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Conventional care: A compliance challenge for research services

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The terms "standard of care" and "conventional care" are commonly used interchangeably in research but have distinct meanings. The confusion often comes from the overlapping definitions of the two terms. A service that is standard of care may not meet the higher threshold for conventional care. Standard of care can be the practice of an individual physician, a recognized treatment for a medical condition, or a comment on research contracts that an item is not included in the total payment because the sponsor has determined it is part of standard medical practice.

Conventional care, as defined by Centers for Medicare & Medicaid Services (CMS), are items or services that are "typically provided absent a clinical trial."[1] These services are covered as part of the routine costs of qualifying clinical trials with the caveat that all other Medicare rules apply. If the items or services would not be covered outside of a clinical trial, payment may not be made during a clinical trial. A determination needs to be made for each potentially billable service if it is being performed for clinical management or data collection and then, finally, whether coverage is supported under Medicare rules.

Supporting conventional care

The availability of standardized guidelines to support the determination of conventional care has increased over the past several years. Professional associations often publish recommendations or guidelines for the management of specific conditions. Most guidelines will include a rating for the level of evidence for each recommendation that indicates the amount of research or consensus that supports the recommendation. The higher the rating, the greater the agreement that the service is useful and effective. The definitions for an association's rating methodology may be included in the guideline's statement, or it can be found on the association's website. Guidelines are relatively easy to locate using the search term "clinical practice guidelines" and a medical condition. Research teams with their expert knowledge are often able to provide additional resources to support conventional care, especially in areas of rare diseases or new medical technologies.

The increase in the availability of guidelines has created opportunities for entities to select formats that best meet their needs. For example, there are two resources currently available for recommendations related to oncology imaging services. The National Comprehensive Cancer Network provides clinical practice guidelines for the management of specific types of cancers.[2] Imaging services are a component of their recommendations.[3] These guidelines are available to individuals that register on the site. Another source for imaging guidelines is published by eviCore healthcare. It provides a single document with diagnosis-specific guidelines for adult and pediatric oncology imaging.[4] General information on imaging services is also included. Periodically reviewing available guidelines can help identify resources that best fit an organization's need.

Subscription services are another option to support conventional care. Research programs that are part of an academic institution or healthcare system may already have access to one or more of these clinical databases. They provide a consolidated resource in one location, and, if needed, licenses can be obtained to share across

multiple users. An UpToDate subscription includes articles on the diagnosis, treatment, and management of medical conditions based upon the latest evidence-based information.[5] The topics are written by experts and peer reviewed for accuracy and completeness. If applicable, the articles provide links to professional or government-sponsored guidelines in the topic outline. Because the content of the topics change as new information becomes available, it is recommended that a process be established to maintain documentation from articles cited as conventional care support.

Lexicomp is another clinical database widely used by healthcare entities.[6] Depending on the purchased subscription, drug information may be available from several resources, including Lexi-Drugs and American Hospital Formulary Service Drug Information. The *Medicare Benefit Policy Manual*[7] lists both of these compendia as approved sources for support of off-label use in an anti-cancer chemotherapeutic regimen. A laboratory section provides a summary and indications for each test. This can be especially helpful for nonclinicians when determining the purpose of a test to support conventional care.

The prescribing information for a current Food and Drug Administration–approved drug can support conventional care when the research study is considering a change in labeling, such as a new indication or combination therapy. Drug labels include a discussion of known adverse reactions and may recommend specific testing prior to therapy. For agents with long-term adverse effects, the prescribing information may recommend monitoring after the completion of therapy. Occasionally, a medical device label will recommend the performance of specific services. Some areas that may be addressed in the label include imaging required to check placement for implantation and follow-up testing to confirm a device is functioning properly. Product labels can vary when a drug or device is available from several manufacturers. In this situation, it is recommended product labels used to support conventional care are maintained for future reference.

Investigational items in the same class or category as approved drugs or devices can have similar follow-up monitoring recommendations. For example, the pharmacological category anti-PD-1 monoclonal antibodies are associated with immune-mediated adverse events that may occur following treatment. CMS has recognized cytokine release syndrome as a known toxicity of Chimeric Antigen Receptor (CAR) T-cell products.[8] The combination of lymphodepleting chemotherapy and CAR T-cell therapy can support clinical monitoring following therapy. Category B devices are similar to devices already cleared by the Food and Drug Administration and can have related follow-up monitoring requirements. Organizations may want to establish policies to outline any limitations and the appropriate use of related items or services to support conventional care.

A search of peer-reviewed medical literature is another possible source to support conventional care services during a clinical trial. The published article must be critically reviewed for accuracy by experts prior to publication. Other sources lacking this level of independent review, such as meeting abstracts, would not be supportive of conventional care. A copy of the article or a library of frequently cited articles should be maintained.