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CMS Releases Clinical Trial Policy

Overview

The Centers for Medicare and Medicaid Services (CMS) revised the national coverage determination (NCD) regarding Medicare coverage and reimbursement of routine costs incurred in connection with beneficiary participation in qualifying clinical research studies effective July 9, 2007. CMS clarified that Medicare will cover items or services for participating beneficiaries if those services would otherwise be covered outside of the trial. In addition, CMS announced it will adopt the proposed addition of Coverage Evidence Development (CED) to the NCD, also currently known as the "Clinical Trial Policy" (CTP).

On July 19, 2007 CMS stated that it is reopening consideration of the NCD to define the circumstances when Medicare coverage will be available. The comment period on the proposed changes is open until August 17, 2007.

This alert summarizes the revisions and discusses how those revisions deviate from the original policy.

Background

The original CTP NCD¹, issued by CMS' predecessor (the Health Care Financing Administration) in 2000, specified the circumstances an item or service would be considered reasonable and necessary, and therefore payable by Medicare, when provided to a beneficiary in the context of a clinical trial. The CTP lists three requirements of a qualified clinical trial:

1. 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., physician services and durable medical equipment) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.

3. 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.

The CTP also defines “seven highly desirable characteristics” of a qualified clinical trial:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. 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;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

The original CTP was designed to encourage voluntary beneficiary participation in clinical trials, with the intent that seniors might receive timely access to appropriate medical technologies.

CMS has indicated its continued commitment to that intent to provide timely beneficiary access. However, CMS also has recognized that the 2000 CTP presented some

administrative challenges that may have threatened to restrict beneficiary access to study participation.

Thus, in July 2006, CMS announced its intent to revise the CTP and, in order to obtain public input and industry recommendations, convened the Medicare Evidence Development & Coverage Advisory Committee (MedCAC) to provide independent guidance and advice to CMS on specific clinical topics. Using the input received from MedCAC, CMS asked the Agency for Healthcare Research and Quality (AHRQ) for further input. Their recommendations from public commenters, MedCAC and AHRQ, were published in a Proposed Decision Memo² that included extensive changes to the existing CTP.

The July 9 Final Decision Memorandum

In its Final Decision Memorandum CMS indicates that, in reaction to the April 2007 proposal, commenters (1) suggested that Medicare contractors had been paying claims for clinical trial services that may have fallen outside the scope of the 2000 CTP, and (2) identified additional Medicare policies and statements that are inconsistent with the coverage outlined in the Proposed Decision Memo. CMS agreed that some existing policies may have been confusing or ambiguous, and therefore revised the 2000 CTP with the intention of clarifying some of the surrounding confusion.

The revisions, in the Final Decision Memorandum, are minor. CMS concluded that the public did not have enough time to comment on the April 2007 proposal, indicating that, “We intend to amend our policies so that they are clear and consistent in terms of our coverage. We recognize, however, that the public has not had an adequate opportunity to comment on those changes.”

Given the confusion regarding the 2000 CTP and some contractors' practice of paying claims that did not meet the terms of the 2000 CTP, CMS issued the decision memorandum to preserve the status quo with the exception of two changes.

Modification of language describing coverage for investigative items or services.

The intent of the 2000 CTP was to provide Medicare coverage for those items and services that are provided outside the trial and to exclude: (1) any items or services that meet the definition of investigational clinical services, and (2) items and services provided solely for purposes of obtaining data for study analyses. CMS recognized that the language had created some confusion.

It is CMS' intent to cover any investigational clinical item or service that would otherwise be covered if outside of the clinical research trial. Thus, the policy section will be updated with the italicized language below (italics added):

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

The investigational item or service, itself; *unless otherwise covered outside of the clinical trial.*³ ”

Addition of a provision of Coverage with Evidence Development (“CED”).

In July 2006, the Agency posted guidelines entitled, “National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development.” (CED) which provides coverage for items and services for which some evidence of significant medical benefit exists, but for which there is insufficient evidence to support a “reasonable and necessary” determination. According to the July 2006 guidelines, if, in an NCD, CMS determines that a technology only is covered when used within a research study, the NCD will define the additional required standards that such a required study must meet. These would then be specific standards that CMS would require to be met in addition to the general standards and the Medicare specific-standards for the

item or service to be covered. Thus, the following language has been added to the Clinical Trial Policy effective July 9, 2007:

The Centers for Medicare & Medicaid Services, through the national coverage determination (NCD) process, through an individualized assessment of benefits, risks, and research potential, 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 NCD⁴.

The July 19 Proposed Decision Memorandum

Further, on July 19, 2007, CMS announced that it is reopening the reconsideration of the CTP NCD and will continue to clarify the terms for continued payment in a clinical trial such that healthcare providers, practitioners, and suppliers can be confident of the circumstances in which Medicare coverage will be available. The proposals for further change include:

- Renaming the CTP the Clinical Research Policy (CRP) and defining “clinical research”;
- Specifying technical and scientific standards that describe good research practices;
- Preserving CMS’ authority to permit CED;
- Redefining coverage for qualifying clinical research studies to avoid confusion with terms used in other contexts;
- Defining “routine clinical services” that are included in “usual patient care”;
- Clarifying how “investigational clinical services” are included in “usual patient care”;
- Clarifying that coverage does not include “administrative services” that are not required to furnish “usual patient care”;

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- Establishing a process that clinical investigators must use to certify to CMS that their study meets policy standards;
- Enumerating types of studies that are excluded from the policy; and
- Clarifying the relationship between coverage under this policy and local coverage determinations.

CMS will be holding at least one conference call to discuss these proposals further before the final policy is released.

Both the CMS Final Decision Memorandum (July 9) and the Proposed Decision Memorandum (July 19) can be accessed at:

<http://www.cms.hhs.gov/ClinicalTrialPolicies/>

¹ Centers for Medicare and Medicaid Services, *Medicare Coverage, Clinical Trials: Final Coverage Decision*, available at: <http://www.cms.hhs.gov/ClinicalTrialPolicies/>

² The Centers for Medicare and Medicaid Services, *Proposed Decision Memo for Clinical Trial Policy (CAG-00071R)*, April 10, 2007 available at <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=186>

³ U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, *Decision Memo for Clinical Trial Policy (CAG-00071R)*, July 9, 2007. Available at <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=186>

⁴ *Decision Memo for Clinical Trial Policy (CAG-00071R)*, July 9, 2007.