Clinical Research Support Office (CRSO)

Coverage Analysis (CA): Frequently Asked Questions

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Or

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1. **Q: What is a Coverage Analysis, and why do I need it?**

   A: Coverage Analysis is a prospective review of all items and services provided in **an NIH-defined clinical trial** to identify how each item may be funded. The process involves a detailed review and application of Medicare's National and Local Coverage Determinations (NCDs and LCDs) as well as specialty guidelines. The process informs your study team of which items may be billed to the patient/their insurance and which will need to be funded by the study. The CA should be done before your budget is finalized to ensure that there will be sufficient funding available for all research-related items.

   a. National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) outline the circumstances for which items and services are reasonable and necessary for the diagnosis or treatment of a particular condition. In the absence of an NCD, an item or service may be covered at the discretion of Medicare Administrative Contractors (MACs) based on LCDs. NCDs apply to all Medicare beneficiaries nationwide while LCDs vary based on region.

2. **Q: What does it actually mean when a clinical trial is considered "Non-qualifying"?**

   A: "Non-qualifying" is a term used by Medicare to categorize clinical trials that don't meet the criteria for additional reimbursement of services. A patient's conventional care can still be provided and billed to the patient/insurance as if they were not enrolled in a trial, but any costs that relate to the trial itself cannot be billed (for example, more frequent labs and scans for monitoring and data collection).

   a. Medicare non-qualifying clinical trials will undergo a "conventional care review". The coverage analyst will complete the QCT checklist and outline any services that are considered conventional care based on national guidelines and federal regulations. Our team will then meet with the PI or their representative to discuss the findings. Please note that NCD 310.1 does not apply to Non-Qualifying Clinical Trials.

   b. Non-qualifying trials may utilize data collected from routine care services, but those are only services that would be performed regardless of the clinical trial. Also note that routine care claims associated with non-qualifying trials will not contain any clinical trial identifiers and should *never* be marked as "Study Related-Bill to Insurance" during first- or second-tier billing review.

3. **Q: Are there any clinical trials/research studies that are exempt from Coverage Analysis but require billing review?**

   A: Studies that do not meet the NIH definition of a clinical trial and biobanks are examples of protocols that are exempt from CA but not from billing review:

   a. Clinical protocols that are not NIH-defined trials should still be submitted to the CRSO for billing review. Inclusion in the CTMS may not be required. However, if the study involves any UK Healthcare billable items, then these charges may need to be processed through Epic. If a study needs to be in Epic for billing, the study will need to be captured in the CTMS, but the build and billing review will be considered a "billing calendar" as the term coverage analysis is only applicable to clinical trials.

4. **Q: What are "UK Healthcare billable items" and how do they affect the CA/billing review?**

   A: A "UK Healthcare billable item" is any service performed at a UKHC facility or by UKHC staff that is documented in Epic and therefore will generate a charge (i.e. clinical services like a physical exam, laboratory services, MRIs at UK Radiology). If a study (clinical research or clinical trial) involves UKHC billable items, it will have to be included in the CTMS and Epic systems so that charge segregation can occur.

   a. If a study does not involve any UKHC billable items (i.e. all services are conducted in research-only space), then Epic inclusion may be optional. For questions about this, please contact CRSOstudyassist@uky.edu.

5. **Q: At what point in my study start-up process should I submit for a coverage analysis? Once I submit, what does the process look like?**

   A: As soon as you have a final protocol and a draft version of your consent form, you can submit your CA request here: https://cctsdata.uky.edu/membership/. This should always occur before your budget is finalized. Once your request is submitted, our Clinical Trial Associates will build a protocol calendar and the coverage analysis will then be applied to the calendar. Once the CA is completed and approved by your team, the budget can be finalized and entered into OnCore as well. (Note: there may be specific instances when an OnCore calendar is not required, so the CA may be processed in Excel. For questions about this, please contact CRSOstudyassist@uky.edu)

6. **Q: If I know for sure that my study sponsor/grant is going to cover ALL of the costs in my clinical trial, do I still need a CA?**

   A: A CA may be expedited under these circumstances if documentation is provided to the CRSO with the CA submission request. If you are certain that no component of the clinical trial will be billed to the patients' insurance (including costs that may otherwise be considered routine), we may bypass our review of billing and provide a CA that reflects all protocol-required procedures as research costs. This might occur if all protocol activities are being performed in CCTS space or the sponsor has provided a fully-funded budget up-front.

