Medicare Research Coverage Initiatives: New Developments

In recent weeks, the Centers for Medicare & Medicaid Services ("CMS") has taken action, or announced its intent to take action, to revise Medicare policies on the coverage of clinical services provided in connection with clinical research through a number of related initiatives:

- announcement of a forthcoming "Question & Answer" document on Medicare coverage of clinical trial services;
- announcement of proposed revisions to the Medicare national coverage decision ("NCD") on clinical trial services issued in 2000; and
- issuance of a revised guidance document for Medicare NCDs that involve coverage conditioned upon additional medical necessity evidence development.

These initiatives demonstrate CMS' intent to ensure greater clarity and coordination on clinical trial coverage policy.

Providers, researchers and research sponsors should be aware of, and prepared to respond to, these clinical trial coverage initiatives.

Question & Answer Guidance

Current Medicare clinical trial coverage policy has provoked confusion and requests for clarification on a number of issues, including:

- the application of Medicare secondary payer ("MSP") rules to services provided in a clinical trial in which the research sponsor agrees to pay for services if the services are not covered by insurance;
- coverage of investigational devices and services provided in connection with those devices;
- coverage of services provided in Phase I clinical trials for diagnosed ill patients based on "therapeutic intent;" and
- coverage and coding for services under the 2000 Medicare NCD for clinical trial services.

CMS officials responsible for clinical trials coverage policy as well as MSP policy have indicated that the agency will soon be issuing a "Question & Answer" document addressing outstanding coverage issues.

Revised Clinical Trial Policy

On July 10, 2006, CMS announced that the agency is reconsidering its clinical trial coverage policy as enunciated in the 2000 Medicare NCD for clinical trial services.

CMS has identified a need to address several issues in the revised policy:

- clarify payment criteria for clinical costs in research studies other than clinical trials;

- devise a strategy to ensure that Medicare covered clinical studies are enrolled in the National Institutes of Health clinical trials registry website;
- develop criteria to assure that any Medicare covered clinical research study includes a representative sample of Medicare beneficiaries, by demographic and clinical characteristics;
- clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials;
- remove the self-certification process (required for certain trials to qualify for coverage under the 2000 NCD) that was never implemented;
- clarify the scientific and technical roles of federal agencies in overseeing investigational new drug exempt trials;
- determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy;
- clarify how items/services that do not meet the Medicare medical necessity requirements but are of potential benefit can be covered in clinical research studies as an outcome of the NCD process;
- clarify whether and under what conditions an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and
- discuss Medicare policy for payment of humanitarian use device costs.

CMS is seeking public comments on the issues identified above as well as any other issues of concern to the public. Public comments on the proposed policy revision may be submitted until August 9, 2006. After the comment period, CMS intends to release a proposed decision memorandum and again solicit public comment. A final policy is to be issued no later than April of 2007.

The CMS announcement is available at: http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=186 and the public may submit comments online through that webpage. The current Medicare NCD for clinical trials is available at: http://www.cms.hhs.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf.

Note that a CMS official has confirmed that the revised clinical trial policy, once issued, will supersede the forthcoming Question & Answer guidance. Also, in its revised guidance document on NCDs involving coverage with evidence development, CMS provides a preview of a potential revision to the clinical trial policy.

NCDs Involving Coverage with Evidence Development

On July 12, 2006, CMS issued a revised guidance document that describes those NCDs that include, as a condition for payment, the development and capture of patient data as a supplement to standard claims data. The guidance document is entitled "National Coverage Determinations with Data Collection as a Condition for Coverage: Coverage with Evidence Development" and is available at http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8.

CMS had previously issued a similar guidance document in April of 2005 as part of a series of NCD guidance documents developed in response to a legislative mandate that the agency publish the factors considered in making NCDs. The revised guidance document responds to public comments received on the prior guidance document, and CMS is seeking additional comments on the revised document.

In the revised guidance document, CMS affirms the purposes of NCDs that provide for coverage with evidence development ("CED"): (1) confirm Medicare current coverage; (2) inform decisions about changes in Medicare coverage; and/or (3) generate clinical information to allow providers to make better informed decisions about care.

