

Stanford Coverage Analysis FAQ

1. What is Coverage Analysis (“CA”)?

- a. Coverage Analysis is a formal review of study documentation and Medicare billing rules to determine which items and services performed as a part of a clinical research study may be legally billed to insurance, and which items must be paid for by the study account (or sponsor).
- b. Stanford’s new CA process is a requirement from SHC and SOM leadership to ensure that billing for clinical research to Medicare (and other third-party payers) is compliant and aligned with industry best practices.

2. What is changing about CA at Stanford?

- a. Going forward, Stanford PIs and study coordinators no longer have responsibility for completing the Research Participant Services (RPS) form or the Routine Care Services Form of the workbook.
- b. The new CA process enhances the existing “workbook,” which will now be referred to as the “Modified Workbook,” and will include a *Qualifying Clinical Trial (QCT) analysis*, to ensure that *Routine Costs* in a clinical trial are eligible for reimbursement under Medicare billing rules¹; and a *Billing Grid* that identifies the billing responsibility for each item/ service performed by the study.
- c. SHC has hired an external consulting firm, Ankura Consulting, to develop the coverage analyses for our clinical research studies. Ankura will complete the QCT analysis and Billing Grid upon initiation of new studies. The billing grid will auto-populate the existing RPS form. The Routine Care Services Form will no longer exist.
- d. Principal Investigators and Clinical Research Coordinators may be required to respond to inquiries from the Ankura team for additional documents, questions about the study, or follow-up on Draft/ Final CA versions.
- e. Sponsor- paid invoiceable clinical services will default to the research account in EPIC as opposed to patient/ insurance.

¹ The coverage analysis process springs from guidance finalized by CMS in 2008 called the “Clinical Trials Policy” which states that: “CMS will pay for the “routine costs” of “qualifying clinical trials” and all other Medicare rules apply.” Additional information about Medicare’s Clinical Trial Policy can be found in Addendum A of this FAQ. To access the CMS Clinical Trials Policy, also known as National Coverage Determination 310.1 (NCD 310.1), please reference addendum click [here](#).

3. What are the investigator and study team member’s responsibilities in the Coverage Analysis process once the draft CA has been prepared by Ankura?

- a. Investigators will be required to review the CA and certify via email to Ankura that they agree with the designations of what is “routine care” and what is being done specifically for research purposes in the study. If you do not agree with the determinations made by Ankura, the consultants will work with you to ensure that there is agreement before a CA is finalized.
- b. Validate that the correct CPT code has been assigned for each item or service included in the coverage analysis.
- c. Utilize the Final Approved CA (Harmonized version of the Modified Workbook) to request the SHC 98 hospital account and to notify the hospital of enrolled patients.
- d. Complete the “Study Account Request Form” and “SHC- Study Enrollment Form” in the modified workbook and submit to SHC Patient Financial Services once the study has been activated and you are ready to enroll participants.

4. Which studies are required to have a Coverage Analysis?

- a. Studies that necessitate clinical services which take place at SHC hospitals and clinics (i.e., clinic visits, laboratory assessments, imaging, drug infusions, etc.) will require a coverage analysis.
- b. The CA requirement includes all sponsored projects as well as unfunded projects and projects funded from gift or department sources.

5. When will the new SHC Coverage Analysis process begin?

- a. November 18, 2019: All new industry sponsored studies with clinical services at SHC submitted to the RMG or CCTO intake process will undergo a Coverage Analysis in the modified workbook.
- b. April 12, 2021: All new grant funded studies (federal, foundation, society, etc.) with clinical services at SHC that have been assigned to IRB panel review on or after April 12, 2021.
- c. Date TBD: All new Investigator- Initiated studies, department funded, gift funded, or unfunded, and other miscellaneous studies with clinical services at SHC and/ or CTRU that have been assigned to IRB panel review will be included in the new CA process at a later date.
- d. Note: Studies that take place at Stanford Children’s Hospital will be included in the new CA process at a later date.

- e. Note: Amendments for studies that have gone through the Ankura Coverage Analysis process will require an Amendment CA.

6. What is the cost to complete a Coverage Analysis for my study?

- a. The cost of a CA for industry sponsored studies is \$2,500 plus indirect costs. The cost of completing a CA will only apply to studies in which the study is industry sponsored.
- b. All other studies, including federally sponsored clinical trials, gifts, department funded, and unfunded studies will not be charged a CA fee. SHC also will waive the fee for Stanford investigator-initiated studies (regardless of external/industry support).
- c. The cost of a CA amendment for industry sponsored studies will not exceed \$1,500 and will depend on the complexity of the amendment.
- d. To assist with budget and contract negotiation, a memo can be provided to sponsors for justification of the CA fee. (“SHC Coverage Analysis Justification Memo”; download [here](#)).
- e. RMG or CCTO will include the CA fee in the sponsor budget for all new studies submitted to RMG or CCTO on or after November 18, 2020.
- f. SHC will generate invoices monthly for the completed industry sponsored CA’s. Invoices will be sent to the respective Department Finance Administrators (DFA) or post-award managers for payment processing. Further instruction is forthcoming.

