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An Introduction to Medicare Coverage Analysis for Drug Trials

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In 2010, the government recovered $4 billion, including $2.5 billion from healthcare fraud judgments, through the efforts of the Healthcare Fraud Prevention & Enforcement Action Team, a.k.a. the Medicare Fraud Strike Force.[1] The Medicare Fraud Strike Force is a team of federal, state and local investigators, including Recovery Audit Contractors (RAC), who are tasked to review medical billing practices to find and recover overpayments made by the government. Although such audits generally do not focus on clinical research, they are likely to review the records of clinical trial subjects at institutions that conduct a significant amount of clinical research. Noncompliant billing is subject to severe penalties under the False Claims Act, but on the other hand, institutions should charge Medicare for reimbursable clinical care items (drugs, devices, procedures, diagnostics and materials).

Before starting a clinical trial, it is therefore good practice to evaluate each item in the protocol to determine whether it can be legally billed to Medicare. The action of completing and documenting this information is called a "Medicare coverage analysis."

Background

In 2000, President Clinton signed an executive memorandum stating that Medicare would pay for certain items related to the conduct of clinical trials.[2] The Health Care Financing Administration (now the Centers for Medicare & Medicaid Services, or CMS) then issued its National Coverage Determination (NCD) policy. The Medicare National Coverage Determination Manual (Chapter 1, Part 4) sets forth coverage rules for clinical trial items. The NCD has four main parts:

- It states which clinical trials qualify for coverage.
- It specifies the costs covered.
- It states that Medicare will consider coverage only for items or services that are otherwise available to the Medicare beneficiary.
- It specifies the claim format for coding and billing these services.

The first step in a coverage analysis is to determine whether the trial qualifies for coverage. For a drug or biologic trial to qualify for Medicare coverage, it must meet one of the following criteria:

- It is funded by a federal agency or cooperative group.
- It is conducted under an IND application reviewed by the FDA.
- It is IND-exempt.

The trial must also meet all three of the following qualifying characteristics:

- The trial falls within a Medicare benefit category.
- The trial has therapeutic intent.
- The trial enrolls patients with diagnosed disease, not just healthy volunteers.

The second step is to determine which specific costs may be covered. In general, covered costs are those that meet one or the following criteria:

- It is typically provided absent a clinical trial (i.e., in conventional care)
- It is necessary for the provision or administration of the investigational item

- It is required for clinically appropriate monitoring of the effects of the investigational item or service
- It is care that is reasonable and necessary arising from the provision of an investigational item or service, or necessary to prevent complications.

Costs that generally are not covered include:

- The investigational item itself
- Items necessary only for data collection purposes and not clinical management
- Items that the study sponsor provides or pays for

Constructing a Coverage Analysis

CMS has divided the country into 15 regions and is in the process of contracting with a Medicare Administrative Contractor (MAC) for each. MACs have been created to consolidate the work of Medicare carriers and fiscal intermediaries (FIs) in processing Medicare claims, including those from clinical trials. Each MAC publishes a Local Coverage Determination (LCD), specifying which items are covered in its region. Although generally similar to the NCD, there are differences from region to region. Through LCDs, state Medicare contractors make more than 90% of coverage decisions. Federal law requires that Medicare contractors seek physician input on their coverage decision process via contractor advisory committees, to ensure that LCDs reflect regional care standards.[3] As a result, the LCD in each region takes precedence over the NCD.

A coverage analysis includes a list of clinical items required by the protocol. Identify items that you think are covered by Medicare, along with the rationale and supporting documentation. First, review each item against the NCD and the LCD for your region. With luck, you will find NCD or LCD documentation that is specific to each item in your coverage analysis, indicating the item is covered for the specific diagnosis, for the study population, and in the requested amount and frequency. If you cannot find the information you are seeking in the NCD or LCD, this does not necessarily mean that Medicare will not cover it.

Site management should establish a risk-based policy for the evidence it considers adequate. Very risk-adverse organizations will only accept LCD and NCD statements of coverage. In addition, carriers, fiscal intermediaries, and MACs publish their rulings for specific circumstances on their websites. If a suitable ruling is not available, position statements by national societies (e.g., the American Academy of Cardiology), systematic literature reviews (e.g., those published in Cochrane Reviews), and peer-reviewed scientific articles can provide a solid rationale for your determination.

Once a coverage analysis has been completed, it should be reviewed by one or more departmental or research administrators to ensure that it meets the organization's standards. Submit your rationale to your MAC, FI or Carrier before you start the trial, to be sure a claim is not rejected or a Medicare inspector cannot make a finding of noncompliance.

To be an effective tool, many individuals in a healthcare organization need access to the coverage analysis. Utilizing web-based clinical trial software or housing these documents on a shared drive with specific departmental and role access are both effective solutions.

Utilization

Although coverage analyses are largely driven by Medicare billing compliance, they should categorize all clinical trial items by payor: Medicare, the insurance company, the study

sponsor, the study subject, or the site itself. Based on the coverage analysis, the billing department will charge Medicare and the other parties.

The only practical way to ensure that exactly the right charges are made to Medicare is to develop and follow a standard operating procedure that outlines who is responsible for documenting when a patient receives covered items. Ideally, this compliance documentation will occur in an integrated electronic system that supports both clinical and billing personnel. To complete the documentation, billing personnel indicate that designated charges have been billed as indicated on the coverage analysis.

Conclusion

An accurate and complete coverage analysis provides a lot of value to both the research participant and the hospital that is conducting the research. For the patients, it provides an accurate accounting of their financial liability before they enroll in a clinical trial. For obvious reasons, the cost section of the informed consent document should reflect the findings in the coverage analysis. The coverage analysis should also be incorporated into any budget detail submitted as part of the clinical trial agreement. Billing according to the coverage analysis will protect patients from unexpected balances not covered by Medicare or their insurance. For the healthcare institution, an accurate coverage analysis will prevent violations of the False Claims Act and provide a basis for budget negotiation with the study sponsor.

References

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