

## DEPARTMENT OF HEALTH & HUMAN SERVICES

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## MEDICARE NEWS

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### **MEDICARE REVISES GUIDANCE FOR NATIONAL COVERAGE DETERMINATIONS WITH EVIDENCE DEVELOPMENT**

The Centers for Medicare & Medicaid Services (CMS) today released revised guidance for national coverage determinations (NCDs) that include, as a condition of payment, the development and capture of additional patient data to supplement standard claims data and help ensure that patients receive appropriate care.

“Our goal is to speed access to valuable new technologies, and to promote the effective use of those technologies by providing patients and doctors with better medical evidence,” said CMS Administrator Mark B. McClellan, MD, PhD.

“In the particular cases where this coverage approach is relevant, our new guidance provides for faster and more effective coverage coupled with more informed clinical decision making,” Dr. McClellan said. “We expect these steps to lead to more appropriate use of beneficial treatments with better health outcomes and fewer unnecessary medical costs and complications.”

This release follows CMS announcement that it is reconsidering its NCD on how it covers clinical research, to better clarify how and when CMS can pay for both routine costs and investigational costs incurred in clinical trials.

Collecting additional patient data as part of the coverage process, Coverage with Evidence Development (CED), generates data on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can 1) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; 2) consider future changes in coverage for the item or service; and 3) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.

When CMS requires CED, the NCD review process might result in a decision to provide coverage only when certain data about patients’ clinical conditions are collected that are not normally present in claims data, or a decision to provide coverage for an item or service for beneficiaries enrolled in a clinical trial. In either case, additional data on outcomes of patients receiving the covered service or item can be well documented.

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The specific data developed through the CED process may help ensure that the care provided to a particular beneficiary is “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,” the standard set by law for Medicare coverage. CMS will review these data collected under the auspices of CED to ensure that care provided conforms to the conditions stated in the NCD.

The CED process may also prove helpful when there have been significant barriers to conducting research about an item or service at the time of the NCD review. In such cases, coverage may be provided for the item or service for Medicare beneficiaries enrolled in a clinical study of it. In this circumstance, the medical evidence must indicate that the item or service is safe and has a high potential to provide significant benefit to Medicare beneficiaries.

By reconsidering its National Coverage Determination on coverage of clinical trials to better clarify its relationship to CED, CMS is providing the public an opportunity to engage in a discussion of those changes.

“The results of the data collection achieved through CED have the potential to improve patient health and physician decision making while speeding access to innovative technologies,” Dr. McClellan said. “This policy should encourage industry efforts to invest in innovations that enhance the care of our beneficiaries while helping doctors employ these innovations, armed with better evidence about how they impact health of Medicare beneficiaries. New evidence resulting from CED should lead to more personalized medical care for our beneficiaries and more effective coverage of certain innovative technologies.”

CMS posted a draft document on April 7, 2005 which drew a large number of public comments. The agency considered this in developing the version issued today, with particular emphasis on responding to concerns raised by the public about the meaning and particular applications of CED and clarifying the legal basis for incorporating CED into the national coverage process.

Based on this feedback, this revised guidance document includes new information on several subjects. For example, it introduces two precepts of CED—coverage with appropriateness determination (CAD) and coverage with study participation (CSP). Distinguishing these two types of CED provides clarity on CMS’ rationale for collecting data and the legal bases that CMS may invoke in order to authorize this collection.

This revision of the CED guidance document is available for review on the CMS’ Coverage website at [www.cms.hhs.gov/coverage](http://www.cms.hhs.gov/coverage).

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