The official instruction, CR8921, issued to your MAC regarding this change, via two transmittals. The first updates the “Medicare Claims Processing Manual” and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3105CP.pdf> on the CMS website. The second updates the “Medicare Benefit Policy Manual” and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R198BP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net/work-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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