7. **Q: Why do you use Medicare guidelines for coverage determinations? What if the trial population doesn't include Medicare beneficiaries?**

   A: Medicare is considered the "gold standard" for insurances nationwide. In terms of Coverage Analysis, since the Medicare and Medicaid programs are the largest public health programs in the nation, they provide the standard guidelines for coverage. The federal policy that implements the coverage of routine costs in clinical trials is (NCD 310.1) under the purview of the Centers for Medicare & Medicaid Services (CMS), which is a federal agency. Each Medicaid state-managed program may have different coverage of routine costs, and each commercial insurance may implement coverage policies. However, the majority of insurance carriers will follow the federal law for coverage as well as the limitations.

Q: What does the term "routine cost" mean?

A: Routine costs are items or services that are typically provided regardless of a patient's participation in a clinical trial. Providers often use the terms "conventional care" or "standard of care" to categorize what services are typically performed. "Routine cost" is more specific to Coverage Analysis as it categorizes not only which services are typically performed, but also which services are typically reimbursed by insurance. NCD 310.1 specifies that routine costs in a qualifying clinical trial also include those items and services required solely for the provision of the investigational item or service, 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.

8. **Q: My clinical trial provides an intervention and is clearly therapeutic – why am I being told its non-qualifying?**

   A: In addition to being interventional and having therapeutic intent, a qualifying trial must also enroll patients with a diagnosed disease, the investigational item or service must fall within a Medicare Benefit Category, and it must be "deemed".

   a. Note that the above requirements also mean the trial must *have* an investigational item or service – if all interventions provided are considered "standard of care" then the trial may not qualify.
   b. A trial is most often "deemed" by an IND/IND Exemption, or by the funding source. Please consult Medicare's Clinical Trial Policy (NCD 310.1) or contact CRSOstudyassist@uky.edu for additional details.

9. **Q: What is the difference in billing between a qualifying and a non-qualifying trial?**

   A: In both instances, services that are truly routine care for the patient population can still be billed to Medicare and third-party insurers.

   a. In a *non-qualifying* trial, the claims for these services will be submitted without clinical trial identifiers (NCT#, Q modifiers, Z00.6 diagnosis code, etc.), and no additional trial-related services may be billed. This same scenario applies to clinical research studies that are neither qualifying or non-qualifying but contain UK Healthcare billable items as explained above.
   b. In a *qualifying* trial, claims will be submitted with clinical trial identifiers, and some additional trial-related costs may be reimbursed (for example: more frequent labs may be covered for monitoring the patient's safety while taking an investigational medication).

10. **Q: I have the FDA IDE letter and finalized protocol documents - why do I need CMS (Medicare) approval for my device trial?**

    A: Unlike other types of Clinical Trials, the NCD 310.1 provision does not apply to device studies. The FDA approval is necessary to comply with the federal rules; however, CMS is the only entity that can Qualify a device trial for reimbursement of routine costs. Without a CMS approval, no portion of an investigational device study may be billable to the patient or their insurance.

        a. In addition to CMS approval for the device trial, a notification to CGS (our local MAC) is required to ensure that proper billing can occur. The CRSO must be notified once confirmation of the notification is received from CGS.

