[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No. ISCORE-RC-112.00	
Medicare Coverage Analysis		Page 1 of 3	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes:	
Prepared by:	Reviewed by:	Approved by:	

Purpose:

This standard operating procedure (SOP) describes the standard operations followed by the [Site Location], [Site Name] and affiliated health systems regarding Medicare coverage and reimbursement for clinical trials according to the CMS National Coverage Determination of 2000 (NCD).

Scope:

This SOP describes the process for determining Medicare coverage to ensure that all research projects involving research protocol related medical interventions and routine clinical services generated from research involving human subjects are compliant with the federal regulations for budget and cost analysis.

Materials:
NA

Responsibility:

This SOP applies to clinical research personnel and administration responsible for the budget and cost analysis involving human research subjects requiring clinical patient care.

Definitions

Centers for Medicare and Medicaid Services (CMS): Set national policy for Medicare, such as regulations, manuals, National Coverage Determinations or “NCDs” and other bulletins and guidance.

Clinical Trials Coverage: A National Coverage Determination (NCD) that allows payment of routine items/services, and payment of the investigational item/service if it is normally covered outside of the trial and meets medical necessity requirements, in clinical trials that qualify for coverage.

Local Coverage Determination (LCD): Local coverage determinations (LCDS) are defined in Section 1869(f)(2)(B) of the Social Security Act (the Act). Approval from the local MAC is required to bill for services related to the use of Category B devices. For information about Local Medical Review Policy (LMRP), refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.

Medicare: Federal health insurance program for people 65+, certain younger people with disabilities, and people with End-Stage Renal Disease.

Medicare Administrative Contractors (MAC): Private health care insurer that has been awarded a geographic area or "jurisdiction" to regionally manage the policies and medical claims for Medicare Part A and Part B (A/B) Fee-For-Service (FFS) beneficiaries. Refer to https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors listing by state.

Medicare Coverage Analysis (MCA): Coverage analysis is a review to determine if a research study is eligible to receive Medicare coverage and outlines what items and services performed as part of the research study should be billed to Medicare.

National Coverage Determination (NCD): Is a United States nationwide determination of whether Medicare will pay for an item or service.

Procedure

1. Staff Requirements

   a. Staff completing cost analysis shall be trained on research billing compliance.
   b. Ensure that qualified personnel are monitoring the claims that are submitted for patients involved in clinical trials to avoid improper or double billing.

2. Upon notification of a new clinical trial, review the protocol and initiate the budget process. Involve all relevant staff to ensure that the budget is comprehensive, accurate and compliant to federal and local regulations.

3. The Sponsor or other eligible source of funding support, other than Third Party Payer, must provide for the costs of performing all research procedures.

4. The budget and Medicare Coverage Analysis (MCA) shall be initiated to determine if the cost is routine, billable to the study sponsors and/or a third-party payer. Each Medicare Administrative Contractors (MAC) may also set local coverage policies for its jurisdiction, known as Local Coverage Determinations ("LCDs").

5. The PI must confirm the accuracy of the information and certify that the trial meets the criteria.

6. For non-qualifying studies, the Sponsor shall provide all costs associated with the Clinical Trial. In the event the Sponsor will not provide all costs, the internal leadership shall review and confirm if internal research support is available.

7. Cost analysis and clinical budgets shall be maintained within the respective study financial files.

Qualification requirements for Medicare Coverage of Routine Costs[1] (for Non-IDE Trials)

Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

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., physicians' service, durable medical equipment, diagnostic test) 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.

In addition to the three requirements above, clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

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.

Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA;
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time, the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs.

Qualification requirements for Medicare Coverage of Routine Costs[2] (for IDE Trials)

1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
2. The rationale for the study 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 study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.

5. The study is sponsored by an organization or individual capable of successfully completing the study.
6. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.
7. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.
8. The study is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov.
9. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.
10. The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

References

[1]Centers for Medicare & Medicaid Services @CMS.gov National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
[2]Centers for Medicare & Medicaid Services @CMS.gov Medicare Coverage Related to Investigational Device Exemption (IDE) Studies
National Coverage Determination (NCD) for Routine Costs in Clinical Trials, manual section number 310.1.
https://www.cms.gov/Medicare/Coverage/IDE/index.html
Coverage related to investigational device exemption (IDE) studies: (1995/2015)
Clinical trial policy (2000/2007): NCDs for Routine Costs in Clinical Trials (310.1)
Coverage with evidence development (CED) (2006/2014): NCD may determine coverage of an item or service only in the context of a clinical study, which typically also involves a registry

History of Revisions to SOP

Effective Date	Nature of Revision