JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 8, No. 3, March 2012 "Happy Trials to You"

The Sponsor's Role in Medicare Reimbursement for Clinical Trials

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Many clinical studies include treatments, procedures, tests and/or physical items that are eligible for reimbursement by Medicare, Medicaid and/or insurance companies. It has become common practice for research sites to prepare a document called a "coverage analysis" to determine which of these costs are reimbursable by third-party payors like Medicare. Although study sponsors normally leave it to the sites to perform the analysis, there are significant advantages for both parties if the sponsor prepares an initial coverage analysis.

What is a Coverage Analysis?

A clinical trial coverage analysis is a document that identifies the appropriate payor (sponsor or third-party payor) for each study service and item. The document is usually a Word table or Excel spreadsheet that lists the items and services down the Y axis and the protocol events and relevant study dates across the X axis. A billing code (e.g., "S" for payable by sponsor, "B" for billable to Medicare, or "NB" for not billable) is assigned to each service and item for the timeframe it is required by (e.g., beginning of each cycle, weekly, end of study, follow-up, etc.). The analyst assigns billing codes based on Medicare's Clinical Trial Policy and relevant local or regional billing rules, depending on where the clinical trial will be performed. A sponsor's coverage analysis might leave the regional analysis to the sites or perform the analysis for just one or a few regions.

The Centers for Medicare and Medicaid Services (CMS) published the Clinical Trial Policy as a National Coverage Determination (NCD) on September 19, 2000. This NCD established coverage criteria for Medicare beneficiaries participating in clinical trials. Although a particular clinical trial may not enroll Medicare beneficiaries, sites implementing a clinical trial should apply the NCD when establishing billing and related internal procedures because most clinical sites receive money from Medicare and are required to abide by all Medicare billing rules. Moreover, many non-governmental, third-party payors are required to follow reimbursement rules similar to Medicare or do so anyway.[1]

Benefits of Sponsor-Prepared Coverage Analysis

While many research sites are highly competent in preparing clinical trial coverage analyses, many others are not and some do not prepare them at all. At minimum, a sponsor-prepared coverage analysis gives sites a head start or a double check for their own coverage analysis. (Sponsor-prepared coverage analyses normally do not consider regional Medicare reimbursement practices.)

Preparing a coverage analysis requires the sponsor to review the protocol, informed consent form, clinical trial agreement, and other study documents to identify intended payors and ensure these documents are consistent with the coverage analysis and each other. For example, sites cannot bill Medicare for costs that the sponsor has said it will cover. In addition, a budget table that says a cost is fair market value prevents the site from billing Medicare for a higher amount that would be acceptable under the NCD. By preparing a coverage analysis, the sponsor can avoid problems that prevent or reduce Medicare reimbursements or waste time in the budget negotiation process.

Sponsors can help the site justify Medicare coverage by properly drafting study documents in other ways. For example, one of the three reimbursement criteria in the Medicare NCD is that the clinical trial has "therapeutic intent." Although the NCD does not specify that the primary objective of a study must demonstrate therapeutic intent, some Medicare contractors and many sites have determined that this demonstration is essential or at least that there is good evidence that the protocol meets this NCD criterion. Therefore, when applicable, the protocol should specify a clinical benefit in the primary objective. For example, if the objective of the study treatment is to lower a biomarker, that treatment effect should be related to a clinical benefit.

Sponsors should also ensure that language in the consent form does not contradict any actual therapeutic intent. For example, avoid language like, "You will not receive any benefit from participating in this clinical trial." In the context of the NCD, better wording would be, "You may or may not benefit from participating in this clinical trial."

Currently, many sponsors ask various physicians about the standard of care and use that data to help develop the protocol and determine the study budget. However, Medicare will often reimburse for services and items that are not standard of care. Further, standard of care is a slippery concept that varies by region, healthcare institution, physician and patient, so it is not the best evidence in a Medicare billing audit. By preparing a coverage analysis, sponsors can both identify additional reimbursable costs and provide solid justification.

The Medicare NCD provides coverage of services like laboratory tests and diagnostic procedures to monitor, detect and/or treat known potential complications of the investigational item(s). Sponsors can support coverage of specific study services and items by explaining in the protocol and/or consent form why they are necessary for covered reasons and not performed solely to collect research data and related purposes.

Sponsors waste money when they pay for services and items that Medicare and other third-party payors will cover. However, sponsors and sites may not want to bill insurance companies because of potential paperwork, privacy, rate increase, and coverage limit implications for the subjects. Nevertheless, with a coverage analysis in hand, sponsors can negotiate lower budgets with sites.

By forcing sites to prepare a coverage analysis during the budget negotiation process, sponsors also waste time, the sites' effort, and often the sponsor's effort in resolving coverage questions and issues. If study documents have to be changed, more time and effort is wasted.

For sites that do not prepare their own coverage analysis, a sponsor-prepared analysis is very helpful when requesting reimbursement rulings from Medicare contractors.

A coverage analysis also provides useful line-item documentation of compliance with the Medicare Law, Anti-Kickback Statute, the False Claims Act, the Stark Law, the new Physician Payments Sunshine Act, and even the Foreign Corrupt Practices Act. This documentation is helpful in the case of governmental audits that might be performed years later.

Items that the coverage analysis determines are reimbursable by Medicare appear in the study budget at zero cost. However, since not all study subjects are eligible for Medicare or other third-party payor reimbursement, the clinical trial agreement should describe how such costs should be paid. To comply with Medicare's secondary payor policy and as best practice, the language should not say, "If a denial is received, the sponsor will cover all costs…" Rather, it should say, "When a subject does not have a third-party payor and when a subject meets the indigent or charity care policy, the Sponsor will cover costs at a rate of…" If the site charges sponsors more than Medicare or other third-party payor rates, these charges must be fair market value and be clearly defined in the clinical trial agreement. It is important to give Medicare the best prices and be clear that the intent is to bill from the

beginning, prior to enrolling a subject. Charging additional fees to cover any shortfall on the clinical side or administrative processing fees is appropriate and should be considered when sites perform a coverage analysis to ensure billing compliance. All of these factors make a strong case for sponsors to get more involved in the coverage analysis process.

Some sites find the coverage analysis too cumbersome and do not want to be financially responsible for any clinical costs, so they ask the sponsor to cover all costs in the trial, regardless of Medicare coverage. It is true that if the subject is not indigent and has a payor that denies coverage, he or she may be financially responsible. For this reason, a study subject must go through the same financial analysis and precertification process that any other patient would undergo. In addition, the consent form must clearly define the subject's responsibility in the event their payor denies coverage. Those subjects may decline participation, due, for example, to a high insurance deductible. The sponsor may agree to cover all costs for all subjects regardless of Medicare coverage, but this can add up to thousands of dollars because all subjects must be treated the same, Medicare or not.

Finally, sponsors might want to consider reallocating some of the cost savings to support more site attention to activities like subject recruiting, informed consent, and subject retention.

In conclusion, a sponsor-prepared coverage analysis can streamline the budget process, illuminate standard-of-care issues from both site and sponsor perspective, and produce budgets that comply with the regulations.

Reference

- "Medicare Coverage for Cancer Research," Ryan Meade, Kelly Willenberg, and Michael C. Roach, Journal of Clinical Research Best Practices, March 2010.

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