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1. Overview

Purpose

These procedures establish the process for the principal investigator (PI) and study personnel, as delegated by the PI, to follow in determining whether a coverage analysis is applicable for a study, and if so, for completing the financial coverage analyses and associated attestations for applicable sponsored or investigator-initiated clinical research activities. This process aids in facilitating clinical research budgeting, billing accuracy and compliance.

Scope

The coverage analysis is applicable to all clinical research projects involving human research subjects, utilizing any facility of Drexel University, which may result in charges billed to a research account, a research participant, or a third-party health insurance carrier, regardless of funding source.

Affiliate institutions, e.g. St. Christopher's Hospital for Children, may follow their own coverage analysis process in accordance with federal regulations.

2. Definitions

Clinical Research – the scientific study of human health and disease to develop new medical treatments, interventions, and health practices. It involves the systematic study of drugs, medical devices, behavioral interventions, and public health strategies to assess their safety, efficacy, and impact on individuals and populations.

Clinical research can be categorized into:

- Interventional Studies (Clinical Trials): Research involving participants who receive specific treatments or interventions to evaluate their effects.
- Observational Studies: Studies that assess health outcomes in groups of people without assigning specific interventions (e.g., epidemiological studies, cohort studies).
- Behavioral and Public Health Research: Investigating how behaviors, social factors, and public health initiatives influence health outcomes.

Coverage Analysis – a uniform method of analyzing the items and services provided in a clinical trial to determine if that item or service can be appropriately billed to Medicare and other insurers.

Qualifying Clinical Trial/Research – a clinical research project that meets the requirements outlined in the Center for Medicare and Medicaid Services Clinical Trials Policy, which may qualify for reimbursement of routine costs from a third-party health insurance payer.

3. Coverage Analysis

The Centers for Medicare & Medicaid Services (CMS) oversees the National Coverage Determinations and the Local Coverage Determinations and defines coverage for routine costs in clinical research projects. Medicare covers the routine costs of qualifying clinical research projects, as defined in the CMS Clinical Trial/Research Policy, NCD 310.1.

Before research services may be billed to a third-party health insurance carrier, the research project must meet the mandated qualifying criteria as outlined in the CMS Clinical Trial/Research Policy,

NCD 310.1. When a research project is determined to be non-qualifying, research services may not be billed to a third-party health insurance carrier, and the research project will be expected to fund all services of the project.

3.1 Coverage Analysis Qualification Criteria

A qualifying Clinical Trial/Research Project must meet all three of the following:

1. The aim or purpose of the project must be an evaluation of an item or service that falls within a Medicare benefit category (e.g., physician's service, diagnostic test) and not excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The research must have therapeutic intent, not exclusively testing toxicity or pathophysiology.
3. Research of therapeutic interventions must enroll participants with a diagnosed disease rather than healthy volunteers; healthy participants may be included as a control group.

In addition to the three required criteria above, clinical research projects should also have the following characteristics:

1. The principal purpose is to test whether the intervention improves the participants' health outcomes.
2. The study is well-supported by scientific and medical information.
3. The study does not unjustifiably duplicate existing studies.
4. The study design is appropriate to answer the research question being asked.
5. The study is sponsored by a credible organization or individual capable of executing the study successfully.
6. The study follows Federal regulations for the protection of human subjects.
7. All aspects of the study are conducted according to the appropriate standards of scientific integrity.

Some clinical research projects are automatically qualified to receive Medicare coverage of their routine costs. Projects that are deemed automatically qualified are:

1. Study funded by NIH, AHRQ, CMS, DOD, and VA;
2. Study supported by centers or cooperative groups that are funded by NIH, AHRQ, CMS, DOD, and VA;
3. Study conducted under an investigational new drug application (IND) reviewed by the FDA; and
4. Study that is IND exempt.

3.2 Routine Costs in a Qualifying Clinical Research Project

Routine costs in a qualifying research project include:

- Items or services that are typically provided absent a clinical research project (e.g. standard of care services).

- All items and services the payor would cover if the subject was not enrolled in a clinical research project.
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered agent), the clinically appropriate monitoring of the effects of the item of service, or the prevention of complications.
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, or the diagnosis or treatment of complications.

Routine costs do not include:

- Items or services that are the investigational item or service itself, unless otherwise covered outside of the clinical research.
- Items or services provided solely to satisfy data collection and analysis needs not used in the direct clinical management of the participant (e.g., monthly CT scans for a condition usually requiring a single scan).
- Items or services customarily provided by research sponsors free-of-charge for any enrolled participant.
- Items and services provided in a non-qualifying research project.

