

# MEDICARE REIMBURSEMENT FOR MEDICAL DEVICES AND PATIENT CARE COSTS ASSOCIATED WITH CLINICAL TRIALS<sup>1</sup>

This advisory provides an overview of the policies of the Centers for Medicare and Medicaid Services (CMS) with respect to Medicare reimbursement for certain medical devices and related patient care services involved in clinical trials approved by the Food and Drug Administration (FDA) or Institutional Review Boards (IRBs). It begins with background information on the FDA's classification system, a factor in determining reimbursement for clinical trial costs in certain instances. It then discusses three CMS policies that support Medicare reimbursement of selected clinical trial costs: Medicare's investigational device coverage regulation of 1995; Medicare's National Coverage Determination on clinical trials and Medicare's coverage with evidence development.

## FDA Medical Device Classification System

FDA classification is an important factor in Medicare reimbursement for selected costs associated with clinical trials. Generally, the agency classifies products for purposes of regulation into three general classes based on the degree of control needed to assure the safety and effectiveness of the device. Devices are classified depending on their intended use as well as the risk the device presents to the patient and the user. Device classification requirements are as follows:<sup>2</sup>

- **Class I** devices must meet certain general controls that relate to issues such as labeling and manufacturing specifications.
- **Class II** devices must meet any performance standards or special controls developed by the FDA for that type of device in addition to meeting the general control requirements for Class I products.
- **Class III** devices are those devices that cannot be classified into Class I or Class II because there is insufficient information to determine the adequacy of general controls, performance standards, or special controls in providing reasonable assurance of their safety or effectiveness. Generally, Class III devices are life-supporting, life-sustaining, implantable devices, or devices that present potentially unreasonable risk of illness or injury.

Most Class I devices are exempted from the FDA's regulatory review process. For the remaining Class I, most Class II and all Class III devices, the FDA must conduct a review before these products can be introduced in the market. FDA product review and clearance of a device occurs by either a detailed review of the device (referred to as a pre-market approval or PMA), or through a more routine pre-market notification (referred to as a 510(k) process).

In many cases, device manufacturers need to obtain clinical data before submitting an application for product clearance. The FDA may issue an **investigational device exemption** (IDE) in order for these products to be shipped lawfully for purposes of conducting the clinical trial.

Additionally, manufacturers or other parties may need to conduct clinical trials for non-significant risk devices that do not require an FDA-approved IDE. These trials are generally managed under the direction of a hospital's Institutional Review Board (IRB).

The FDA assigns a special identifier number that corresponds to each device granted an IDE. The FDA also assigns all approved IDEs to one of two categories to assist the Medicare program in determining coverage for such devices. The two categories are as follows:<sup>3</sup>

- **Category A: Experimental/Investigational** – Innovative devices believed to be in class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved and the FDA is unsure whether the device type is safe and effective).<sup>4</sup>
- **Category B: Non-experimental/Investigational** – Devices believed to be in classes I or II, or devices believed to be in Class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of the 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 approval for that device type.<sup>5</sup>

## Medicare Policies for Reimbursement of Clinical Trial Related Costs

Under certain circumstances, Medicare may reimburse providers of care for certain costs associated with clinical trials. This section discusses three general alternatives for reimbursement: reimbursement available through the Medicare investigational device coverage regulation; reimbursement available through Medicare's National Coverage Determination on clinical trials and reimbursement available through coverage with evidence development.

### *Medicare Investigational Device Coverage Regulation*

In 1995, the Medicare program announced that it would reimburse providers for costs associated with some IDE-approved clinical trials.<sup>6</sup> Under this regulation, Medicare provides for coverage and reimbursement for certain costs associated with non-experimental/investigational (Category B) device trials. In order to be reimbursed, the device must be used in an FDA-approved clinical trial, and its application must be reasonable and medically necessary.

With respect to medical necessity, Medicare coverage of Category B device trials is subject to the same process and criteria used by Medicare contractors (referred to as fiscal intermediaries (FIs), carriers, or Medicare administrative contractors (MACs)) when making decisions for legally marketed devices and related procedures. In addition, coverage is limited to beneficiaries meeting the FDA-approved IDE study protocol requirements.

