PROPOSED CLINICAL RESEARCH POLICY DECISION MEMO

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Open Door Forum

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CMS Proposed Decision

- **The proposed revisions to the Clinical Trial Policy address the following categories of issues:**
  - **Definitions of terms**
  - **Standards of a clinical study**
  - **Coverage**
  - **A process to ensure that standards are met**
  - **Other issues**

DEFINITIONS

Clinical Research

Clinical research means any systematic investigation involving human participants which is designed to contribute to generalizable knowledge and which involves a clinical intervention, care delivery strategy, or diagnostic technique designed to potentially improve predefined health outcomes.

Administrative Services

Administrative services are defined as all non-clinical services, such as investigator or coordinator salaries; protocol development; recruiting participants; data quality assurance activities; statistical analyses; dissemination of findings; and study management. Administrative services also include clinical services provided to solely satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.

Investigational Clinical Services

Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

Routine Clinical Services

Items and services that:

- are covered for Medicare beneficiaries outside of the clinical research study;
- are used for the direct patient management within the study; and,
- do not meet the definition of investigational clinical services.

Usual Patient Care

Usual patient care includes routine clinical services and investigational clinical services in clinical research when the investigational clinical services would be covered outside of the clinical research and the clinical research meets the standards for a clinical research study outlined in this policy.

STANDARDS

Proposed Standards

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- The research study is well-supported by available scientific and medical information.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects.
- All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

Proposed Standards

- The research study has a written protocol
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
- The clinical research study is registered on the ClinicalTrials.gov
- The research study protocol specifies the method and timing of public release of results.
- The research study protocol must explicitly discuss subpopulations.
- The research study protocol must discuss how the results are to be generalized to the Medicare population.

COVERAGE

Coverage

- Usual patient care
- CED

APPROVAL PROCESS

Approval Process

- Self- Certification
- Coverage with Evidence Development

Self-Certification

- Letter to CMS
- CMS reviews for completeness
- Study title and NCT number listed:
  - CMS website
  - Federal Register
  - ClinicalTrials.gov
- Modifiers added to claims for patients in any study indicating that the study is included on one of the above locations

Coverage with Evidence Development

Through the NCD process, CMS 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 an evidence-based determination, are reasonable and necessary only when provided in a clinical study that meets the requirements defined in that NCD.

Exclusions

- Simple non-comparative case reports and case series;
- Retrospective studies;
- QA, QI, PI;
- Prospective studies that do not change the behavior of patients and physicians

OTHER POLICIES

Other Policies

- Local Coverage Determinations are effective
- Investigational Device Exemptions regulation unchanged
- Humanitarian Device Exemptions are not addressed in this policy
- Medicare Prescription Drug Plan not effected by this policy

Transition

This policy will not apply to any clinical research study that was covered under any previous policy that has begun enrollment prior to the effective date of this decision.

Timeline

- Public comment period
  - Closes August 18, 2007
- Final National Coverage Determination
  - By October 17, 2007

More information

- Proposed decision memorandum https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=210

- Coverage with Evidence Development guidance document http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8

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