



Coverage of Routine Patient Care Costs in Clinical Trials Position Statement

Approved by the ASCO Board of Directors, March 2005

For people with serious or life-threatening illness, like cancer, completely satisfactory or curative treatment often is not available. Those patients are nevertheless able to receive state-of-the-art therapy through high-quality clinical trials, offering not only an important treatment option but an opportunity to advance medical knowledge.

Cancer patients face a number of obstacles to clinical trials enrollment. One of the barriers is the potential denial of third party payment for the routine patient care costs for those enrolled in clinical trials. Historically, payers have denied coverage for care provided in a clinical trial, arguing that such care is “experimental” and therefore not a covered benefit.

Current Clinical Trials Coverage

The American Society of Clinical Oncology (ASCO) and its partners in the patient advocacy community have sought, over the course of more than a decade, to reform clinical trials payment policy in public and private health plans. These efforts have resulted in reforms in Medicare payment policy and in enactment of legislation to ensure clinical trials coverage in more than 20 states.

In 2000, in response to Congressional pressure and cancer community advocacy, the Clinton Administration issued an Executive Memorandum setting a policy for coverage of the routine patient care costs for Medicare beneficiaries enrolled in clinical trials for all diseases.

In addition to action by Medicare, a number of states have enacted legislation that would ensure coverage of routine patient care costs in clinical trials (coverage ranges from cancer clinical trials only to trials for all diseases) by those health plans that are regulated by the state. Some of those states have adopted, either in statute or in implementing regulations, the coverage standards of the Medicare program. In several states without clinical trials coverage mandates, third party payers have entered into voluntary agreements to cover routine costs in clinical trials. States continue to engage in efforts to improve coverage in state plans.

ASCO Position

These federal, state, and private sector initiatives reflect widespread recognition of clinical trials coverage as a critical element of quality cancer care. However, not all of the initiatives meet the standards for coverage endorsed by ASCO, and a significant number of cancer patients remain beyond the reach of these reimbursement reforms. ASCO recommends that every cancer patient should have access to clinical trials under the criteria defined below.

Standards for Clinical Trials Coverage

The following ASCO standards should remain the standard for Medicare coverage and should serve as the model for state legislative initiatives, including provisions governing coverage under state-funded programs like Medicaid, as well as mandates for private insurance and managed care plans.

The cost of medical care provided when a patient with serious or life-threatening disease is entered on a Phase I, II, III, or IV (post-marketing) clinical trial – including hospital, physician, and other health care items and services as well as the cost of approved drugs for labeled or unlabeled uses which might be part of the regimen¹ – should not be denied coverage when all of the following are demonstrated:

- Treatment is provided with a therapeutic intent²;
- Treatment is being provided pursuant to a clinical trial approved by one of the National Institutes of Health (NIH), an NIH cooperative group or an NIH center; the Food and Drug Administration (FDA) in the form of an investigational new drug (IND) or new device (IDE) exemption; the Department of Defense; the Department of Veterans Affairs; or a qualified non-governmental research entity as identified in National Cancer Institute guidelines or center support grants;
- The trial is conducted according to a written protocol, which includes the following elements: trial design and scientific justification, criteria for inclusion and exclusion, outcome measures, statistical analysis plan, conflicts and other ethical controls, and publication policy;
- The protocol has undergone scientific review by a group of independent and qualified experts;
- The clinical trial has been reviewed and approved by a qualified institutional review board (IRB);
- The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training;
- There is no non-investigational therapy that is clearly superior to the protocol treatment; and
- The available clinical or preclinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy.³

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¹ Items and services required by the design of the trial should be covered, except those items or services normally paid for by other funding sources such as the cost of certain investigational drugs, the costs of any non-health services that might be required for a person to receive the treatment, and the costs of managing the research.

² Treatment with therapeutic intent may be aimed at improving patient outcome relative to either survival or quality of life.

³ While these standards refer to clinical trials involving “treatment” or “therapy”, the same principles would apply equally to trials of interventions to prevent, rather than treat, diseases.