11. **Q: The specialty guidelines for my study population recommend that a specific service be performed - why is it designated as a Research cost on the Coverage Analysis?**

    A: There are a few possible reasons for this, but most likely there is a coverage limitation imposed by a Medicare via the NCDs or LCDs. The limitation may be based on frequency, diagnosis, or absence of specific signs/symptoms. Please review the justification provided for that item in the CA, or contact CRSOstudyassist@uky.edu for specific details.

12. **Q: What other sources do you consult in order to complete a coverage analysis?**

    A: In addition to Medicare's National and Local coverage determinations, we review nationally recognized, evidence-based guidelines. This includes specialty guidelines for specific patient population in a trial (i.e., NCCN, AHA, UpToDate), FDA medication labels, as well as the Lexicomp and NCCN Compendia for detailed information about on- and off-label medication coverage.

13. **Q: Can patients be billed for routine services in clinical trials if their insurance does not cover the service?**

    A: Yes. The Coverage Analysis exists in part to help protect patients from undue financial burden. If a service is billed to insurance as part of a clinical trial and denied, it will be the patient's responsibility to cover the cost of that service. This can cause unnecessary financial hardship to the patient, and reduce the likelihood of their continued participation in clinical trials.

14. **Q: I've always negotiated my study budget without a Coverage Analysis. How does the CA help me, and why do I need it before I finalize my budget?**

    A: There are a LOT of important reasons to use your CA as a tool for budgeting:

        1. Maximizing resource allocation:
            a. The CA provides a detailed forecast of which services in your trial are likely to be reimbursed and which are not. With a clear outline of costs billable to insurance,

your team can put grant/sponsor funding toward those services that are not reimbursable.

2. Maximizing revenue:
    a. The institution may forgo a significant amount of revenue due to unanticipated claim rejections. With a CA to guide billing, many claim denials could be entirely avoided.
3. Compliance:
    a. Equity: With very few exceptions, all participants in a clinical trial should be billed (or not billed) for the same services. The CA evaluates billing for the general population enrolling in the trial, so any service billed to Medicare/third-party for one patient should be billed for all. Particularly, any service covered by the sponsor for one participant needs to be covered for all participants.
    b. Double-billing: Using the CA to guide your budget helps to ensure that funding for a particular service comes from one, and only one, reimbursement source. (Example: If an EKG is designated BILL in your CA, you should not have a line item for EKG in the final sponsor/grant budget). Whether or not it is intentional, double-billing is considered fraud and may result in investigations and sanctions.

15. Q: What happens if I promise a service free of charge in the ICF, but then bill insurances for the same service?

A: Two problematic scenarios can occur here:

1. When you promise a service to the participant in the ICF you're setting the expectation that they won't pay the cost of that service in any way. By billing the item to their insurance *instead of* the sponsor you make the patient's treatment subject to deductibles and co-pays. This increases the financial burden of participation.
2. If you bill an item promised in the ICF to the participant's insurance *in addition* to billing the sponsor, this is called double-billing and is a violation of the Federal False Claims Act.

16. Q: How should time and effort be captured in my study budget?

A: Research time and effort related to a procedure should always be accounted for separately from the procedure itself. For instance, you need to bill the actual EKG procedure to insurance, but there is additional research time and effort related to the EKG that needs to be covered by the study sponsor. If they are combined in a single line item ("EKG") it allows the opportunity for an accidental bill to be sent to both insurance and the sponsor for the entire procedure. This can cause unnecessary confusion, but more importantly can result in double-billing.

17. **Q: Are NIH-sponsored clinical trials always considered Medicare Qualifying?**

A: No - a study does not automatically qualify for Medicare reimbursement simply because it is funded by NIH. Medicare billing rules still apply and the trial must still meet the additional qualifying criteria outlined in NCD 310.1 to receive Medicare coverage of routine costs.

18. **Q: What do I do if services for my study are not billable to Medicare or other third-party payors?**

A: If patient care costs in your study are determined by the CA to not be billable to Medicare or other third-party payors, the Principal Investigator must secure other appropriate sources of funding. This is an important reason to have a CA completed before you finalize your budget.

