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Medicare Coverage for Cancer Research

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Medicare beneficiaries have numerous treatment options under Medicare, including a great variety of clinical trials. Most cancer studies meet the criteria of Medicare's Clinical Trial Policy (CTP) for coverage of routine services provided as part of the study.[1] Medicare generally covers "routine costs" (defined below) in these studies, as long as the scheduled services are not paid by the sponsor or promised free in the informed consent. However, with government coverage comes the need for regulatory compliance.

Medicare is the largest health insurance program in the United States. Coverage by Medicare's cousin, Medicaid, is governed by state law, but many states follow Medicare rules for coverage of services provided during a clinical trial. Because Medicaid coverage varies from state to state, we will limit the discussion in this article to Medicare.

Medicare covers people age 65 or older. Additionally, in October 2008, the Centers for Medicare & Medicaid Services (CMS) published a list of 50 cancer diagnoses that automatically qualify a person to be considered disabled by the Social Security Administration. After a waiting period, these patients also qualify for Medicare enrollment, no matter their age.

Cancer studies pose enormous operational challenges when the sponsor pays for services, services are promised free in the informed consent form, the study is not a qualifying trial (discussed below), or an item or service is not a "routine cost." Charges for non-billable services, by definition, cannot appear on a claim for Medicare reimbursement. Catching these charges and preventing them from going to Medicare can be extremely difficult to accomplish operationally. It is especially difficult for cancer studies because of their complexity and the multitude of physicians and clinical departments involved in the care of each patient. Not only must each department bill Medicare correctly, but they must also coordinate to avoid overbilling across departments.

Medicare reimburses "routine costs" in qualifying clinical trials. If a study is not a qualifying clinical trial, then none of the services required by the protocol are covered. This does not mean that Medicare covers no services for the patient. It still covers items and services for treatment of complications that arise from non-qualifying clinical trials, as well as services that are medically necessary but not in the protocol.

What is a qualifying clinical trial?

Under the CTP, "routine costs" are covered when a research study meets the criteria of a qualifying clinical trial. Although CMS set out 10 criteria of a qualifying clinical trial and a self-certification process when it first released the CTP in September 2000, it never operationalized the self-certification process. Instead, CMS has adopted a two-step qualification process. The first step, in essence, looks at seven characteristics that CMS requires a study to have in order to be a qualifying study. CMS believes that five types of studies always fulfill these seven criteria, thus the following types of studies are deemed to have the required characteristics:

- Studies funded by NIH, CDC, AHRQ, CMS, DOD or VA
- Studies supported by centers or cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD or VA

- Studies conducted under an IND application
- IND-exempt studies
- Studies conducted under the Coverage with Evidence Development process

As mentioned above, CMS never operationalized the self-certification process whereby investigators would have been able to certify that a study had the seven required characteristics. Consequently, if a study is not one of the above types, then it is not a qualifying clinical trial and none of the protocol-required items or services can be billed to Medicare, including items and services that normally would be covered outside the trial. In other words, if a non-qualifying clinical trial requires a test that would have been standard-of-care in the absence of the clinical trial, Medicare still does not cover it.

In the second step of the qualification process, the study must also satisfy all three of the following additional criteria:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must have therapeutic intent. It must not be designed exclusively to test toxicity or disease pathophysiology.
- Trials of therapeutic interventions may only enroll patients with diagnosed disease, rather than healthy volunteers. However, trials of diagnostic interventions may enroll healthy patients in a control group if a control group is scientifically necessary.

There are different rules for Medicare coverage of device trials. As this article is about cancer trials, which are overwhelmingly drug trials, we will not address the device trial rules, except to make two points: First, device trials generally should be submitted to the institution's Medicare contractor's medical director for approval prior to billing for any of the items or services on the trial. Second, if the trial qualifies for coverage, then the analysis of which items and services can be billed to Medicare is the same for device trials as for drug trials, i.e., the CTP governs which items and services in a qualifying device trial can be billed to Medicare.

Most cancer drug studies pass the first part of the test for qualifying trials because of National Cancer Institute funding through cooperative groups or because the study drug is being evaluated under the Food and Drug Administration's (FDA's) investigational new drug (IND) application process. If the study sponsor does not volunteer the IND number to the site, the site can request it from the sponsor.

Many cancer clinical trials also meet the three criteria in step two above because they enroll cancer patients to study therapeutic use of treatments in the "drugs and biological" Medicare benefit category. Most cancer studies enroll patients who have already been diagnosed with a disease.

The most controversial criterion for drug trials is the requirement of therapeutic intent in the study design. CMS on the national level has not issued a clear statement on what sufficiently constitutes therapeutic intent. It has largely delegated interpretation of the therapeutic intent criterion to local Medicare contractors. If CMS has not weighed in on a topic, it allows Medicare contractors to interpret Medicare rules in their own regions. Medicare contractors have adopted a variety of positions on therapeutic intent. For example, many have indicated that Phase I drug trials, by their nature, are not sufficiently therapeutic. Some Medicare contractors perform a case-by-case review based on the study design, disregarding any expression of the investigator's intent.[2]

Figure 1 presents a tool for collecting information on the qualifying clinical trial criteria. If all four questions can be answered "yes," the study is a qualifying trial. However, if the answer to any of the four questions is "no," the study is not qualifying.

Figure 1. Medicare Clinical Trial Qualifying Criteria

Qualifying Criteria	Yes	No	Notes
Is the study one of the types of studies designated by CMS?			
Does the investigational item or service fall into a Medicare benefit category?			
Is the study designed with therapeutic intent?			
Does the study enroll patients with diagnosed disease?			

What are routine costs?

