FAQ

What is a Coverage Analysis (CA)?

A coverage analysis (CA) is a detailed review of a clinical trial to determine which items and services are billable to Medicare and which are the sponsor's responsibility.

- CA applies Medicare's billing rules to determine coverage under Medicare.
- Conventional care items and services are billable to insurance.
- Research items and services are not billable to insurance and must be billed to the study sponsor.

What studies require a CA?

UC San Diego Health Policy UCSDHP 342.2 – Clinical Research Billing notes the following regarding CA requirements:

- Requires a CA: If a study uses a UC San Diego space capable of capturing charges.
- Exempt from CA: Studies in which all protocol services occur in a UC San Diego space that is not capable of capturing charges.

What is the difference between Standard of Care (SOC) and what is billable to Medicare in a clinical trial?

Even if a service is considered SOC by medical professionals, that doesn't automatically mean Medicare will pay for it. Sometimes procedures that are considered routine in medical care are not covered by Medicare. Medicare only covers services that meet specific rules, including:

- Billable to Medicare (if all rules are met):
    - Items or services normally provided to patients outside of a trial (also called conventional care);
    - Services to deliver the investigational item (e.g., drug administration);
    - Monitoring for safety or side effects;
    - Care related to complications from trial participation;
    - Meets Medicare's reasonable and necessary rule;
    - Has documentation to support appropriateness of the bills submitted to Medicare (Clinical Trials – Medical Policy Article A52840), and
    - Must not be statutorily excluded from Medicare Coverage or limited by an NCD or LCD
- Not billable to Medicare:
    - Items or services done only for research purposes that aren't part of regular care;
    - The investigational item or service itself (unless already covered by Medicare);
    - Items or services provided free of charge by the sponsor
    - Items or services lacking guideline/compendia support
    - Conventional care items that are paid for by the sponsor.
    - Items or services statutorily excluded from Medicare Coverage or limited by an NCD or LCD.

Some services that are commonly used in clinical practice are not covered by Medicare. For example, routine physicals or screening tests might be standard in a clinic, but not reimbursable under Medicare rules. For example, a screening pregnancy test before chemotherapy for cancer is clearly SOC but not allowed by Medicare.

If everything in my study is SOC, do I still need a CA?

Yes, a CA is still required. Centers for Medicare and Medicaid Services (CMS). mandates mandatory reporting of specific study details for all clinical trial claims submitted to Medicare. The CA ensures your study information is properly reviewed and routed to revenue cycle, so it can be accurately included in CMS claims.

Who makes the billing rules?

Billing rules originate from:

- Centers for Medicare and Medicaid Services (CMS)
- Medicare Benefit Policy Manual, most commonly Chapter 14 – Medical Devices and Chapter 15 – Covered Medical and Other Health Services
- Medicare's Routine Costs in Clinical Trials (NCD 310.1)
- Medicare's National Coverage Determinations (NCDs)
- Medicare Administrative Contractors (MACs) Local Coverage Determinations (LCDs)
    - In California, the local MAC is Noridian. Active LCDs are available here.

Why do you use Medicare guidelines for coverage determinations, especially if the study doesn't include Medicare participants?

Medicare guidelines are used because they serve as the "gold standard" for Coverage Analysis. The CMS defines routine cost coverage in clinical trials. While state Medicaid programs and commercial insurers may have their own policies, many align with or reference Medicare standards.

Why are screening tests not allowed?

CMS NCD 310.1 excludes services that are done to determine trial eligibility or for data collection.

If insurance denies the claim, who is responsible for the costs?

It depends on the reason for the denial and whether the service was billed correctly.

- If billed correctly:
    - If an item or service is appropriately billed to insurance and the insurer still denies the claim:
        - Then the responsibility may fall onto the patient.
- If billed incorrectly (e.g., a research-only item submitted to insurance):
    - Medicare and other payers consider this noncompliant billing and the institution is responsible for the risk and the cost.
    - Under federal law, billing for non-covered services can trigger penalties and mandatory refunds.

Institutions are generally prohibited from billing patients for services that were inappropriately billed to or denied by Medicare due to non-compliance with coverage rules.

If a non-billable item (e.g., a purely research procedure or screening test) is billed and denied, the institution cannot pass that cost to the patient.

What is the institutional risk if bills are inappropriately sent to insurance, especially federal payers?

Inappropriate billing can trigger:

- False Claims Act investigations
- Fines and settlements (millions of dollars in some cases)
- Loss of Medicare billing privileges
- Institutional reputational harm

Who determines the CA and the institution's tolerance for billing risk? How are differences of opinion resolved?

The Office of Coverage Analysis Administration (OCAA) and Revenue Cycle collaborate to ensure compliant billing for clinical trials.

