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MEDICARE COVERAGE ANALYSIS IN ONCOLOGY TRIALS: 3 KEY CHALLENGES

Alexandra Burleigh, Medicare Coverage Analyst

Clinical trial billing non-compliance can have substantial financial repercussions due to an extremely complex billing process. Though this is the case for many studies, it is particularly significant to oncology trials.

Based off of Medicare's Clinical Trial Policy (i.e. NCD 310.1), the Medicare Coverage Analysis (MCA) is one of the most useful documents for facilitating clinical trial billing compliance throughout the course of a study. It determines whether or not a clinical trial qualifies for coverage and outlines which specific items and services are billable to Medicare. The MCA sets the framework for clinical trial billing compliance as a whole and is particularly useful during oncology clinical trials which are susceptible to improper billing due to the combination of routine care and research items and services. Three key challenges involved in oncology clinical trial billing compliance will be discussed in this article, including determination of therapeutic intent, standard of care versus conventional care, and routine costs versus research. Fortunately, these issues can be alleviated by conducting a thorough MCA early in the process.

1. Determination of Therapeutic Intent

One of the requirements for a trial to qualify for Medicare coverage is that it must have therapeutic intent. Therapeutic intent of phase I trials in particular has been a debated issue in the oncology community. The American Society of Clinical Oncology as well as other leading cancer organizations, have released position statements that phase I oncology trials do have therapeutic intent. However, it is still unclear as to Medicare's viewpoint on this issue. Thus, institutions are left to determine their own internal policies regarding phase I oncology trials and can utilize the MCA to document these policies and make determinations regarding routine costs.

2. Standard of Care vs. Conventional Care

A common misconception regarding oncology clinical trials is that the investigator determines which items and services are "standard of care." However, standard of care is not the same as conventional care in the eyes of Medicare. Conventional care is a much broader and more objective term. What may be standard of care for one investigator may not be conventional care to Medicare. Conventional care can be thought of as a national standard of billable items and services. The purpose is to maintain consistency among providers and ensure that physicians are not conducting certain services more often than others unless it is medically necessary. In turn, the MCA can be utilized to document, from an objective standpoint (i.e. based on published clinical guidelines), what is considered conventional care.

3. Routine Costs vs. Research

Unfortunately, the distinction between which items and services are "routine costs" and which are conducted for research is not always clear. This tends to be especially problematic in federally funded trials, as there is often limited funding and few items and services are paid for by the sponsor. It is commonly believed that if a trial is federally funded, then all of the items and services are billable to Medicare. What is important to note, however, is that Medicare and other federal funding agencies do not necessarily communicate with each other regarding these trials, and although a trial is funded by one governmental agency does not mean that everything is billable. Further, what may be required for a study may not fall within the guidelines of what are considered "routine costs" outside the realm of a clinical trial. For example, a CT scan may be conventional care every 4 cycles during chemotherapy based on published clinical guidelines. However, the study may require CT scans every 2 cycles of chemotherapy to satisfy study endpoint criteria. Thus, the MCA is useful for documenting specifically those procedures that are billable and those that are either paid for by the sponsor or an alternative funding source.

Although challenging, it is possible for institutions to contribute to the advancement of science by participating in oncology clinical trials, while still maintaining an effective billing compliance process. The MCA can mitigate these risks by serving as a crucial tool for determining if a trial qualifies for Medicare coverage and for making objective billing determinations that can be utilized throughout the clinical trial.