Clinical Research Billing Compliance Frequently Asked Questions

Coverage Analysis/Prospective Reimbursement Analysis and Routine Costs of Qualified Clinical Trials

1. What is a "Qualified Clinical Trial"?

A qualifying clinical trial (QCT) is a trial that meets the requirements set forth in the Clinical Trial Policy (NCD 310.1) by the Center for Medicare and Medicaid Service (CMS). Once a trial has been determined to be a QCT, the routine costs associated with it are billable to and reimbursable by Medicare and third party payors.

As outlined below, there are **three (3) mandatory criteria** and **seven (7) desirable characteristics** to be designated a QCT.

The "**3 requirements**":

1. The study evaluates an item/service within a Medicare benefit category that is not statutorily excluded,
2. The study has therapeutic intent, and
3. Trials of therapeutic interventions must enroll patients with diagnosed disease (but may enroll healthy control group.).

And: "Deemed" to meet the additional required 7 Desirable Characteristics because it falls into one of the following:

4. Funded by NIH, CDC, AHRQ, CMS, DOD, and VA
5. Supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, VA
6. Conducted under an investigational new drug application (IND) reviewed by the FDA
7. Exempt from having an IND under 21 CFR312.2(b)(1)

7 Desirable Characteristics:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants'
1. 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.

Self-certification by the Principal Investigator was initially contemplated but never implemented by CMS and may not be used to determine whether a study qualifies for coverage.

http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true

2. Which items/services are covered as "Routine Costs" of a Qualified Clinical Trial?

Once it is determined that the study is a Qualified Clinical Trial, the following will be covered under the Medicare Clinical Trial Policy as a "routine cost" of the study so long as it is not agreed to be paid or paid by the sponsor and it is not promised free to the subject in the informed consent:

1. Items or services that are typically provided absent a clinical trial (e.g., “conventional care”);
2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

ALL OTHER MEDICARE RULES APPLY - (e.g. MEDICAL NECESSITY must exist at the time the item or service is provided and must be documented to support the claim.)

3. What items/services are not considered "Routine Costs" of a Qualified Clinical Trial and are therefore not billable under Medicare rules?

Although the study is determined to be a Qualified Clinical Trial, the following will NOT be covered:

1. The investigational item or service itself, unless otherwise covered outside of the clinical trial;
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
3. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

4. What is a "Coverage Analysis/Prospective Reimbursement Analysis"?

A Coverage Analysis/Prospective Reimbursement Analysis is a review to determine if a research study is a deemed and qualifying clinical trial pursuant to Medicare's National Coverage Decision (NCD) and will outline what items and services pertaining to a research study can be billed to Medicare and other commercial payors, or can be paid by the study sponsor or other funding source.

OnCore (Clinical Trial Management System) is the current system of record for Coverage Analyses/Prospective Reimbursement Analysis performed on trials conducted at UC Irvine Health.

5. When is the Coverage Analysis/Prospective Reimbursement Analysis required?

The Coverage Analysis/ Prospective Reimbursement Analysis Process is required for all clinical studies performed within UC Irvine Health regardless of funding source (including unfunded studies) for the patient care clinical procedures and research related items.

All new and legacy clinical studies, including Investigator-Initiated studies, (whether funded or unfunded) that may include any clinical or research related items, tests, procedures, interventions, or other services performed on study subjects at UC Irvine Health.

6. What is "therapeutic intent" in a clinical trial?

The trial must have therapeutic intent in order to be a qualifying clinical trial. It cannot be designed to exclusively test toxicity or disease pathophysiology. Trials with therapeutic intent must have an objective/aim that assesses the effects of the intervention on patient outcomes (i.e., prolongation of life, shrinkage of tumor, or improvements in quality of life).

7. Why does a study need to be evaluated for qualifying clinical trial status?

The CMS Clinical Trial Policy (NCD 310.1) requires that trials meet the qualification criteria outlined to receive reimbursement for routine costs associated with the care of subjects enrolled in therapeutic clinical trials. If a trial does not “qualify” under the Clinical Trial Policy then the costs for all items and services related to the clinical trial are not billable to Medicare or insurance providers and must be paid by the study sponsor. All other Medicare billing rules apply.

8. Why should Medicare rules for determining coverage be applied to studies that do not enroll patients with Medicare?

These coverage determinations are considered the "gold standard" on which private insurance carriers base their coverage decisions.

9. What are NCDs (National Coverage Determinations) and LCDs (Local Coverage Determinations)?

The National Coverage Determinations (NCDs) Manual describes whether specific medical items, services, treatment procedures, or technologies are reimbursed by Medicare. In the absence of an NCD, an item or service is covered at the discretion of Medicare Administrative Contractors (MACs) based on Local Coverage Determinations (LCDs). The MAC for the University of California Irvine Health is Noridian and their LCDs can be found here: https://med.noridianmedicare.com/web/jddme/policies/lcd/active

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