


Clinical Research Support Office (“CRSO”) STANDARD OPERATING PROCEDURE

SOP NUMBER CRB-SOP-5001	TITLE Coverage Analysis
EFFECTIVE DATE 08/30/2019	WRITTEN BY CRSO Director

APPROVAL	
	August 29, 2019
_____ SIGNATURE	_____ DATE

1. POLICY STATEMENT

The University of Kentucky (“UK”) through the Clinical Research Support Office (“CRSO”) conducts a formal Coverage Analysis (“CA”) process to ensure compliance with clinical research billing rules and regulations. Any clinical research involving human subjects as defined by the National Institutes of Health (“NIH”) that needs to follow the Institutional Review Board (“IRB”) process will be subject to a CA.

The formal CA is a systematic review of clinical trial documents to determine the billing designation for those items and services that will be performed during the study. The CA is based on the rules and regulations pertaining to Medicare coverage decisions in clinical trials. The Centers for Medicare & Medicaid Services (“CMS”) oversees the National Coverage Determinations (“NCDs”) and the Local Coverage Determinations (“LCDs”) and defines the coverage of Routine Costs in Clinical Trials. The national policy governing the fiscal coverage of clinical trials is documented under [NCD310.1](#).

The NCD 310.1 contains general provisions only applicable to clinical trials; however, the totality of NCDs issued by CMS contains specific provisions that either limit or expand coverage for procedures, targeted diagnoses, or treatments for all Medicare beneficiaries.

2. PURPOSE

The purpose of this policy is to formalize the UK CA process that is observant of the rules and regulations surrounding billing and payment for routine costs in clinical trials. All institutions conducting clinical trials must follow the federal provisions issued by CMS including the CA to determine routine costs even if the participant is not enrolled in the

Medicare program.

CONSIDERATIONS

All UK clinical trials with billable services are required to utilize the Clinical Trial Management System ("CTMS") for documenting, tracking, maintaining and monitoring study services, financials, procedures and visits. The Principal Investigator ("PI") is responsible for the services that will be billed to the sponsor, study account, the enrolled participants or third-party insurance during each visit for each procedure performed.

3. SCOPE

This policy is applicable to all UK clinical trials that meet the criteria under the [definition of a clinical trial](#) issued by the NIH as defined in the UK minimum footprint criteria.

4. RESPONSIBILITIES

Principal Investigator or designee

- Prepare and submit all documentation as required under the Clinical Trial Activation SOP;
- Notify CRSO proactively when the status of the study has changed (i.e., IRB not approved, substantial changes in the protocol while performing the CA, and hold status) as soon as it is known;
- Ensure that there is clear and consistent language in the approved protocol, ICF, clinical trial agreement, budget or funding memo, regarding research related services and standard of care services (routine costs);
- Ensure through clear documentation that the study participants are aware of the procedures and services occurring at each visit and which will be covered by the research study and under what circumstances the participant and/or his/her insurer may have a potential financial obligation;
- Ensure submitted documents for CA include contact information for the unit in charge of the medical billing management of the study should the research subject have any billing questions;
- Participate in the intake meeting (as needed) and the CA review and provide timely approval within 7 business days of the CA draft notification to avoid delays;
- Request the plan codes following the UK's internal written guidance and not before obtaining the final CA from the CRSO;
- Maintain correspondence, CA final letter, and other records associated with clinical trials billing, including UK's institutional systems of record (e.g., CTMS, HQPM).

CRSO Coverage Analyst

- Review the documents submitted, resolve any questions, determine if a trial is qualifying or non-qualifying, and prepare a draft CA for review;
- Provide justification for all billing designations with federal provisions as required for clinical trials;
- Provide clarification as needed, and timely resolve issues so that the study teams can proceed with the next steps in the process;
- Prepare a detailed CA in the CTMS for all qualifying clinical studies regardless of funding source, identifying items and services considered routine costs and those that must be billed to research studies;
- Enter the CA grid in the CTMS, obtain peer review quality control, and complete the sign off;
- Review non-qualifying trials and prepare the official response to the study teams in a timely manner to ensure they can proceed with the next steps in the process;
- Inform the Billing Integrity Manager about potential financial risks uncovered during the CA process that cannot be solved or addressed without escalation;
- Upload the final letter in CTMS for study teams to facilitate the process of obtaining a plan code.

