Making Coverage Analysis Determinations for Outside-the-Box Situations

By Leslie Ramsey

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There's no getting around making careful coverage analysis determinations. It's an essential part of what sites need to do to stay compliant on billing practices. However, questions do arise in areas where there is little to no guidance. Here is an overview of some of those problem areas and what experts suggest are possible solutions.

COVID-19

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Under pandemic conditions, guidelines are changing from week to week. Missing an update could result in charging a patient's insurance carrier for something the sponsor should pay for or vice versa.

"We started with no [COVID-19] guidelines or very limited guidelines," says Amanda Miller, manager of quality and development at WCG PFS Clinical, "and now there are more guidelines available. And whether it was having no guidelines or now where there are guidelines available, they haven't solved all of the coverage analysis questions."

Sites should make sure they are using the most recent version of guidelines rather than relying on documents they may have downloaded in previous weeks, Miller says. "Keep checking and checking back again and again," she says, "because it is changing that fast."

There also is still very little information about coverage for post-hospitalization treatment, Miller says. "We've been waiting for more information to become available because as more time has passed there have been more patients discharged from the hospital [and] there doesn't seem to be kind of a standard guideline or frequency available yet," she says.

Repeated COVID-19 testing is one area lacking guidance. "Scientifically, it makes sense why they're doing this, why it's important to monitor the viral load, but at this point in time, there are not guidelines that support repeat testing," she says. "And testing [guidelines] may vary at the local level as well, so watch out for those."

Miller advises documenting the version of guidelines used in the CA. "By the time you finish negotiating the budget, a new set of guidelines could be available at that point, so you want to make sure it's clear what version was being used."

Sponsors also are supporting sites by adjusting protocols to accommodate changes to the CA guidelines. "The sponsors are delivering a lot of it into the protocol design and schedules, and on the site side, sites are starting to recognize changes to the way that they see patients currently or new requirements they might not have had prior to COVID-19," she adds, especially as they move operations off-site.

"The biggest change we've seen is telehealth being incorporated into trials and being allowed by sponsors," she says. Fortunately, Medicare has updated guidelines to cover telehealth visits for all beneficiaries at the same rates as in-person visits, she adds. Sites should be sure to include the new telehealth codes in their claims.

Sites also should keep their billing determinations as consistent as possible with the trial's original CA if patients already are enrolled. Even if guidelines have changed, new participants shouldn't be billed differently. "It can create kind of a compliance headache," Miller says.

And COVID-19 is having an impact on nonCOVID trials, forcing sites to use new methods, in many cases without clear guidelines. "Whether it's through amendments or new studies opening up, we're seeing sites and sponsors take COVID-19 into account when they're reviewing and opening new studies," she says.

Keeping Up with CAR-T Cell Rules

Hospitalization of CAR-T study participants has become increasingly acceptable as a billable item.

New types of research can lead to coverage questions, especially in oncology, where CAR-T cell therapy is blurring the line between research and standard of care.

Sites and researchers are still learning, and guidelines, rules, etc., are being frequently updated, Miller says. Sponsors, too, are adapting to the new information.

Hospitalization of CAR-T study participants has become increasingly acceptable as a billable item. Today, most guidelines state that hospitalization is recommended for many of these patients.

Miller says some sponsors don't require hospitalization, but many sites have adopted this as their standard with CAR-T therapy. It's important to be aware of the difference. If a site hospitalizes a patient even when the

protocol doesn't mandate it for all patients, it should document the rationale for the decision and factor it into the CA.

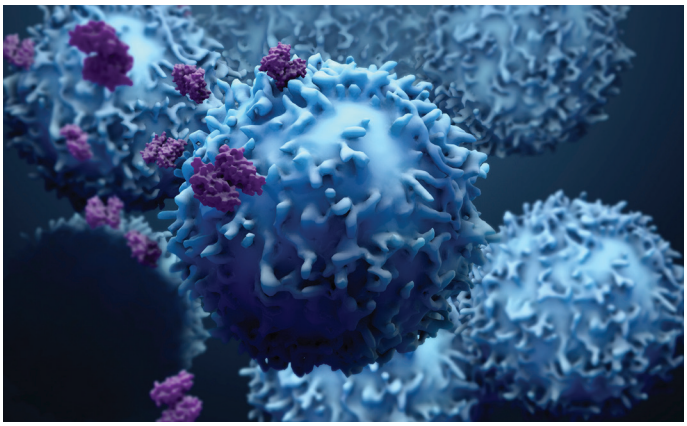
Post-treatment testing follows a completely different pattern than most oncology studies, which use cycles and repetitive testing. In CAR-T, most protocols are the one-time treatment followed by a period of intense monitoring and frequent testing.