7. How will studies be identified that require Coverage Analysis?

- a. RMG and Stanford Cancer Clinical Trials Office (CCTO) will identify studies requiring a CA through their respective intake processes.
- b. The eProtocol application will include a new form that asks if your study requires clinical services that take place at Stanford Health Care, and/ or at Stanford’s CTRU.

8. What is the process for Coverage Analysis?

- a. Ankura will be notified by RMG or CCTO of new studies with clinical services at SHC. Ankura will also receive a weekly report from eProtocol identifying clinical trials that have been assigned for IRB panel review. Ankura will review the protocol to assess whether a coverage analysis is needed. Once all essential documents to complete the CA have been received, Ankura will complete an Initial Draft CA in 10 business days. This can happen concurrently with other study- initiation

activities, with the exception of budget development which is predicated on the CA.

- b. The Principal Investigator will be required to review and approve the Initial Draft CA, either at the time of the kick-off meeting with RMG or CCTO, or within 10 business days of receiving the CA. Ankura will then issue an Initial Approval CA. PI approval should be submitted via email to: StanfordCAintake@ankura.com.
- c. Process for resolving coverage disagreements:
 - i. Change to billed to Study Account: If an item or service was initially determined to be conventional care, but the Principal Investigator determines that it should be billed to the study account (or sponsor). Ankura should be notified and the CA will be updated.
 - ii. Change to billed to Insurance: If an item or service was initially determined to be for research purposes, but the Principal Investigator indicates that it is conventional care and should be billed to insurance, then published supporting documentation (i.e. peer reviewed literature) should be provided to Ankura for review. Since deliberation via email correspondence can be complicated, a call may be scheduled with Ankura and the project manager and/or PI to work through any questions. If sufficient supporting documentation is not available and consensus is not able to be met regarding the coverage determination, the matter may be escalated to PFS for review and appeal.
- d. Ankura will ensure that the Final CA is in alignment with the final approved Informed Consent Form and fully executed Clinical Trial Agreement/ Notice of Grant Award, including sponsor budget/ Funding Sheet, once IRB approval has been granted and contract/ award has been executed.
- e. Clinical Research Coordinators will submit the Final Approved CA to PFS to initiate an SHC 98 account request and to notify PFS of newly enrolled subjects.
- f. Amendments that require protocol changes and/ or budget modifications will require a CA Amendment and should be submitted to RMG or CCTO.

9. Why is Coverage Analysis necessary?

- a. CA ensures accurate billing to insurers for standard of care services delivered as part of clinical research studies performed with SHC patients.
- b. The federal government has stepped up its efforts to ensure that the Medicare and MediCal programs have been appropriately billed for the routine care (or standard of care) services performed as part of any clinical research studies and this enhanced coverage analysis process is a positive step in ensuring ongoing billing compliance throughout SHC.

- c. The government expectation and the undisputed industry best practice is to document compliance with the CMS Clinical Trials Policy by preparing a formal written analysis of clinical trials to determine if they meet the policy “qualifying” criteria, and to determine by independent, nationally recognized written standards what is considered “routine care” for the underlying disease condition of patients enrolled in the study.

10. Who should I contact for further questions about the Coverage Analysis process?

- For questions, please email: StanfordCAintake@ankura.com.
- CCTO will distribute additional information pertaining to the CA process to all investigators involved with cancer-related clinical research.
- More information regarding the Coverage Analysis policy and procedure will be forthcoming on RMG, Spectrum, and SHC PFS websites.

Addendum A:

Medicare’s National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

The [Medicare National Coverage Determination 310.1 \(“NCD 310.1”\)](#), also known as The Clinical Trials Policy (“CTP”), is the national driver for research billing compliance as it presents the biggest billing risk for institutions who bill the government for items and procedures in clinical trials, and it is also the most comprehensive policy amongst all payers. States that require insurance companies to provide coverage during clinical research tend to follow Medicare rules. Additionally, the Affordable Care Act’s private insurance rules for coverage during certain research studies closely resembles the Medicare rules. Therefore, most institutions around the country use NCD 310.1 as a proxy for all patients in all studies.

The Clinical Trial Policy states that Medicare covers the “*routine costs of qualifying clinical trials*, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.”

Ankura’s Coverage Analysis will include a Qualifying Clinical Trial (QCT) analysis to first determine if the study qualifies for coverage; and a billing grid to identify which items and services required by the protocol are routine costs and eligible for Medicare coverage versus those items are service that are not routine costs as defined in the CTP, and therefore must be covered by a research sponsor (or other funding sources).

What are Routine Costs?

- Items or services that are typically provided absent a clinical trial (e.g., conventional care);
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

Routine costs exclude the following:

- The investigational item or service, itself unless otherwise covered outside of the clinical trial;

- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

What is a Qualifying Clinical Trial?

Any clinical trial receiving Medicare coverage of routine costs must meet the following four requirements:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
4. Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA; Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and VA; Trials conducted under an investigational new drug application (IND) reviewed by the FDA; or drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1).