If the Medicare contractor determines that a Category B device trial is covered, payment will be made for device and related costs. The amount is based on, and may not exceed, the amount that would have been paid for a currently used device serving the same medical purpose that has been approved or cleared for marketing by the FDA.<sup>7</sup> In cases involving a hospital stay, the payment (based on the Diagnosis Related Group or DRG) ordinarily will not be affected.

Providers of care seeking Medicare reimbursement for clinical trial device and patient care costs should first consult with their local Medicare fiscal intermediary, carrier or MAC for specific instructions, as well as a determination of Medicare reimbursement. A directory of local Medicare contractor websites can be found at:

[http://www.cms.hhs.gov/ContractingGeneralInformation/Downloads/02\\_ICdirectory.pdf](http://www.cms.hhs.gov/ContractingGeneralInformation/Downloads/02_ICdirectory.pdf).

If a Medicare contractor determines that the Category B trial is not eligible for reimbursement, payment for medical and hospital services that are related to the use of device are also not covered.<sup>8</sup> However, Medicare payment may be made for services to treat a condition or complication that arises because of the use of a non-covered Category B device, or from the furnishing of related non-covered services associated with a Category B trial.

Medicare contractors are also responsible for making coverage determinations on non-significant risk devices that are the responsibility of the hospital's IRB.<sup>9</sup> Contractor determination of coverage is made by applying the same criteria as that applied to FDA-approved IDE Category B devices.

There are special billing instructions for hospitals and physicians who are submitting claims for reimbursement of clinical trials involving an investigational device under the investigational device regulation. Such submittals must include information about the device under study, as well as additional coding modifiers. For more details about specific billing instructions, refer to the *Medicare Claims Processing Manual* at:

<http://www.cms.hhs.gov/manuals/downloads/clm104c32.pdf> (section 68).

In addition, effective April 7, 2008, CMS will be implementing revised billing instructions. For more details, refer to CMS transmittal 1418 at:

<http://www.cms.hhs.gov/transmittals/downloads/R1418CP.pdf>.

### *Medicare National Coverage Determination on Clinical Trials*

In addition to Medicare investigational device coverage, the program provides for coverage of routine costs associated with patients enrolled in qualified clinical trials. Specifically, this coverage determination expands Medicare coverage of clinical trials to include certain products that do not qualify for coverage under the 1995 investigational device exemption coverage regulation described above and are not yet FDA approved, such as pharmaceutical products and certain Category A medical devices.

The current National Coverage Determination (NCD) detailing the requirements of such trials and outlining the costs eligible for reimbursement can be accessed at

[http://www.cms.hhs.gov/mcd/viewncd.asp?ncd\\_id=310.1&ncd\\_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials](http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials).

In order for a clinical trial to be eligible for coverage under Medicare's NCD, it must meet certain conditions. These conditions are listed in Appendix A. Some clinical trials are presumed to meet these characteristics and automatically qualify to receive Medicare coverage. These trials include the following:

- Trials funded or supported by centers of cooperative groups that are funded by the National Institutes of Health, the Center for Disease Control and Prevention, the Agency

for Healthcare Research and Quality, the Center for Medicare & Medicaid Services, the Department of Defense, or the Department of Veterans Affairs

- Trials conducted under an investigational new drug (IND) application reviewed by the FDA
- Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until qualifying criteria are developed and the certification process is in place.

Based on these criteria, if a clinical trial qualifies for coverage, Medicare will reimburse providers for routine patient care costs associated with such clinical trials. The definition of routine cost is provided in Appendix B. Payment for routine costs is based on the payment methodology specific to the provider and the type of service provided (e.g. physician schedule, lab fee schedule, durable medical equipment (DME) fee schedule, reasonable charge, etc.).<sup>10</sup> Where the payment is bundled (e.g. DRG payments), Medicare will adjust amounts paid for non-covered investigational items and services for which payment should not have been included as part of the bundled payment.

The Medicare Modernization Act of 2003 expanded the national coverage policy for clinical trials by authorizing coverage for routine costs related to Category A devices.<sup>11</sup> (The devices themselves are not covered by this provision.) Effective January 1, 2005, Category A devices used in the “diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition” will qualify, provided other requirements outlined herein are met. Other Category A devices will be eligible for coverage on or after January 1, 2010.

