Coverage Analysis of Clinical Research	CR-106
Clinical Research Standard Practices	**Effective Date:** December 2022

SCOPE AND PURPOSE The document is applicable to the people and processes of the following Penn State College of Medicine and Penn State Health entities specified below engaged in clinical research:

Entities:

[ ]	Penn State Health Shared Services	[X]	Penn State College of Medicine
[X]	Milton S. Hershey Medical Center	[X]	Medical Group – Academic Practice Division
[X]	St. Joseph Medical Center	[X]	Medical Group – Community Practice Division
[X]	Holy Spirit Medical Center	[X]	Penn State Health Life Lion, LLC
[X]	Hampden Medical Center		

Roles:

[X]	Principal Investigators	[X]	Regulatory Specialists
[X]	Sub-Investigators	[X]	Key Study Ancillary Personnel
[X]	Study Coordinators/Associates	[X]	Financial Analyst/Research Accountants
[X]	Data Specialists	[X]	Central Research Office Personnel

This policy describes the processes associated with the requirement that a coverage analysis be conducted for any clinical research study in order to appropriately determine the billing status of both the study and those items and services provided to research participants as part of the research study. As clinical research often occurs in conjunction with customary care of patients, the coverage analysis is a front-end approach to assist in ensuring routine care and research items/services are handled appropriately and in compliance with all applicable laws and regulations.

POLICY AND PROCEDURE STATEMENTS

1. A coverage analysis is required if it is "possible" (either appropriately or unintended) for a charge to be captured in the billing system. A coverage analysis is not needed if a trial does not include any billable items/services, solely uses existing specimens, or purely involves collecting data based on clinical progression.
    a. A complete coverage analysis is not required when the initial review of study materials indicates that the study is solely collecting data that is obtained from usual care

2. This procedure shall apply to all clinical research studies regardless of the funding source (i.e., external sponsor, internal funds, non-profit or government funding, or any combination thereof). The coverage analysis must be performed by an individual not otherwise associated with the conduct of the study

3. The internal Medicare Coverage Analysis Manual, updated annually, shall serve as the guide to performing the coverage analysis.

4. The coverage analyst will review study documents to determine if the clinical research study qualifies for Medicare reimbursement based on the Clinical Trial Policy (CTP) established through the national coverage determination (NCD) and local coverage determination (LCD) process.

5. The coverage analyst will identify routine costs that may be billed to the third-party payer and/or study participant. The responsibility of all other charges falls to the sponsor/funder (either internal or external, or combination thereof) of the trial.
    a. Items/services completed for the sole purpose of assessing a participant's eligibility to participate in a research study would not be deem "routine cost" per CTP. As such, these items/services are responsibility of the sponsor/funder

6. The rationale for differentiation between routine costs and research items/services paid by Sponsor will be documented by the coverage analyst and accompanied by the construction of a corresponding draft billing grid. Rationale will be supported by appropriate citations from the following (list in hierarchical order):
    a. National and Local Coverage Determinations (NCDs and LCDs);
    b. National guidelines (e.g., academy, association, etc.) in support of local clinical practice;
    c. Medical Literature; and,
    d. Institutional/Principal Investigator historical documentation of usual/routine care.

7. If sponsor's budget template includes payment for an item/service that could considered routine, the item/service will initially be considered a research cost and billable to Sponsor. This determination may be revised based on budget negotiations and further evaluation of citations listed above.

8. A review of the coverage analysis will be performed during the Protocol Feasibility and Budget Meeting (when applicable), with subsequent updates documented as necessary.

9. Upon request, the study team (Principal Investigator or designee) will provide the coverage analyst with clarifications and/or additional supporting documentation (e.g., national clinical guidelines, academy/association guidelines, medical literature, etc.) necessary to complete the coverage analysis.

10. Upon execution of the clinical trial agreement, or awarding of the grant, the finalized coverage analysis documents will be uploaded into the clinical trial management system STAR

11. Where a protocol amendment revises items/services, the coverage analyst will review and provide documentation of billing determinations. The revised finalized coverage analysis documents will be uploaded into the clinical trial management system STAR

RELATED POLICIES AND REFERENCES

A Training Manual for Clinical Research Billing Compliance; Aegis Compliance & Ethics Center, LLP; April 2009

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1); Center for Medicare & Medicaid Services; Version 2, 09 July 2007

APPROVALS

Authorized:	Kevin Gardner, Jr., MS, BSN, RN, CCRC Director, College of Medicine Clinical Trials Office Adam McDowell, BA, JD, CRA Director, Office of Research Affairs, Contracts Thomas Brydebell Director, Office of Research Affairs, Grants Elizabeth Galgocy, MEd, RN, CIP Director, Research Quality Assurance, Human Research Trials
Approved:	Neal Thomas, MD, MSc Associate Dean of Clinical Research Sheila Vrana, PhD Associate Dean of Research

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CONTENT REVIEWERS AND CONTRIBUTORS

Director, College of Medicine Clinical Trials Office

Director, Office of Research Affairs, Contracts

Director, Office of Research Affairs, Grants

Director, Research Quality Assurance, Clinical Trials

ATTACHMENTS

A. Rationale for Performing a Coverage Analysis

B. Definitions Related to Coverage Analysis

HISTORY OF REVIEWS AND REVISIONS

December 2022	
Scope and Purpose, Roles	Updated "Financial Analyst/**Research Accountants**". Added "Regulatory Specialists" and "Central Research Office Personnel."

RATIONALE FOR PERFORMING A COVERAGE ANALYSIS

The purpose of a coverage analysis is to determine Medicare's qualifying status of the research study and make billing determinations for items/services required during the course of the clinical research study. A coverage analysis is necessary to determine the responsibility of charges in a clinical trial. Per the National Coverage Determinations Manual, Section 310.1, Medicare will only reimburse for clinical trial items/services when a clinical trial "qualifies" for coverage and the items and services are "routine costs". The coverage analyst, following Medicare policies, determines if a clinical trial qualifies for coverage and subsequently identifies those items and services that may or may not be billed to a third-party insurer.

It is recognized that not all participants who enter into research studies will be Medicare beneficiaries. However, Medicare rules are used to qualify a clinical trial primarily because it is the largest single payer in the United States and also because Medicare drives the reimbursement rules in the Unites States.

DEFINITIONS RELATED TO COVERAGE ANALYSIS

Coverage Analysis: A systematic objective review of study-related documents to determine the billing status of both the study and those items and services provided to research participants as part of the research study.

National Coverage Determination (NCD) for Routine Costs in Clinical Trials: A policy coverage decision (CMS Publication Number 100-03: NCD Manual, Section 310.1) effective for items and services furnished in a clinical trial setting. It outlines conditions under which Medicare will cover the routine costs in qualifying clinical trials.

Qualifying Clinical Trial: The study must be one of four types of trials that CMS (Centers for Medicare & Medicaid Services) has deemed to meet certain characteristics. Additionally, the study must have three necessary requirements: fall within a Medicare Benefit Category; therapeutic intent; and, enrollees with a diagnosed disease. (Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.)

Research Item/Service: Any item, service, or procedure required by the approved Institutional Review Board protocol that does not meet the definition of routine costs as defined by CMS.

Routine Costs (based on NCD 310.1):

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- 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.

Sponsor: The organization that funds a clinical research study, often used interchangeably with funding agency.

Third-Party Payer: An organization other than the patient (first party) or health care provider (second party) involved in the financing of personal health services (e.g. Medicare, Medicaid, Blue Cross, Aetna, etc.).