Some frequent testing is justified by Medicare guidelines, and post-treatment testing falls under conventional care and/or monitoring of complications. However, that does not mean every post-treatment test in the protocol is billable to insurance.

Prescribing information on package inserts for FDA-approved products include some monitoring recommendations. Some may recommend an initial test, but not subsequent testing. Such testing may happen in a hospital setting, so some of those considerations may come in to play.

According to Miller, many sites are comfortable billing more frequently than for other oncology treatments due to the intensity of the therapy.

One aspect of CAR-T studies is fairly straightforward. Most sites consider T-cell harvesting, or leukapheresis, to be research because it is used to develop the study product. And sponsors don't usually push back on this, Miller says. In fact, many offer to pay for it at the start.



Phase 1 Oncology

Another area of complication in phase 1 is oncology trials that study multiple tumor types.

Even when there are guidelines readily available, there still are gray areas. Making coverage determinations for phase 1 studies in particular can prove complicated.

Protocols include various tests to monitor the patient for potential side effects and complications. But in phase 1 trials, there's limited or no product-risk data available, so that eliminates the NCD 310.1 "prevention of complications" umbrella that would potentially support billing insurance.

The question becomes, should you bill a patient for such monitoring when there is limited side effect data for phase 1 studies? Many sites choose to only bill for tests and procedures included in the clinical practice guidelines. Some sites reference back to other internal

standard practices related to the indication that have been developed for use outside of clinical trials. For example, routine labs during chemo infusion visits may be standard for certain patients.

Another area of complication in phase 1 is oncology trials that study multiple tumor types. When a trial only focuses on one type of cancer, you can focus analysis on one set of clinical guidelines. When working across tumor types in one study, you may have to consider several different guidelines. This becomes even more complicated as clinical recommendations across cancer types are not always consistent. Is it reasonable to check all sets of guidelines? That may not be possible, because some protocols don't define the types of cancer that will be studied. They simply specify any solid tumor expressing a particular biomarker.

How do sites manage this complex mix-and-match of recommendations? Approaches vary. Some sites will want to analyze based on each disease. Most, however, will want it to fit into one billing grid, in one pattern. They want to keep it simple; they want to come to a standard determination for billing consistency.

One option is to categorize it all as sponsor-paid research. Many sites would conclude that, because there's no standard recommendation for all cancer types enrolling, they'll just make it research and ask the sponsor to pay for it. But it's difficult to justify billing for a CT scan if it's not recommended in central nervous system cancers, for example.

Some phase 1 studies will require a hospitalization for the first dose of the study product, or first two or three doses. Technically, you could say this falls under "prevention of complications" in NCD 310.1, Miller says. You're monitoring participants closely to catch any serious reaction quickly. After all, outside of research, most patients aren't hospitalized for the first dose of a drug.

When deciding whether to bill for a hospital stay, she says sites should consider whether there is any indication in the guidelines that patients would be hospitalized, absent the trial. Sometimes in blood cancer studies, they are. But in many phase 1 studies, most sites aren't comfortable billing that hospitalization because, outside of research, that's just not something that would happen, she says.

Making Determinations on Off-Label Drug Use

Medicare provides multiple options for off-label use, but in many cases, there may not be support for all the drugs in a particular trial.

Many protocols include off-label medications, but who pays for them? Medicare will cover an off-label drug on a case-by-case basis under the following conditions:

- There is support in a compendium;
- There is support in a peer-reviewed journal (for anti-cancer medications, the journal must be on an approved list);
- Use of the medication is an accepted standard of medical practice (non-anticancer medications only).

Medicare provides multiple options for off-label use, but in many cases, there may not be support for all the drugs in a particular trial. A good way to start researching off-label medications is to check the protocol for journal citations.

Before researching off-label drug resources, Miller says, it's important to know the following about the protocol:

- Inclusion criteria details;
- Whether the drug is being given in combination with other medications; sometimes, even the order in which the medications are administered makes a difference;
- Why the drug is being given: to treat the underlying condition; as a premedication with one of the other study medications; in preparation for medical intervention (e.g., conditioning therapy in a CAR-T or stem cell study).

