A METHODOLOGICAL APPROACH TO COVERAGE ANALYSIS

To ensure appropriate reimbursement for the services provided to a patient in a clinical trial, research sites must develop a budget for each study. One important step in developing a clinical trial budget is conducting a "coverage analysis," also known as Medicare Coverage Analysis, sometimes referred to an MCA.

An MCA identifies the services for which U.S. Centers for Medicare & Medicaid Services (CMS) will pay under the Medicare Clinical Trial Policy also known as NCD 310.1. A methodical analysis ensures that a research site receives appropriate and correct reimbursement for services. It also helps avoid compliance pitfalls with regard to inappropriate billing.

The Risk of Non-Compliant Billing

Providers are not permitted to bill Medicare for medical care and services for which the clinical trial sponsor has agreed to pay.

Failure to comply can result in severe penalties, as well as civil and criminal actions. There have been some high visibility cases in which health systems and academic medical centers have settled allegations of violation of the False Claims Act. Some settlements have resulted in payment in the millions of dollars to the U.S. government

A Methodical Approach

Determining the eligibility of a clinical study's related tests, procedures or interventions for Medicare coverage requires a detailed review of the clinical events specified in the protocol to determine which can be reimbursed. This sometimes cumbersome and time-consuming process is essential.

The first step is to determine whether the trial qualifies for coverage. To qualify, a trial should meet these criteria:

- The purpose of the trial must be to evaluate an item or service that falls within a Medicare benefit category. For example, physicians' services, durable medical equipment and diagnostic tests would be covered; cosmetic surgery and hearing aids would not.
- The trial must have a therapeutic intent. Does it potentially improve the participants' health outcomes? In other words, it cannot be a study designed exclusively to test toxicity or disease pathophysiology.
- The trial will enroll patients with a diagnosed disease rather than healthy volunteers.

These three requirements are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics. Here is where institutions must work closely with their investigators, as well as the study sponsors, to ensure documentation in answer to these questions:

[1] LINK TO: https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies

- Is the principal purpose of the trial to test whether the intervention potentially improves the participants' health outcomes?
- Is the trial supported by available scientific and medical information or is it intended to clarify or establish the health outcomes of interventions already in common clinical use?
- Does the trial duplicate any existing studies?
- Is the trial design appropriate to answer the research question being asked in the trial?
- Is the trial sponsored by a credible organization or individual that is capable of executing the proposed trial successfully?
- Does the trial comply with federal regulations relating to the protection of human subjects?
- Are all aspects of the trial being conducted according to the appropriate standards of scientific integrity?

Some trials are deemed to have these desirable characteristics and automatically qualify. The following are examples of trials that would automatically qualify:

- Trials funded by a federal agency, such as the National Institutes of Health, the Centers for Disease Control and Prevention or the U.S. Department of Veterans Affairs, among others.
- Trials supported by a center or cooperative group that is funded by a federal agency.
- Trials conducted under an investigational new drug application reviewed by the Food and Drug Administration.
- Drug trials that are IND-exempt (see the Medicare Coverage Clinical Trials Final National Coverage Decision for Routine Cost in Clinical Trials for more details)

National vs. Local Coverage Determination

Analysis becomes even more complicated when considering Local Coverage Determination, the policies written by local or regional fiscal intermediaries representing CMS. This is where many of the pitfalls occur and where many institutions get lost, and also where state Medicare contractors make the majority of coverage decisions. A procedure or test may be covered in New York, but not California.

How device trials differ

In 2015, CMS and regulatory agencies streamlined the process of assessing coverage for IDE device trials. Sponsors, or device manufacturers, must submit trials to CMS for review and approval at the national level. Prior to this change, sponsors and sites had to wait until IRB approvals were obtained and submit documents to the local Medicare contractor. This CMS approval process2 applies to category A and B trials, as considered by the FDA:

- Category A devices are experimental, "...a device for which 'absolute risk' of the device types has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective." In other words, they are novel, which there is not enough information about the devices to make them eligible for reimbursement for the device itself.

[2] LINK TO: https://www.cms.gov/Medicare/Coverage/IDE

- Category B devices are non-experimental, or investigational, meaning "...a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type." These are similar to devices already in the marketplace, and the study is evaluating a modification.

That said, institutions must still conduct the coverage analysis to determine what is clinical care vs. research.

Standardizing and streamlining the process

Establishing an algorithm of questions and a process to collect the appropriate documentation is essential. It is also important that institutions conduct this analysis as efficiently and expeditiously as possible to minimize the risk of study initiation delays.

These are some of our recommendations for best practices.

- *Centralize*
  Centralizing the process of collecting and archiving all the relevant components, such as protocol, consent, sponsor budgets, contracts, FDA letters, etc., can ensure a degree of consistency in the review process. Some institutions are considering centralized MCAs, similar to central institutional review boards, which have been demonstrated to accelerate the start of studies at many institutions.

- *Standardize*
  Establish a standard operating process that defines the procedure from the time a provider sees a patient when the service is provided, to how the service is documented and communicated to the payers. This should include how institutional electronic health records and clinical trial databases should communicate with each other.

- *Educate*
  Provide ongoing education to research personnel. Experience and knowledge vary widely from one institution to another, and there is a shortage of well-trained analysts with this expertise. Additionally, research and billing staff should understand regional and state differences in coverage.

- *Collaborate*
  Work with the investigator to review the informed consent carefully to clarify costs, FDA status, visits and procedures; you should also review the entire protocol, not only the schedule of events. Additionally, work closely with the study sponsor — the pharmaceutical or device company — to differentiate between routine care and care provided by the sponsor.

Alex Morillo is the program director for Coverage Analysis at the Biomedical Research Alliance of New York (BRANY—www.brany.com). He works with research institutions across the country to ensure projects meet the requirements for Medicare reimbursement. He also provides assistance to research sites in Medicare billing compliance self-audits. Before joining BRANY, he worked in the clinical trials office for New York University, where he managed a portfolio of over 200 clinical trials.