TIP SHEET- **COVERAGE ANALYSIS**

UC Irvine Research Coverage Analysis

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What is a Coverage Analysis (CA)?

A coverage analysis decides, before enrollment, who pays for every item and service in your protocol — so participants and payers are billed correctly. It is a line-by-line review of the protocol's schedule of events and procedures. Each item is labeled as routine standard of care billable to insurance (S) or research-only paid by the study or sponsor (R). The billing determinations are driven by National Coverage Determinations (NCDs) that dictate whether a specific medical item, service, procedure, or technology can be billed to insurance.

When is it required

Generally, any study that uses UCI Health space, staff, or services, or that could generate a charge in Epic, needs a complete CA before the first participant is enrolled.

At UCI, the coverage analysis is performed by an independent, credentialed, outside vendor. This service is coordinated through the Center for Clinical Research (CCR).

Why it matters for the Informed Consent (ICF) discussion

The informed consent discussion between the Principal Investigator and potential participants must include a discussion about costs associated with participating in the clinical research protocol. Participation costs should be aligned with the billing determination in the Coverage Analysis. The consent's costs section must say the same thing the CA says. Participants should know what insurance may be billed for, what the study covers, and that copays or deductibles may still apply and be the responsibility of the participants.

Billing Grid Interpretation (Common Designations)

Coverage Analysis Determination	Coverage Determination	What it means	Who pays
S	Routine/Standard of Care	Care the participant would get anyway, or routine cost in a qualifying clinical trial	**Participant's insurance (with research claim identifiers). Co-pays or deductibles may apply.**
R	Research Study Budget or Research Team Time and Effort	Items the sponsor supplies or study team performs specific to research protocol	**Sponsor/Study internal account (KFS) listed in OnCore**
N/A	Bundled service, not separately billed	This is not the same as "not billable"; service is included in another billable item	**Covered within the billing of another service or excluded from billing grid for separate claims**