Coverage Analysis (CA): Frequently Asked Questions

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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 determine how each item should 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 can 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 all research-related items can be negotiated with the sponsor.

      a. National Coverage Determinations (NCDs) 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 Local Coverage Determinations (LCDs). NCDs apply to all Medicare beneficiaries nationwide, while LCDs vary based on region

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

   A: Yes! Studies that do not meet the NIH definition of a clinical trial, and compassionate use/expanded access protocols are exempt from CA review.

3. **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/. As a reminder, this should always occur before your budget is finalized. Once your request is submitted, our CTMS team 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 a CRSO Coverage Analyst)

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

   A: A CA may be able to 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 procedures are research costs. This might occur if all protocol activities are being performed in CCTS space, or the sponsor has provided a full-funded budget up-front.

a. This version of a CA should only be requested when you have documentation that full funding will be provided for the study. If any charges are not funded by the research study, a full review will be needed to determine whether or not insurance billing is an option. This may cause delays in study start-up and may result in unanticipated costs.

5. **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 Coverage Analysis, because the Medicare and Medicaid programs are the largest public health programs in the nation. The federal policy that implements the coverage of routine costs NCD 310.1, is 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 may follow the federal law for coverage and limitations.

6. **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 which services are typically reimbursed by insurance.

7. **Q:** What does it actually mean for a clinical trial to be "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. Routine costs 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 data collection)

   a. Observational, data collection, and registry studies are all examples of Medicare Non-qualifying Trials. They may utilize data collected from routine cost services, but those services would be performed regardless of the clinical trial, and the claims will not contain any clinical trial identifiers

8. **Q:** My clinical trial provides an intervention and is clearly therapeutic – why am I being told it's 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 a CRSO Coverage Analyst 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.
   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 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 federal agency 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.

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 NCD or LCD. 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 a CRSO Coverage Analyst 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 specialty guidelines for specific patient population in a trial (ex. NCCN, UpToDate). We also utilize 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 pay?

    A: Absolutely. The Coverage Analysis exists in part to help protect patients from undue financial obligations. If a service is billed to insurance as part of a clinical trial and denied, the bill will become the responsibility of the patient to pay. This can cause unnecessary financial hardship to the patient, and reduce the likelihood of their participation in future 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 would be entirely avoided
    3. Compliance
        a. Equity: With very few exceptions, all participants in a clinical trial should be billed for the same services. The Coverage Analysis 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 (See *Medicare "No Legal Obligation to Pay"* question, below, for additional details on this)
        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 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, at least. 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 federal offense.

16. Q: Can I "title" an item in my budget as a procedure, but charge the sponsors time and effort?

A: No, this one of the quickest ways to compromise compliant billing practices. If you need to budget time and effort of each individual procedure, the time and effort should be a separate line item. For instance, you need to bill the actual EKG procedure to insurance, and the time and effort related to the EKG billing to the 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 routine costs on an NIH-sponsored clinical study automatically billable to Medicare?

A: Not always. 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. in order 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: This is another reason it is important to have a CA before you finalize your budget. 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.

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 studies, regardless of the funding source. Therefore, it is important to perform an itemized coverage analysis/prospective reimbursement analysis 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. However you view it, it will include the procedures from your protocol SOE, billing designations assigned to each procedure, and a justification for 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 CTMS 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 (all procedures are listed, and are scheduled at protocol-indicated time points) the CA is "applied to" the calendar. Each visit will have a billing designation assigned to it

b. Billing designations:
   i. 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
   ii. In addition to the primary billing designations, you may also see supporting designations. 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 should be figured into the study budget
      2. BILL(CT) – the (CT) indicates that the item is billable to insurance, but only because it is part of a qualifying clinical trial. These items are 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.