3.3 Coverage Analysis Billing Matrix

A coverage analysis billing matrix identifies all clinical items or services associated with a clinical research project, including identification of the financially responsible payor for each service, such as the research project sponsor, other funding source, or a third-party health insurance carrier. The billing matrix is intended as a guide to use in determining which items and services are billable to a third-party health insurance carrier based upon the research protocol, informed consent, coverage determinations, coverage decisions, and federal guidelines. All items and services billed to a third-party health insurance carrier must be supported by medical necessity.

The Billing Matrix should contain the following:

- All time points that may occur within the study and the acceptable date range for each.
- The name or description of all billable services.
- The CPT code for all billable services.
- The responsible financial payor of each service at each time point.
- Supporting justification for all services billable to a third-party health insurance payor.

The matrix should be completed with each item receiving a designation code. Common billing designations include:

- R - Research (research-specific, billed to the study)
- SOC – Standard of Care (routine care, bill to the participant or insurance)
- CL – Central Lab (Sponsor providing payment for services)

3.4 Investigational Device Trial/Research

Device studies must comply with separate regulations related to Medicare coverage of devices (42 CFR 405.201-405.215 and 411.15 and 412.406). CMS relies on the FDA's approval category for Investigational Device Exemption (IDE) studies when making a coverage determination. Unlike non-device studies where the investigator/institution is responsible for confirming qualifying clinical research criteria, device studies must receive pre-approval from CMS for Medicare coverage of IDE studies. Instructions for seeking approval of Category A and B IDE studies can be found in Section 20.1 (C) of the Medicare Benefit Policy manual. While the approval process is different for an Investigational Device Trial/Research, the routine costs language of NCD 310.1 remains applicable to device research.

Category A Devices are considered experimental/investigational where safety and effectiveness has not been resolved. The following applies to Category A Device research:

- CMS prior approval of the research project is required. This is initiated by the research sponsor.
- The device itself is not billable to a third-party health insurance carrier.
- Routine costs as identified in NCD 310.1 may be billed to a third-party health insurance carrier in CMS approved Category A Device research.

Category B Devices are considered non-experimental/investigational where the device safety and effectiveness has been resolved and has minimal risk. The following applies to Category B Device research:

- CMS prior approval of the research project is required. This is initiated by the research sponsor.
- The device may be billable to third-party health insurance carriers in a CMS approved research project.
- Routine costs as identified in NCD 310.1 may be billed to a third-party health insurance carrier in CMS approved Category B Device research.

3.5 Non-Qualifying Clinical Research

Protocol-required services must not be billed to a third-party health insurance payor in a non-qualifying clinical research project. This includes services that would otherwise be considered routine costs in a qualifying research project and standard of care services that would be done regardless of the research project. If the service is required in the protocol and is determined to be non-qualifying, it may not be billed to a third-party health insurance carrier.

3.6 Medicaid Attestation Form

The Consolidated Appropriations Act of 2021 added a requirement for state Medicaid programs to cover the routine patient costs for qualifying clinical trials, in alignment with the criteria established by NCD 310.1. For qualifying clinical research, a Medicaid Attestation Form must be signed to confirm the appropriateness of the research study and is the mechanism to document that a clinical research study meets the qualifying criteria for a specific Medicaid beneficiary.

Key requirements for the Medicaid Attestation Form include:

- CMS requires documentation confirming the trial's appropriateness.
- The form must be signed by the Principal Investigator (PI) and, if applicable, a Referring Physician.
- It must be completed and dated before any clinical trial activity begins.
- Once complete, the form must be uploaded to the participant's medical record.

4. Responsibilities

4.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

4.2 Principal Investigator Responsibilities

The PI retains overall responsibility for the study and delegating study tasks as appropriate. The PI is accountable for compliance with the CMS Clinical Trial/Research Policy, NCD 310.1 and appropriate billing for research services. The PI is responsible for ensuring that study personnel, as applicable, are properly trained on this requirement, qualifying clinical research requirements, coverage analysis, and the Medicaid attestation process. In addition, the PI is responsible for the requirements as described in ORI-002 Procedures for Principal Investigator Eligibility and Responsibilities and HRP-070 Investigator Responsibilities.

5. Resources

- CMS Clinical Trial/Research Policy, NCD 310.1
- Medicaid Attestation Form

6. Revision and Workgroup Members

6.1 Revision

Version 001/Effective Date 05/22/2026 - Original Document: Coverage Analysis and Qualifying Clinical Research

6.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup & Advisory Members:

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