



## Coverage Analysis During the Pandemic: What You Need to Know About Non-COVID Trials

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*During WCG's Advanced Coverage Analysis Workshop, held in Fall 2020, Amanda Miller, manager of quality and development at WCG PFS Clinical, provided an in-depth look at various challenges involved in making coverage determinations, and offered strategies and tactics for overcoming them. This piece focuses on a very fluid area: The impact of COVID-19 on non-COVID studies.*

As with everything else in our lives, COVID-19 is having an impact on coverage analysis for trials unrelated to the pandemic. Perhaps the most important thing to keep in mind is, in this uncertain environment, it's essential to stay up-to-date on guidance. Things change. For example, several disease guidelines have been updated to include information about managing patients with a certain underlying condition during the pandemic. We expect to see more updates. That might affect your coverage analysis.

With that in mind, here are two important considerations.

## Be as consistent as possible

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Throughout 2020, we've seen protocol amendments to address challenges with in-person visits, including adjustments to scheduling. Don't be tempted to change billing designations from the original coverage analysis: Remember to keep the billing determinations consistent with the original coverage analysis if you've already enrolled patients.

So, for example, if you had a cycle five day one physical exam marked as billable to the patient, try to keep that

the same in both versions.

The temptation is to say, "Oh, it'd be really nice if we just updated this little thing." But it can create kind of a compliance headache if you start to update visits and change billing determinations midstream.

If change is needed, don't do it unilaterally. Perhaps there is a valid justification to make a change. If you think there's some compliance-related reason patients should not have been billed for something, talk to the compliance and billing departments about that-- before you just make the update. There are rules and regulations for billing corrections that need to be taken into account.



## COVID testing for non-COVID studies

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So far, there hasn't been much guidance on COVID testing, making it difficult to say when it's justified or not justified. But as these guidelines are updated, you might start to see more specific recommendations.

The Medicare COVID website does say they support it to rule out COVID. You might be able to use that as part of your justification, if you need it. As with the other areas we've discussed, we're expecting to see more guidance on when it's appropriate to test as more information becomes available about COVID.

Some hospitals have adopted a policy of testing everyone who is admitted. If you're not one of those sites, and the protocol appears to be including testing only for inclusion/exclusion, you can cite that in your coverage analysis as a reason for making it research. But it's important to keep up not only with the guidance, but your facility's testing policy; both are subject to change.

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