19. **Q: Do Clinical Research Billing Compliance laws, rules, and regulations apply *only* to Industry sponsored studies?**

A: No. Medicare and Private Payor rules and requirements for documentation, coverage, and billing apply to ALL clinical trials regardless of the funding source. Therefore, it is important to have an itemized coverage analysis completed to identify which protocol services are billable**.**

20. **Q: How will my CA look in OnCore?**

A: In OnCore, you can view the CA either in a consolidated list or as a visit-by-visit billing grid. Both views will include the procedures from your protocol SOE, billing designations assigned to each procedure, and a justification outlining how that billing designation was determined.

a. Procedures: Before a CA can be performed, the calendar must be created. This is normally done by the CRSO CTASBI Team and it will generally include all items and services performed as part of the clinical trial (physical exams, lab work, imaging, informed consent, etc.). Once the OnCore calendar is complete, the CA is "applied to" the calendar. Each procedure will have a billing designation assigned to it at each scheduled visit.

b. Billing designations:

a. The primary billing designations you will see in OnCore include:

1. R, which indicates a sponsor-paid item, or
2. BILL, which indicates an item billable to patient/insurance
3. In addition to the primary billing designations, you may also see supporting designations and billing modifiers. Supporting designations are paired with primary designations in order to indicate specific information for your budgeting process.

1. R(T) – the (T) indicates time and effort, and because it is paired with an R billing designation, it is research-related and should be figured into the study budget
2. BILL1 – the 1 indicates that the item is billable to insurance, as part of a qualifying clinical trial. These items are considered routine costs of a clinical trial and are supported by NCD 310.1.

c. Justifications: In the "Comments" section of OnCore, the coverage analyst will provide details and references to support the assigned billing designation for each procedure. For example, if a drug is being used for an approved, off-label use, the justification should include information from a drug compendium (i.e. Lexicomp) that outlines why the item can be reasonably billed to Medicare/third-party insurance. This information should be able to aid in supporting a claim or appealing a denial if one is issued.

21. Q: Does my research study have to be active in Epic?

A: Your study is required to be in Epic if any of the following circumstances are applicable:

a. Your study involves UKHC billable items, that is clinical services that are documented in the medical record and provided at a UKHC facility or by any provider.

22. Q: How does having my study in Epic relate to the CA information in OnCore?

A: Having a study in Epic will require research billing review to be done for all subjects that are enrolled in your study with an active status in OnCore.

a. Each time a subject is seen at UK Healthcare (whether or not it's related to your study) all charges from their visit will be held in a report for review. Each encounter will need to be reviewed individually by a study team representative to confirm whether or not the charges are research-related. There are 3 different ways that charges can be "bucketed" in Epic for billing:

1. **Study Related – Bill to Study**: These are charges that are being covered by the grant/sponsor and are designated "R" in the CA.
2. **Study Related – Bill to Insurance**: These charges are considered routine costs related to a clinical trial. Any services that are part of the protocol SOE and are being billed to insurance should fall into this bucket. They will be billed to insurance with research modifiers on the claim. **Note**: this bucket should *never* be used for charges that are part of a Medicare non-qualifying trial, or Non-NIH defined, or simply clinical research protocols.
3. **Not Study Related**: These charges are a patient's conventional care unrelated to the study they are enrolled in. These are services performed that do not align with the protocol SOE (i.e. a flu shot ordered as conventional care for a subject enrolled in an unrelated dentistry study).

24. Q: What happens if my study is a Bio-Bank but I am gathering tissue from a standard of care/ conventional care surgery?

A: You will need a billing review conducted by the CRSO to determine if your protocol contains billable items. Most likely the extra time you spend collecting the tissue, the professional fees, and anesthesia will be charged to the study as research procedures. You should never expect to conduct a conventional care surgery adding research procedures charging the insurances for these. Epic requires complete documentation of clinical services, including those performed for research purposes only as those are considered clinical services regardless of the payer.