It should be noted that the Medicare investigational device coverage regulation discussed previously provides coverage for the investigational device itself. In contrast, Medicare’s National Coverage Determination (NCD) on clinical trials does not provide coverage of the Category A investigational device, but rather provides for coverage only for routine care costs.

In July 2007, CMS revised this NCD and clarified that routine costs include investigational items and services typically covered outside of the clinical trial. In addition, CMS expanded the national coverage policy to include trials conducted under Medicare’s Coverage with Evidence Development (CED). Specifically, CMS, through the national coverage determination (NCD) process may determine that certain items and services for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a “reasonable and necessary” determination, are only reasonable and necessary when provided in a clinical trial that meets the requirements defined in that NCD. For more information on CED, please see below.

No further changes were made to the policy pending CMS’ review of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85 which was passed on September 27, 2007. CMS wants to ensure that future changes to this policy would not impose duplicative or inconsistent obligations to those posed by the FDA.<sup>12</sup>

## *Medicare Coverage with Evidence Development (CED)*

CMS also provides for a coverage mechanism, referred to as coverage with evidence development (CED), in order to extend coverage for selected medical procedures, contingent upon the collection of additional data.<sup>13</sup> CED is only relevant after a formal National Coverage Determination request has been initiated. In general, CED allows for coverage of FDA-approved<sup>14</sup> medical technologies and services when improvements in health outcomes have not been conclusively demonstrated, although evidence exists to suggest that coverage may provide an important patient benefit.

There are two types of coverage with evidence development.

- **Coverage with Appropriateness Determination (CAD):** The item or service is covered only when specific data are submitted in addition to claims data to demonstrate that the item or service was provided as specified in the NCD.
- **Coverage with Study Participation (CSP):** The item or service is covered only after a formal National Coverage Determination request has been initiated and it is provided within a setting in which there is a pre-specified process for gathering additional data, and in which that process provides additional protections and safety measures for beneficiaries, such as those present in certain clinical trials.

### **Coverage with Appropriateness Determination (CAD)**

Most National Coverage Determinations have restrictions ensuring that competent professionals are providing care to the appropriate patients. CMS may have concerns that the beneficiaries receiving the item or service are meeting the conditions of coverage specified in the NCD.

In these cases, CAD allows CMS to ensure that the new technology is provided appropriately to patients meeting the specified characteristics by requiring the reporting of data that is not routinely reported on the claim form. The additional clinical data is submitted to a database or registry specifically designed for collecting data specified by the NCD in question. CMS will only accept data from registries conforming to accepted standards; however, CMS will not routinely be involved in the development, oversight, or maintenance of the databases or registries.

### **Coverage with Study Participation (CSP)**

Coverage with study participation (CSP) allows CMS to issue a determination of coverage for an item or service upon conditions that it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise. The following list includes some of the evidentiary findings that might lead CMS to provide coverage under CSP. Without CSP, these items and services would be noncovered.

- Available evidence has not evaluated outcomes that are relevant to Medicare beneficiaries

- Research has failed to address adequately the risks and benefits to Medicare beneficiaries for off-label or other unanticipated uses of a drug, biologic, service or device
- New applications may exist for diagnostic services and devices already on the market, but little or no published research supports Medicare coverage at the time of the National Coverage Determination request
- Sufficient evidence about the health benefits of a given item or service to support a reasonable and necessary determination is available only for a subgroup of Medicare patients. Other patient subgroups require additional evidence to determine if the item or service is reasonable and necessary.

CMS will decide whether certain trials will be covered under CSP. This decision will be based on whether the studies conform to certain standards of the National Coverage Determination on clinical trials and address evidence requirements specified in the NCD for the particular item or service.

