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# An Introduction to Medicare Coverage Analysis

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Investigational sites obtain payment for clinical research studies from two major sources: the study sponsor and third-party payors, such as Medicare, Medicaid and insurance companies. Medicare coverage analysis (MCA) is the process of determining which study costs will be covered by Medicare. The site can negotiate with the study sponsor to cover the balance of the study budget. Medicare sets the standard that other third-party payors generally follow.

Study sponsors generally do not expect to pay for standard-of-care items and services (e.g., conventional care, clinically appropriate monitoring of the effects of the item or service and the prevention of complications) that Medicare or other third-party payors would cover as a routine cost.

The first step in MCA is to analyze the study protocol and related documents to identify all study-related items and services that might be billable to Medicare, other third-party payors or the sponsor. The second step is to determine which of those items and services are, in fact, billable to Medicare or other third-party payors and document the justifications. During this process, Medicare coverage analysts develop a detailed understanding of the study and create a billing grid (spreadsheet) that details their findings.

A thorough MCA provides the following benefits:

- Ensures the site is aware of all study-related items and services.
- Ensures the site identifies and correctly bills all chargeable items and services.
- May identify items and services that, because they differ from the site's standard practices, could require extra time or create opportunities for protocol deviations.
- In the informed consent process, provides accurate information to study participants about their financial responsibilities.
- Streamlines the billing process by determining in advance which charges will be billed to Medicare.
- Minimizes the risk of violating federal laws against improperly billing Medicare and Medicaid, which can trigger substantial penalties.
- Helps avoid double-billing.
- Generates detailed documentation for internal as well as potential Medicare billing audits.

## Medicare Rules and Regulations

In 1965, Congress established the Medicare and Medicaid programs as Title XVIII and Title XIX, respectively, of the Social Security Act of 1935.

In 2000, President Clinton issued an executive memo directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs ... and costs due to medical complications associated with participation in clinical trials." The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services

(CMS)) responded to the executive order on Sept. 19, 2000, with the Clinical Trial Policy National Coverage Determination (NCD) for Routine Costs in Clinical Trials.

In July 2007, CMS published a memorandum that revised the 2000 NCD, providing much of today's framework for clinical research billing compliance; for example, the following:

- Clarified that items and services in a clinical study are covered by Medicare if they are covered outside the clinical study in regular clinical care (e.g., in postmarketing studies).
- Added coverage for items and services in clinical studies that are employed to gather data to support Medicare coverage, known as "coverage with evidence development (CED)."

In October 2007, CMS put the July memorandum into effect as NCD 310.1, stating the following:

> "Effective for items and services furnished on or after July 9, 2007, 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."

NCD 310.1 is a "peer-coverage rule" to other national and local coverage determinations. (Medicare regional contractors issue local coverage determinations.) In other words, because NCD 310.1 does not overrule these other determinations, they may place limits on but not expansions of Medicare coverage.

**Qualifying Clinical Trials**

According to NCD 310.1, a qualifying clinical trial (QCT), i.e., a study eligible for Medicare coverage, must meet the following criteria:

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

- 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' services, durable medical equipment, diagnostic tests) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- 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.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials should also have the following desirable characteristics (however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage):

- The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
- The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The trial does not unjustifiably duplicate existing studies.
- The trial design is appropriate to answer the research question being asked in the trial.

 

- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
- The trial is in compliance with federal regulations relating to the protection of human subjects. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

A clinical trial is deemed to automatically meet the seven desirable characteristics if it is:

- Funded by the National Institutes of Health (NIH), the Centers for Diseases Control and Prevention (CDC), the Agency for Healthcare Research and Quality (AHRQ), CMS, the Department of Defense (DOD) or the Veterans Administration (VA).
- Supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or VA.
- Conducted under an investigational new drug application (IND) reviewed by the FDA.
- A drug trial exempt from having an IND under 21 CFR 312.2 (b)(l).

**"Routine Care" vs. "Standard of Care"**

Medicare covers what it calls "routine care." A hospital formulary is a similar concept. Standard of care consists of a much broader range of treatments and varies from medical facility to medical facility and from physician to physician. In the mind of most physicians, standard of care is whatever they believe to be the best treatment for a specific patient under specific circumstances.

Although Medicare's annual budget exceeds $800 billion, it cannot afford to cover every treatment. CMS considers medical necessity as the overarching criterion. Many new treatments are very expensive and, while they may be approved by the FDA, they have not yet met Medicare's criteria for routine care.

Medicare and its regional contractors issue frequent coverage exceptions. Coverage rules can be found in the following places:

- Medicare Coverage Database
- National coverage determinations (NCDs)
- Local coverage determinations (LCDs)
- Medicare benefit policy manuals
- Appropriate-use criteria programs
- Coverage with evidence development

**Phase 1 Studies**

Most Phase 1 studies examine toxicity, pharmacokinetics and/or disease pathophysiology, and do not have a therapeutic intent, so do not qualify for Medicare coverage. However, Phase 1b studies may have therapeutic intent (e.g., in cancer studies where the treatment is too dangerous for healthy volunteers so it must be tested on patients with the disease). To the extent that items and services relate to the treatment, they may qualify for Medicare coverage.

**Medicare Coverage of Adverse Events**

An MCA can also include a list of likely adverse events so, if one occurs, Medicare billing can proceed smoothly. However, per the Medicare Secondary Payor Rule, Medicare will not pay

for an item or service to the extent that payment has been made or can reasonably be expected to be made by the study sponsor. CMS has taken the position that the sponsor's agreement in an informed consent form or clinical trial agreement to pay for costs related to research-related injuries make the sponsor the primary payor. Submitting a claim to Medicare when the sponsor has not first been billed could be considered a "false claim," with potentially significant penalties.

## The Medicare Coverage Analysis Process

An effective MCA process:

- Verifies that the study qualifies as a QCT;
- Thoroughly reviews the protocol and all related documents, including the sponsor's proposed budget, the sponsor's draft informed-consent form, the investigator's brochure and the pharmacy manual;
- Creates a billing grid that lists items and services down the side and the schedule of visits and other events across the top;
- In the billing grid, captures all study items and services that may be billable to the sponsor or Medicare and third-party payors;
- Where available and appropriate, adds CPT and ICD-10 codes. Include Q0 and Q1 modifiers to identify services provided during a clinical study. When necessary, clarifies codes with the sponsor. Codes (and payments) can vary depending on various factors, (e.g., whether the study participant is a new or established patient);
- Obtains pricing information from your chargemaster;
- Classifies items and services that can or cannot be billed to the sponsor, Medicare or third-party payors. Determines which items and services constitute routine care. Medicare does not cover the cost of investigational items or services unless otherwise covered outside of a clinical study, but it does cover items and services required for the provision of the investigational item or service as a routine cost in clinical trials (e.g., administration of a noncovered chemotherapeutic agent); and
- Compiles supporting documentation and justifications for items and services detailed in the billing grid.

## Conclusion

Medicare coverage analysis is a critical component of the clinical research financial lifecycle and regulatory compliance. A capable Medicare coverage analyst must be detail-oriented and have in-depth knowledge of numerous arcane rules.

## Resources

"Medicare Clinical Trial Policies," retrieved June 6, 2021, from https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies.

"National Coverage Determination (NCD) for Routine Costs in Clinical Trials," retrieved June 6, 2021, from https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1.

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