

## [Coverage Analysis](#)

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### **What is Coverage Analysis?**

Coverage Analysis (CA) is a financial review of a Clinical Research Study that is required to be performed pursuant to the [National Coverage Decision \(NCD310.1\) and Federal Clinical Trials Policy \(CTP\)](#). [UCLA Policy 915](#) requires Coverage Analysis review 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) that allows for billing certain study required items/services to insurance pursuant to applicable laws and regulations; and
2. Determine and document billing designations for all patient care costs required by the study. Billing designations 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 that should be paid for by research funding and/or support.
3. Document and reference applicable billing regulations, insurance coverage decisions, and supporting information that support Routine Costs insurance billing.

### **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, and nationally recognized peer-reviewed publications are often utilized as resources to support Coverage Analysis billing designations.

For additional information and/or questions, please email [CoverageAnalysis@mednet.ucla.edu](mailto:CoverageAnalysis@mednet.ucla.edu) . Please see [Related Guidance](#) for further information.

Last updated: 18 Jun 2018

### **Coverage Analysis at UCLA Health System**

Coverage Analysis at UCLA is performed centrally by The Financial Coverage & Activation (FCA) team within the

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Dean's Office School of Medicine and Clinical and Translational Science Institute (CTSI).

## How is Coverage Analysis Initiated?

Coverage Analysis is integrated in the ResearchConnect study activation and budget development process at UCLA. **When a new clinical research study application is submitted in the [UCLA webIRB system](#), the FCA team is automatically notified to begin the Coverage Analysis and budget development process.**

## Financial Coverage & Activation Process

Once the FCA team receives an automatic notification that a new clinical research study has been submitted in the UCLA web-IRB system, the FCA team will transfer the Core Study Documents (draft informed consent, protocol, investigator brochure and device manual if applicable) from the [UCLA webIRB system](#) into the OnCore Clinical Research Management System, and begin the Financial Coverage & Activation Process by performing the following tasks:

1. Evaluate whether any UCLA Health System resources are required;
2. Evaluate whether any core ancillary department services are required (e.g. Laboratory/Pathology, Radiology, Investigational Pharmacy and/or Industry Clinical Trial Contracting) and trigger automatic notifications to ancillaries and study teams, as applicable;
3. Evaluate whether study required items/services will be: (1) all billed to the study sponsor and/or internal study account; or (2) all billed to the participant and/or their insurer(s); or (3) a mix of patient/insurance costs and study costs.

Please [click here](#) for more contact information. Please see [Related Guidance](#) for more information.

Last updated: 21 Nov 2016

## Device study Coverage Requirements

Investigators participating in an Investigational Device Exemption (IDE) Study that plans to request reimbursement for study procedures and materials from Medicare or third-party payers must ensure the following:

1. [CMS IDE study coverage](#) has been approved by CMS or local Medicare contractor
  - CMS approval of coverage for [Category A](#) devices applies to the routine care items and services required by the study, but not the experimental device
  - CMS approval of coverage for [Category B](#) devices allows for coverage of the routine care items and services required by the study as well as the investigational device.
2. Other devices that may be covered by Medicare include
  1. Premarket Approval (PMA)
  2. Humanitarian Device Exemption (HDE)
  3. 510(k) approved devices
  4. IRB-approved Non-Significant Risk (NSR) devices
3. UCLA Value Analysis Committee (VAC) approval has been granted – If the study requires UCLA to purchase or use a new or replacement technology/device, then a [VAC Request Form](#) must be submitted for review

## Drugs Study Coverage Requirements

Medicare will cover the cost of QCTs that are conducted under an Investigation New Drug (IND) reviewed by the FDA. IND exempt studies are deemed automatically qualified for coverage until further qualifying criteria are available. Once the qualifying criteria are available, the Principal Investigators of the study must certify that the study meets all qualifying criteria for Medicare coverage of routine costs. The new qualification will apply to the prospective study charges generated.

Please [click here](#) for more contact information. Please see [Related Guidance](#) for more information.

Last updated: 18 Nov 2016

Last updated: 11 Oct 2016

- Group 1
  - [Clinical Research Information Systems](#)
  - [Clinical Research Business Partners](#)
- Group 2
  - [Office of Research Administration](#)
  - [Jonsson Comprehensive Cancer Center](#)
- Group 3
  - [Office of Human Subjects Protection](#)
  - [CareConnect Website](#)

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