CSP is intended to result in new evidence that assists CMS in the coverage process for an item or service. If the research is published in a peer-reviewed journal, the evidence will be used in an NCD reconsideration to determine if a change in Medicare coverage is appropriate. In addition, CSP results in clinical evidence influencing clinical practice and helping Medicare beneficiaries and providers make the most appropriate diagnostic and therapeutic decisions.<sup>15</sup>

## Appendix A

In order for a clinical trial to be eligible for coverage under Medicare's national clinical policy, the following is required:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- It trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

In addition, the clinical trial should have the following desirable characteristics in order to qualify:

- The principal purpose of the clinical trial is to test whether the intervention potentially improves the participants' health outcomes;
- The trial 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;
- The trial does not unjustifiably duplicate existing studies;
- The trial design is appropriate to answer the research question being asked in the trial;
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity.<sup>16</sup>

## Appendix B

Routine costs associated with clinical trials include the following:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care).
- Items and services required solely for the provision of the investigational item or service. (e.g., administration of a noncovered chemotherapeutic agent).
- Items and services required for the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
- Items and services that are medically necessary for the diagnosis or treatment of complications arising from the provision of an investigational item or service.

Routine costs of clinical trials exclude:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial
- Items and services-
  - For which there is no Medicare benefit category
  - Which are statutorily excluded
  - Fall under a national noncoverage determination
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

- 
- <sup>1</sup> Information presented in this document is current as of January 15, 2008. Any subsequent changes which may occur in coding, coverage and payment are not reflected herein.
- <sup>2</sup> Refer to the following: <http://www.fda.gov/cdrh/devadvice/3132.html>
- <sup>3</sup> Medicare Benefit Policy Manual, Chapter 14, Medical Devices. To access, go to: <http://www.cms.hhs.gov/manuals/Downloads/bp102c14.pdf>.
- <sup>4</sup> Category A devices include the following: (1) Class III devices of a type for which no marketing application has been approved through the pre-market approval process for any indication for use; and (2) Class III devices that would otherwise be in Category B but have undergone significant modification for a new clinical indication for use. (Refer to 42 CFR §411.406 Addendum).
- <sup>5</sup> Category B devices include the following: (1) Class I, II, or III devices under investigation to establish equivalence to a previously/currently marketed device; (2) Class III devices whose technological characteristics and clinical indications for use are comparable to a PMA-approved device; (3) Class III devices with technological changes that represent advances to a device that has already received pre-market approval, i.e., generational changes; (4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new clinical indication for use, and no significant modifications to the device were required; (5) Class III devices that were in commercial distribution before May 28, 1976, and become the subject of an IDE after the FDA requires pre-market approval; (6) Non-significant risk device investigations for which the FDA required the submission of an IDE. (Refer to 42 CFR §411.406 Addendum)
- <sup>6</sup> Refer to Federal Register, vol. 60, no. 181, September 19, 1995. To access, go to: [http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=48417&dbname=1995\\_register](http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=48417&dbname=1995_register)
- <sup>7</sup> Refer to 42 CRF Part §405.209.
- <sup>8</sup> Non-covered services include those that are: (1) furnished in preparation for the use of a non-covered device; (2) furnished contemporaneously with and necessary to the use of a non-covered device; and (3) 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 CFR Part 405, Subpart B, §405.207(a))
- <sup>9</sup> Medicare Carriers Manual, Transmittal 1704, May 25, 2001. To access, go to: <http://www.cms.hhs.gov/transmittals/downloads/R1704B3.pdf>.
- <sup>10</sup> Claims Processing for Medicare Beneficiaries Participating in Medicare Qualified Clinical Trials, Program Memorandum Transmittal AB-01-130 which can be found at <http://www.cms.hhs.gov/Transmittals/Downloads/AB01130.pdf>.
- <sup>11</sup> Medicare Modernization Act Section 731(b) codified at Soc. Sec. Act 1862(m).
- <sup>12</sup> Decision Memo for Clinical Trial Policy (CAG-00071R2) Link: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=210>
- <sup>13</sup> CMS. National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development. July 12, 2006. [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8)
- <sup>14</sup> Federal Register, Vol. 68, No. 187, September 26, 2003.
- <sup>15</sup> CMS. National Coverage Determinations with Data collection as a Condition of Coverage: Coverage with Evidence Development. July 12, 2006.
- <sup>16</sup> CMS. National Coverage Determination, Routine Costs in Clinical Trials (310.1), Effective, July 9, 2007.