# What is a Coverage Analysis and Why are they Important for Research Programs?

A coverage analysis is an evaluation of a clinical research study that is done in order to determine if the study sponsor or the patient/insurance will pay for each item or service required by the study. A coverage analysis is a critical component of all clinical research compliance programs, and numerous parties play essential roles in the clinical research billing compliance process, both before and after a study begins. This will help sites understand the basics of a coverage analysis, why they are an integral part of all compliant research programs, and how they can impact sites.

## Research Billing Compliance Basics

Successful billing compliance requires that all involved parties have access to necessary information, local and federal laws are followed, and patients are accurately billed. When formal research billing compliance guidelines were first developed, research sites began receiving millions of dollars' worth of fines for violations. In response, many institutions developed a coverage analysis (CA) process to ensure they were meeting the applicable billing guidelines. Research sites should ensure that their billing compliance team is familiar with the body of guidance documents governing billing best practices, including:

- **Clinical Trial Policy (NCD 310.1)**
  - Basis of research billing compliance (non- IDE devices)
  - States that Medicare will cover routine costs of a qualifying clinical trial
  - Defines "qualifying clinical trial" and "routine costs" and addresses non-covered items

- **Medicare Benefit Policy Manual, Chapter 14 – IDE Devices**
  - Basis of research billing compliance for device studies
  - Medicare will cover routine care items for certain device types

- **Medicare Coverage with Evidence Development**
  - Program for Medicare to collect additional data about certain items/services to determine if and when the item should be covered for their patients
  - Provides coverage for certain items/services only in the context of an approved clinical study and/or submission of data to a registry

Developing a coverage analysis process that considers these regulations can help sites avoid common billing compliance issues such as double billing (billing the patient/their insurance for an item the sponsor is paying for), improper billing (billing the patient/their insurance for non-covered items), and inconsistent billing practices.

## Conducting a Coverage Analysis

The overall goal of a CA is to determine if the study sponsor or the patient/insurance will pay for each billable item orservice required by the study. Each item or service should have one payer – either the patient/ insurance or the sponsor. Charging both parties, also known as double billing, is a major compliance issue.

A CA includes information for billers, budgeters, and clinical teams and shows each protocol-required visit and the activities at each visit. The justification for why the patient should or should not be billed for each protocol-required item/service is also included. To develop a comprehensive CA, sites typically review the:

- Protocol
- Sponsor budget
- Contract
- Consent form
- Relevant details from the study team
- National clinical practice guidelines
- Applicable billing regulations
- Other study specific information (e.g investigational product label)

It is important that all of the relevant study documents are incorporated into the review, to ensure alignment. Sites can run into issues if they promise the patient there will be no charges to their insurance for a test, but then forget to include that test in the sponsor budget.

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## How are Site Teams Impacted by Coverage Analysis?

Before a study opens, coverage analysts may ask site staff about several aspects of the study to ensure compliance. Study logistics such as where the study will take place, whether patients will be hospitalized, and who will perform certain activities should be addressed. Standard of care frequencies, including how often the investigator plans to order scans or repeat a test, will be of interest to coverage analysts as well.

Once the study opens, be sure to review and use your CA to maintain compliance. A CA that sits in your shared drive will not lead to compliance – you must use it! Reference the CA to answer cost questions during the consent process or any billing-related questions. Having a well-documented, regularly used CA in place is your best tool to ensure compliance.

## How can Non-Compliance Impact Sites?

The consequences of non-compliance can make it extremely difficult for sites to conduct business as usual, and the costs go beyond the obvious financial penalties (fines and paybacks). Audits take significant resources to manage. If there are findings from those audits, corrective action plans can take even more time and effort to implement. Non-compliance also puts future work at risk as sponsor may be reluctant to partner with institutions with known issues.

## Conclusion

A coverage analysis is a fundamental part of every compliant research program, and understanding the essential role they play in the clinical research billing process is crucial for the success of research sites.

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609.945.0101
**www.wcgclinical.com**