- OCAA is responsible for developing the CA by reviewing the protocol and applying Medicare rules (e.g., NCD 310.1).
- Revenue Cycle determines the institution's tolerance for billing risk, as they are ultimately responsible for submitting claims and ensuring compliance with payer rules.
- If there are disagreements regarding billing determinations, the issue may be escalated to Revenue Cycle for final review. They assess the compliance and financial risk and decide whether a given item or service should be billed.

This shared decision-making helps ensure that all billing aligns with regulatory standards and institutional policy.

Do we rely on the NCI or NIH for a CA? If not, why not?

No, we do not rely on the NCI or NIH for a CA.

- While the NIH or NCI may fund, sponsor, or endorse a clinical trial, they do not conduct a formal coverage analysis that accounts for regional Medicare billing considerations or institutional requirements.
- Billing decisions must comply with CMS rules, including National Coverage Determination (NCDs) and any applicable Local Coverage Determinations (LCDs).
- Some studies may provide a national coverage analysis (NCA). When a NCA is provided, OCAA will review the NCA, but create a local CA that incorporates local policies. The local CA often does not align with the NCA.

Can we bill the sponsor if the insurance denies a claim?

No, you cannot bill the sponsor after insurance denies a claim as this would violate Medicare's Secondary Payer (MSP) rule, which requires Medicare to be the payer of last resort. Sponsors cannot be used as a backup payer after insurance denial. If a sponsor agrees to cover a specific item or service, it must do so consistently for all participants, not just those without insurance or limited coverage.

I have received a CA for review, now what?

The Principal Investigator (Study Team) is responsible for the timely review and acceptance of the CA. When you receive a CA from OCAA:

- Review the CA to confirm your agreement with the billing designations.
- Provide support (guideline, compendia, or journal) for any designations that OCAA deemed as research, but you feel may be billable to insurance.
- Respond promptly to all questions from the CA team.
- Timely review and acceptance of CA to reduce study start up time.
- Provide updated study documents (protocol amendments) to OCAA.

I do this all the time in the clinic, why is it considered research in the CA?

While a procedure may be standard in clinical care, it can be considered research in the CA for several reasons.

- When the **protocol enrollment is overly broad**. If a study's inclusion criteria allow participants who fall outside the population typically covered under conventional care, even if some patients qualify for billing under standard guidelines, not all will. If OCAA cannot justify billing for all enrolled patients, then the procedure is defaulted to **research** for consistency and compliance.
- When procedures are done **only at screening or end of treatment** for **all participants**, regardless of clinical signs or symptoms, they are considered **research-driven**. Because they are not based on individual medical need, they are captured as a **research cost**.
- **Off-label** usage of drugs or devices must meet Medicare's guidelines for coverage.
- When the item or service is **limited by an NCD or LCD.** Common NCDs and LCDs that limit coverage for standard of care testing/procedures. A few examples are below.
    - NCD 190.23: Lipid Testing - Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. **While lipid screening may be medically appropriate, Medicare by statute does not pay for it**. Lipid testing in asymptomatic individuals is considered to be screening.
    - NCD 190.17: Prothrombin Time (PT) **Repeat testing is limited absent changes in the underlying medical condition.**
    - NCD 20.15: Electrocardiographic Services **There is no coverage for ECG services when rendered as a screening test.**
    - LCD L35526: B-type Natriuretic Peptide (BNP) **Screening tests are statutorily excluded.**

When is off-label use of an anti-cancer drug billable?

Off-label use of FDA-approved anti-cancer drugs may be covered if it meets *medically accepted* criteria. This means the use is supported by:

- Recognized drug compendia such as:
    - AHFS-DI
    - NCCN (Category 1 or 2A)
    - Micromedex (Class I, IIa, or IIb)
    - Clinical Pharmacology (supportive narrative)
    - Lexi-Drugs (Evidence Level A, Use: Off-Label)
    - If a compendium lists the use as unsupported, not recommended, or equivalent, it is not covered.
- Peer-reviewed medical literature showing:
    - Adequate representation of the patient population and cancer type
    - Sound study design and meaningful clinical outcomes
    - Exclusion of abstracts or manufacturer-sponsored supplements

If none of these supports the off-label use, or if the use is explicitly not indicated by CMS or FDA, coverage will be denied.

Can Medicare cover off-label use of a drug that isn't used for cancer treatment?

Yes, Medicare may cover off-label (unlabeled) use of FDA-approved drugs for non-cancer conditions if the use is considered medically accepted. This determination is made by Medicare contractors based on:

- Major drug compendia
- Authoritative medical literature
- Accepted standards of medical practice, such as documented by guidelines