

OFFICE OF COVERAGE ANALYSIS ADMINISTRATION (OCAA)

FAQ

What services does OCAA provide?

OCAA provides both coverage analysis services as well as budgeting services for research studies conducted at UCSD.

COVERAGE ANALYSIS (CA):

What is a coverage analysis?

A CA is a detailed spreadsheet indicating all possible charges generated within the clinical study. It is a systematic review of clinical trial documents, published practice guidelines, and Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) to determine the billing status of items and services that are documented in the research protocol and/or research plan.

Why is a coverage analysis needed?

To ensure compliance and that charges are properly routed for billing. This will also help ensure that your patients do get billed incorrectly.

The False Claims Act prohibits any person or entity from submitting false claims to any government entity. The purpose of the CA is to review all clinical research documents (protocol, contract/grant, budget, and consent form) to ensure harmonization and consistency amongst billing language.

Why are we following Medicare's Clinical Trial Policy NCD 310.1, if not all our patients are Medicare patients?

Medicare is considered the "gold standard" for coverage and billing guidance. Medicare is the Nation's largest reimbursement program for health care. Several states have passed legislation requiring commercial payers to follow Medicare rules. California SB37, passed on 12/4/2000, addresses clinical research billing for cancer trials in California. Federal PPACA (Affordable Care Act), Section 10103 requires commercial payers to cover routine care for "qualifying clinical research studies".

How do I know if my study requires a CA?

If your study has charges that will be routed via Epic or you have labs or imaging that will be performed locally at UCSD.

*Clinical research Studies that will **not require** a Coverage Analysis are studies, such as, retrospective studies or data studies. Also, studies with a blood draw only that are sent to a central lab for processing.*

How do I submit for a coverage analysis review?

*To trigger OCAA review for **new studies, at the time of initial submission** in Quali Protocols, select 'Events/procedures billable to sponsor/insurance/research participant' within the Research Characteristics section of the application.*

Jump to:

- Project Basics
- General Information ✓
- Study Personnel
- Funding
- Study Population ✓
- Research Characteristics**
- Informed Consent ✓

Research Characteristics

The research will involve the following. Carefully review then select all that apply or "None of the Above."

Clinical Trial

Collection of Information/Biospecimens

This research is, or involves, the following. Carefully review then select all that apply or "None of the Above."

Events/procedures billable to sponsor/insurance/research participant

Will biospecimens be collected or processed at UCSF/RCHSD in a clinical site?

No

What do I do if I already submitted my study to the IRB?

*To trigger OCAA review **for new studies, after initial submission** in Quali Protocols, reach out to your OIA analyst to move the study into OCAA Ancillary Review.*

When should I submit for CA review?

Ideally you should request for a CA review at the time of initial IRB submission so that OCAA can add your study to our work queue as soon as possible to help reduce delays in activation of the study.

How do I request a CA review for amendments?

To trigger OCAA review for amendments, answer "Yes" to OCAA Review within SECTION A: Study Classification section of the application.

SECTION A: Study Classification

OCAA Review

Is this an amendment where review of the study is conducted by an external IRB and the changes do not meet the criteria for OIA submission and are being submitted only to trigger OCAA review?

Yes

No

When should I notify OCAA of a new, renewal or amendment to an existing coverage analysis?

We suggest you include ocaa@health.ucsd.edu in your initial e-mail correspondence to the appropriate research contract office (for example, OCTA or OCGA internal paperwork).

What happens after I have submitted the request for CA review?

OCAA will receive a notification from Quali protocols for 'ancillary review'. If the study meets the requirements for a coverage analysis it will then be added to the work queue. Once a CA analyst is assigned they will reach out to the study team when the CA is complete or if they have questions.

How do I request an update on CA status?

Email the OCAA inbox OCAA@health.ucsd.edu to request an update, include IRB#. Or, if your study has already been assigned to an analyst you can reach out to them directly.

What documents are required for OCAA to begin working on my CA?

Study protocol/research plan, ICF and IB (investigational brochure)

Can I send documents directly to OCAA?

All required documents should be uploaded to Quali protocols before work can begin on your CA. In the event of an amendment you can also send documents to the OCAA inbox (in addition to Quali) so that we can review for a possible CA amendment.

After OCAA has built the CA what are the next steps?

The CA will be sent to the study team for review and approval. Once approved, the CA will be sent to the Velos team for calendar build. The study team will be notified via email when the study has been activated in Velos.

BUDGET SERVICES:

What types of budget services does OCAA provide?

OCAA provides budget services for industry initiated/sponsored clinical trials.

How do I request budget services from OCAA?

Submit requests through our online form. Click [HERE](#).

**Submissions for NEW budgets may also be requested through Quali Research at the time of your Quali Proposal submission.*

What do I do if I have questions about the budget process or to get status updates?

Email the OCAA inbox at OCAA@health.ucsd.edu. Or if your budget has already been assigned you can reach out to your budget analyst directly.