CRSO Research Billing Integrity Manager

- Facilitate the completion of the CA process stages, and remove barriers to ensure the CA process is effective and that it follows the billing rules set forth by the federal regulations governing clinical trials billing;
- Ensure the CA process follows the prioritization defined by UK and the CRSO management team;
- Collect and report metrics to maintain a streamlined process and to ensure process improvement over time;
- Resolve issues escalated by the study team and coordinate with the CRSO Director when needed to ensure timely problem resolution;
- Conduct reconciliations between the final CA and the budget in the CTMS and ensure that discrepancies are addressed before they are released;
- Manage the billing integrity program for all clinical trials in the CTMS by conducting periodic reviews, routine sampling and root cause analysis of billing errors.

5. PROCEDURES

1. The following are required documents to initiate a coverage analysis and should be submitted per the Clinical Trial Activation SOP:

- Final protocol to be submitted to IRB for approval
- Informed Consent in draft form
- Clinical Trial Agreement
- Draft budget or funding memo
- FDA IND approval
- FDA IDE approval*
- CMS IDE approval*

*Regardless of IDE promise to pay by sponsor, all IDE studies must have CMS approval.

2. Coverage Analyst identifies and documents 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.
3. Coverage Analyst schedules an intake meeting if necessary, with the study teams no later than 72 hours after the initial submission described in 5.1 or participates in a department intake meeting already scheduled.
4. Coverage Analyst conducts an initial review of the submitted documents and prepares the internal checklist form with the information received prior to the intake meeting.
5. Coverage Analyst participates in the intake meeting and resolves initial questions needed to proceed with the CA.
6. Coverage Analyst thoroughly reviews the final protocol, ICF and other documents and ensures:
 - That the documents are consistent
 - That the ICF does not promise financial payments not supported by the protocol
 - That the ICF offers payment of items promised by sponsors in the protocol
7. Coverage Analyst determines and documents billing designations for all procedures and services documented in the protocol. Billing designations for protocol related 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 including time and effort.
8. Coverage Analyst documents and references applicable billing regulations, insurance coverage decisions, and supporting information that support Routine Costs insurance billing.
9. Coverage Analyst contacts the study teams once the CA is finalized and asks for in-person or virtual meeting availability for study teams that are not familiar with the CA process and if needed to present the CA. For study teams that are already familiar

- with the CA process, the analyst will provide the CA document or will inform the team that the document is available in the CTMS system for their review.
10. Once the teams have received notification that the CA is ready for review, they will have 7 calendar days to respond for either clarifications or further examination of specific items. The analyst will have 15 calendar days after the request for changes to process the revisions and close the CA.
 - 10.1 Coverage Analyst provides further explanation if needed, and updates the CA based on clarification or additional information from the study teams (e.g., sponsor agreement to cover additional procedures).
 11. Coverage Analyst finalizes the CA and provides the study team an official letter outlining next steps.
 12. Coverage Analyst enters the CA into CTMS and follows all protocol and calendar signoff processes.
 13. Study team must provide coverage analysis documentation when submitting for a plan code.
 14. **Escalation process and problem resolution for CA issues:** The escalation process should be utilized when agreement cannot be met between the CRSO Billing Integrity Team and the study team's representatives and the PI. The escalation process is designed to provide further explanation and justification for the billing designations as requested by the PI or study teams.
 - 14.1 First step additional review:
 - 14.1.1 The Billing Integrity Manager reviews the issues and provides a statement with a potential resolution to leadership (CRSO Operations Director, CRSO Director)
 - 14.1.2 The summary is presented to the PI
 - 14.1.3 If the PI is not in agreement with CA at this stage, then proceed to second step for additional review.
 - 14.2 Second step for additional review occurs between the department and UKHC Finance external to the CRSO. Any escalation not resolved via the above additional review should reference that process.

6. ATTACHMENTS

None

7. REFERENCES

CRSO Clinical Trial Activation SOP
Coverage Analysis Work Instructions
Coverage Analysis Workflow
UK Minimum Footprint