During a qualifying clinical trial, Medicare covers "routine costs" if the items and services would normally be covered by Medicare if the services occurred in the absence of a research study. The term "routine cost" is a defined term; it does not necessarily mean what the physician believes is "routine" or "standard of care." The CTP sets forth its own criteria for "routine costs." Routine costs include:

- Items or services that are typically provided absent a clinical trial (e.g., conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service — in particular, for the diagnosis or treatment of complications

In simple terms, a "routine cost" is one of the following:

- Conventional care
- Administration of the investigational item
- Detection, prevention and treatment of side effects

Conventional care is analogous to "standard of care," but the distinction is a bit vague and situational. While "standard of care" can have a loose meaning, such as "the hospital's normal practice," "conventional care" usually requires objective evidence, such as recognized treatment guidelines or articles in medical journals.

For cancer studies, there is a wealth of conventional care material in the form of practice guidelines. The National Comprehensive Cancer Network publishes extensive practice guidelines by cancer site and stage. Many of the guidelines are updated multiple times during the year. The American Society of Cancer Organizations also publishes practice guidelines. The Agency for Healthcare Quality Assurance maintains a website with access to practice guidelines for numerous specialties. The Oncology Nursing Society has developed Evidence-Based Clinical Practice Guidelines, a guide to finding, critically appraising, and

using evidence to solve clinical problems for cancer patients. It provides links to websites that are useful in finding evidence on a particular topic or clinical problem.

A broad range of protocol items and services for detecting and preventing side effects qualify as “routine costs.” Many laboratory tests and other diagnostic services are performed to detect and manage side effects of drug therapy. If the provider can connect the reason for the diagnostic service to a known potential side effect of any drug used in the study, then it can be justified as a routine cost. However, if there is no persuasive evidence or rationale for a possible side effect, CMS relates the service or item to a research purpose and does not accept it as a routine cost.

Administration of the investigational item as a routine cost was a significant expansion of coverage when CMS first issued the CTP. The study drug may not be billable to Medicare because it has not been approved by the FDA or is provided free by the sponsor, but Medicare will pay for its administration.

Before billing Medicare for any service or item provided as part of a clinical trial, it is important to be sure the sponsor is not paying for the service or item through the clinical trial agreement and that the service or item has not been promised free in the informed consent form.

While CMS has been generous in its definition of “routine costs” under the CTP, there is an important caveat, namely that “all other Medicare rules apply.” Medicare does not cover all routine costs in regular clinical care and does not make exceptions for clinical trials.

In cancer studies, two common non-covered services that might otherwise meet the definition of routine costs include certain PET scans and self-administered drugs used to prevent or treat hypersensitivity. CMS has complex rules about which PET scans it will cover and for what indications, regardless of whether the scan is medically necessary. If Medicare has stated that it will not cover PET scans in the patient population under study in the trial in question, any protocol-required PET scans in that study cannot be billed to Medicare, even if they are “routine costs” under the CTP.

Another example is a common drug called dexamethasone, which is used for hypersensitivity to chemotherapeutic agents. This drug is FDA-approved for treating hypersensitivity and is standard treatment both prophylactically and in response to allergic reactions. Medicare covers dexamethasone when administered intravenously but not when provided to the patient as a tablet for self-administration in a hospital outpatient or physician clinic setting. Medicare has different rules for prescription drugs under the Medicare Part D prescription drug benefit program, and dexamethasone may be covered if medically necessary and provided by a retail pharmacy pursuant to a physician’s prescription. But, in this article we are focusing on billing by hospitals and providers under Medicare Parts A and B.

“Routine costs” do not include items like data collection, quality of life assessments, or tests done more often than “routinely” outside the trial. For example, an EKG performed six months after the last infusion, when previous research shows the cardiac side effects manifest themselves within a couple of days after infusion, would appear to be for research purposes and would not be billable as a routine cost. However, if the study drug is known to be cardiotoxic, performing an EKG at screening to get a baseline reading or to keep individuals who already have severely impaired cardiac function off the study would be a routine cost because they can prevent side effects. Similarly, EKGs done shortly after infusion would be routine costs.

Summary

Medicare covers “routine costs” in qualifying clinical trials. However, before billing any protocol-required services to Medicare, even those that are “standard of care,” research sites must determine whether the clinical trial is a “qualifying” clinical trial.

There is a two-step process to determine whether a study is a qualifying clinical trial. First, the study must be one of five types of studies that CMS has deemed to have seven desirable characteristics. Second, the study must meet three required criteria. If the study fails either part of this two-part test, it is not a qualifying clinical trial and none of the protocol-required items and services is billable to Medicare, even if it would be covered outside the trial. Phase I trials are particularly at risk for failing the qualifying clinical trial test because of absence of therapeutic intent.

If the study is a qualifying clinical trial, then “routine costs” in the trial can be billed to Medicare, as long as the item or service is otherwise covered by Medicare. Routine costs are those items and services that are (a) considered conventional care under some objective criteria, (b) performed or used for the prevention or detection of complications of the treatment, or (c) are for the administration of the investigational item. Plus, all other Medicare rules apply, so a service or item that is not covered outside a clinical trial will not be covered when performed or given as part of a qualifying trial, even if the item or service is a “routine cost.” Most self-administered drugs are such non-covered items.

Finally, research sites that want to bill Medicare for clinical trial services must develop mechanisms and processes for (a) analyzing each study to determine whether it is a qualifying clinical trial, (b) determining which protocol-required items and services in a qualifying clinical trial are routine costs and which are not, and (c) communicating the results of those two analyses to their charge capture and billing systems in order to prevent billing Medicare for items and services it does not cover.

References

1. http://www.cms.hhs.gov/clinicaltrialpolicies
2. FAQs 2006; FAQs 2007

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