CMS does identify two key revisions in the guidance: (1) a discussion of the two statutory bases for CED, and (2) clarification of the meaning of CED. The guidance document also discusses the collection and use of Medicare data generated, researcher access to Medicare data generated, and funding for data sources. Significantly, CMS touches upon the relationship between CED and its Medicare clinical trial coverage policy (to be revised).

Statutory Basis. CMS emphasizes that statutory authority exists for CMS to issue an NCD providing coverage for an item or service under two different statutory provisions:

- CMS determines, based on available evidence, that an item or service is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." An NCD issued under this statutory authority may involve CED *if the NCD conditions coverage on the submission of specific data in addition to claims data* to demonstrate that such item or service was provided in accordance with the relevant NCD. *See* 42 U.S.C. §1395y(a)(1)(A).
- If the available evidence is not adequate for CMS to determine that an item or service is "reasonable and necessary," an item or service may still be covered with CED *if the relevant item or service is provided in a setting in which a process for gathering additional data has been pre-specified* and there are additional protections and safety measures for patients, such as those present in certain clinical trials. *See* 42 U.S.C. §1395y(a)(1)(E).

Meaning of CED. CED is appropriate only when other forms of coverage are not justified by available evidence. CED encompasses two different types of conditional coverage which correspond to the different statutory bases.

- Coverage with Appropriateness Determination ("CAD"). If CMS finds sufficient evidence that an item or service is "reasonable and necessary" but determines that clinical data not generally available on claims forms are needed to ensure that such item or service is being provided to appropriate patients in the manner outlined in the NCD, CMS may apply a CAD. Providers will be required to submit the additional data to databases or registries set up for collecting data specified in the applicable NCD.
- Coverage with Study Participation ("CSP"). CMS may decide to cover certain items or services for which the available evidence is currently inadequate to determine if an item or service is "reasonable and necessary" but where additional data would offer valuable information on the health impact of such items or services on Medicare patients and where a research setting offers added safety, patient protections, monitoring, and clinical expertise.

Data Sources. Registries and research studies are the two major types of data sources for CED.

- Registry. An NCD may require that data be sent to a centralized database. Data collected under CAD generally will be submitted to an approved registry and forwarded to CMS for evaluation of whether the item or service was provided in accordance with the NCD. Data submission to a registry may also be necessary within clinical studies required under CSP.
- Research. Medicare may also cover services provided to Medicare beneficiaries enrolled in a research study that provides data and information used to evaluate the item or service. Such studies must be designed to produce evidence that could be used in a future NCD that would focus on whether the item or service should be covered as "reasonable and necessary." CMS will only reimburse for clinical research that meets the standards of a qualified

clinical trial to be set forth in the revised Medicare NCD for clinical trial services. Note that, in its discussion of the revised clinical trial policy, CMS indicates that the requirements that a clinical trial must meet to fall within the scope of the policy will be expanded to include: (1) the trial must be listed in the National Library of Medicine clinical trials database; and (2) the sample of study subjects in the trial should include individuals representative of the Medicare population with the condition described in the NCD.

Termination of CED-Required Data Collection. Termination of data collection depends on the source of the data and the type of CED (*i.e.*, CSP or CAD). In the case of research studies, the end to data collection is predetermined in the study protocol. The requirements of the applicable NCD generally will determine the length of the data collection by registries (*e.g.*, data from the registry provides satisfactory answers to the questions posed in the NCD), although for certain data collection, the termination date is more fluid (*e.g.*, data generated demonstrates an unacceptable level of adverse events).

Funding CED-Required Data Collection. With regard to clinical trials, CMS will exercise its discretion in determining the research that will be funded and may pay for the investigational and routine clinical costs of an item or service for a clinical trial in an NCD requiring CED. For registries, CMS will pay for the clinical costs of patient care for which data collection is required but will not provide financial support for registry development and maintenance.

Access to Data. Researchers may have access to the CED data in accordance with the applicable system of Record's Routine Uses if they enter into a Data Use Agreement with CMS. CMS also concludes that others outside of the Medicare program may find the CED data useful and indicates that the information gathered under CED will be made available for public use in accordance with usual Medicare rules for claims and clinical information.

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