It can be difficult to identify resources to make billing determinations for unlabeled use of a drug, says Miller, who recommends several tactics. Start by finding out if the study department considers the drug to be standard of care and usually bills the drug outside of research. The study team may have the documentation needed.

Another approach is to ask the sponsor for more details about how it determined the medication was standard of care and what documentation it has beyond what is in protocol, but be sure to review any documentation provided by the sponsor and confirm it meets guidelines for billing Medicare or private insurance.

It's also possible to ask the sponsor if it will provide or reimburse for the medication. If you are struggling to find documented support for billing an off-label drug, Miller says, that may be a good indication that it is not medically accepted under Medicare guidelines. In these cases, pushing the sponsor to cover the cost of the drug may be the best option.

Coverage Analysis for Nonqualifying Trials

There is no regulation limiting coverage just because it is also being done as part of a trial.

Medicare's guidelines in NCD 310.1 outline the criteria to determine which trials qualify for coverage of routine costs. "One of the common questions we hear," Miller says, "is what should we do if a trial does not meet the qualifying criteria?"

Some sites choose to take a relatively conservative approach and decide they will not bill for any items or services required on a nonqualifying trial. This approach, however, presents operational and consistency issues when faced with studies where there is no external funding or when the sponsor refuses to pay for these items. Sites that choose this approach are often faced with the dilemma of either turning down studies or opening studies that don't have sufficient funding to cover costs.

"More commonly," Miller says, "we see institutions determine that they may bill Medicare for items and services that would be covered outside the context of a clinical trial." For example, if a patient with lung cancer is receiving regular CT scans, an institution following this approach may continue to bill Medicare for those CT scans during a nonqualifying trial as long as the protocol does not require scans more frequently than the patient's standard care dictates.

The underlying argument is that this patient would have received the scans regardless of enrolling in a clinical trial, Miller says, and there is no regulation limiting coverage just because it is also being done as part of a trial.

She notes that, under this approach, a site cannot bill Medicare for any items and services that are only covered based on NCD 310.1. Coverage for services such as the IV administration of an investigational drug are only supported by NCD 310.1 and would not normally be covered outside a qualifying clinical trial. Therefore, you would not have any supporting justification to bill Medicare for the IV administration of an investigational item in a nonqualifying clinical trial.

The same logic applies for tests done to monitor potential complications of the study drug. This is expanded coverage supported only through NCD 310.1. Unless those tests would have been done as part of the patient's standard of care, they are typically not billable to insurance if required by a nonqualifying clinical trial.

Negotiation Strategies for Coverage Analysis Decisions

Because flipping determinations can increase the budget considerably, the matter may have to be escalated to a higher sponsor authority, especially if the site is negotiating a budget with a CRO.

Once CA is complete, sites may still need to convince sponsors of the logic behind their determinations. If the CA determines something falls under research, Miller asks, how do you address this with the sponsor or CRO that likely thinks most of the items fall under standard of care?

First, she advises, if the CA has discovered no support for billing these items as standard of care, a site should acknowledge them when it sends the CA to the sponsor. Otherwise, she says, you're waiting for the sponsor to come back and ask, "Why didn't you make everything research in this study? Why did you switch all of our determinations?"

Sites also should share their information, Miller says. "Don't simply say, 'We think everything is research.' That's not going to help them. Say something like, 'We recognize that you thought everything was standard of care. When we did our analysis of this, we found, based on the following reasons, we didn't feel comfortable billing these and we would like you to pay for them.'" Miller also offers suggestions for how to approach a sponsor with some specific items for which the site would like to "flip" the sponsor's coverage determination:

- If the only documented side effects of the investigational drug are from preclinical studies in animals, let the sponsor know the site doesn't bill patients for monitoring unless there are human side effects.

- If medical necessity can't be documented for all protocol-required imaging, it is important to call this out and document in discussions with the sponsor so that unsupported imaging is included in the budget.
- Many phase 1 studies require frequent testing, sometimes more frequent than allowed in coverage guidelines. A site should know what frequency it is comfortable billing and let the sponsor/CRO know this.
- If it's a study enrolling multiple solid tumor types with imaging, a site can say it is not confident it will have documentation for every patient and doesn't feel comfortable billing in that case.

Because flipping determinations can increase the budget considerably, the matter may have to be escalated to a higher sponsor authority, especially if the site is negotiating a budget with a CRO. The more information you have, Miller says, the better everyone along the line will understand why you made the determinations you did.

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