

Why Your Institution Should Conduct a Coverage Analysis

A coverage analysis, or a Medicare coverage analysis, is an integral part of clinical research compliance programs. Yet properly preparing for a coverage analysis is a highly involved and technical process, and many institutions lack the talent, training and speed needed for execution.

“Healthcare providers have an obligation to ensure their claims are accurate before they submit them to Medicare, Medicaid, or commercial insurance payers, and this is a process that a research site needs to go through in order to ensure they are doing their due diligence before pushing their claims out the door.”

— LEAH GUIDRY, MANAGING DIRECTOR, HURON

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In the following Q&A, Leah Guidry, a Huron managing director, provides her expert insight on why an institution should conduct a coverage analysis and some of the best practices and common pitfalls when doing so.

Q: For those who may be new to research billing compliance, could you explain, at a high level, what exactly a coverage analysis entails?

A: It is the evaluation of a clinical research study to assist with budgeting process, as well as with the billing process. The evaluation entails reviewing various study documents to determine whether or not the study qualifies for Medicare billing.

It is a process that enables the research site, be it a university, hospital, or an academic medical system, to determine which elements of the research study they can bill.

[A coverage analysis] does two main things for a research site: First, it helps them with their research finances to make sure that they are covering all the costs of conducting a clinical trial. Second, it makes sure they are compliantly billing the government and other third-party payers for services provided to research subjects.

Q: In general, how has the medicare clinical trial policy impacted medicare billing?

A: It's been very positive for research sites. It clarified what the rules are in terms of billing Medicare for clinical trial services. In many ways, it has opened up another avenue of payment for research sites.

Prior to the clarity the government provided in the 2000 National Coverage Decision, and then the clinical trial policy in 2007, research sites either didn't bill for the services provided to research participants, billed only the sponsor, or billed both and ran the risk of double billing.

But the policy also provided a significant hurdle because it is a complicated process, and many organizations aren't able to do it well. It's a process that requires an understanding of two very disparate areas — one being clinical research and the other being healthcare billing.

It's very difficult to find a person with expertise in both bodies of knowledge. Thus, people need significant training and oversight — at a high cost to an institution. That high cost and the significant oversight needed, means that many people conducting the coverage analysis do not get the training and support they need to do an effective job.

Q: Why should academic medical centers, hospitals and/or small research organizations consider conducting a coverage analysis?

A: Healthcare providers have an obligation to ensure their claims are accurate before they submit them to Medicare, Medicaid, or other commercial insurance providers. This is a process a research site needs to go through to ensure their due diligence before pushing claims out the door.

We also recognize there is a business component to all of this. Interest in financial performance is important as well. As a result of a coverage analysis, an organization can make sure it is evaluating all costs relating to conducting a clinical trial, ensuring that all of costs are covered. In addition, organizations are

not unknowingly underwriting a clinical trial simply because they didn't do a proper or a full analysis.

Q: What are the common pitfalls of an Ad Hoc Coverage analysis?

A: First: Improper billing. Chronic improper billing can lead to a government investigation. Over the last 15 years or so, the government has had a record of investigating research sites for improperly billing services provided to clinical trial participants. Having a sound [coverage analysis] process in place mitigates this risk.

Second: Finding the right people to actually do the analysis. This is a significant problem in the industry right now. Achieving proper billing is a complicated process. It requires that whoever is conducting the analysis understand both clinical research and each of the clinical research documents.

In addition, these people must analyze those documents against clinical trial policy rules and proper billing procedure. Finding all of these skills and knowledge-base in a single person is a significant challenge.

Q: What institutional qualities make coverage analysis outsourcing so useful?

A: One of the things clients very much struggle with is the turnaround time between when the research organization is first approached about doing the clinical trial, and the point at which they enroll that first subject. In that time, there are a whole host of things that need to occur, and the coverage analysis is just one of them.

Through outsourcing, we take the coverage analysis burden off of the client, helping them collapse that turn-around time window and making them more attractive to industry sponsors.

When you choose to outsource your coverage analysis with Huron, we provide a quality product that your billing department can use to evaluate their claims and determine what can and cannot be billed. Outsourcing also manages compliance pitfalls and risks.

Have questions about coverage analyses? To learn more about the process, Huron and how our experts can help your organization, visit our research enterprise solutions website.

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