What is Coverage Analysis?

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Coverage Analysis (CA) is a financial review of a Clinical Research Study that is required to be performed pursuant to the Federal Clinical Trials Policy (also known as the National Coverage Decision (NCD310.1)). In brief, Coverage Analysis is a three-step process (additional info below) that evaluates whether a study meets the Federal definition of a Qualifying Clinical Trial (QCT), and evaluates whether certain study-related services may be considered Routine Costs billable to patients and/or their insurers under Federal law. A Coverage Analysis is often associated with development of a billing grid, a tool which facilitates compliant clinical research billing, that distinguishes financial responsibility for study-related services between study funding and patients/insurers. UCLA Policy 915 requires Coverage Analysis be performed for any clinical research study requiring UCLA Health System resources, including but not limited to any patient care costs.

Coverage Analysis Review Objectives

1. Identify and document whether a study is a Qualifying Clinical Trial (QCT), as defined by Federal law, that may support billing certain study required items/services to insurance pursuant to applicable laws and regulations; and
2. Determine and document financial responsibility for all patient care costs required by the study. Financial responsibility for study required items/services may either be:
    - Routine Costs that may be billed to a study participant and/or their insurer(s); or
    - Study Costs for items/services that are primarily required for research purposes and should be paid for by research funding and/or support.
3. Evaluate Medicare Coverage (via National and/or Local Coverage Determinations), and document support for items/services considered Routine Costs billable to patients/insurers.

How Routine Costs are Determined

The Centers for Medicare & Medicaid Services (CMS) provide guidance to help differentiate Routine Costs from Study Costs. National and Local Coverage Determinations, professional medical association guidance, commercial drug compendia, and nationally recognized peer-reviewed publications are often utilized as resources to support Coverage Analysis billing designations.

Coverage Analysis & Financial Activation Fees

Study	Applicable Fee effective 3/1/25
Non-Profit Funded Studies (including NIH)	N/A
Industry-Sponsored Studies	$2,950
Industry-Sponsored Budget Amendments (per occurrence)	$1,250

Coverage Analysis and Financial Activation and amendment fees include the administrative cost of evaluating the QCT status for clinical research studies and development and protocol-driven updates of a compliant billing grid in the UCLA Clinical Research Management System. Fees listed above represent the direct cost of the associated service and are subject to the applicable UCLA indirect rate.

For additional information and/or questions, please email CoverageAnalysis@mednet.ucla.edu. Please see Related Guidance for further information.

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