



# HCFA FACT SHEET

September 19, 2000

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## MEDICARE COVERAGE ROUTINE COSTS OF BENEFICIARIES IN CLINICAL TRIALS

*Overview: The Health Care Financing Administration has issued a final national coverage decision to implement President Clinton's order for Medicare to cover the routine health care costs of beneficiaries in clinical trials. It not only implements the President's order to cover the "routine costs" of Medicare beneficiaries in clinical trials, but also expands the definition of such costs to include payment of most other beneficiary costs that were previously non-covered. This decision finalizes a proposed decision issued in August.*

**Reassuring Beneficiaries, Encouraging Research.** This national coverage decision is intended to encourage the greater use of clinical trials by older Americans. Clinical trials serve as the first step toward providing new clinical innovations to the forefront of medical practice. In announcing the decision to assure Medicare coverage to those in clinical trials, President Clinton noted that many seniors and people with disabilities were reluctant to participate in trials for fear they would lose their Medicare coverage. Assuring Medicare beneficiaries that their routine costs will be covered is expected to increase their participation in clinical trials. Medical researchers believe that higher participation by older Americans and those with disabilities in clinical trials could lead to faster development of therapies. The knowledge gained from clinical trials will lead to better health care for Medicare's more than 39 million beneficiaries.

**Covered Costs.** Medicare will pay most of the costs of beneficiaries in clinical trials. Payment will include costs associated with providing items and services that would otherwise be covered by Medicare if they were not provided in the context of a clinical trial. Also covered are items and services required "solely for the provision of the investigational item or service." For example, Medicare will pay for the administration of a chemotherapy drug that is being tested in a trial, including the provision of anti-nausea drugs to prevent complications from the chemotherapy drug. Medicare also will pay for monitoring and evaluation, device implantation, and other costs, such as room and board as part of a hospital stay required as part of a clinical trial, for trials of importance to Medicare beneficiaries.

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**All Beneficiaries Will Be Covered.** All Medicare beneficiaries will be eligible for the coverage while in clinical trials meeting federal standards. The new policy is binding on all the private contractors that process and pay Medicare claims as well as Medicare+Choice managed care plans. The Balanced Budget Act permits Medicare to pay additional funds on behalf of Medicare+Choice organizations to compensate them for significant costs associated with national coverage decisions. Coverage becomes effective with this final national coverage decision. Coverage decisions are not retroactive.

**Things Not Covered.** Medicare will not pay for the investigational intervention being tested in a trial. And it will not pay for items and services provided solely to satisfy the data collection needs of the trial. It also will not pay for anything being provided free by the sponsor of the trial to any trial enrollee.

**Registry of Trials.** HCFA is developing a registry of ongoing clinical trials in which routine beneficiary costs are being reimbursed by Medicare. This registry will track Medicare expenditures associated with clinical trials. HCFA also will use the information contained in the National Institutes of Health and Food and Drug Administration clinical trial registries ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) to develop a national registry of all clinical trials receiving Medicare reimbursement for their routine costs.

**Eligible Trials.** To ensure the safety of Medicare beneficiaries, the final coverage decision establishes a process to determine which clinical trials are eligible for its participants to receive payments for routine medical costs. The HCFA decision requires that clinical trials must meet specified criteria in order to be approved for Medicare coverage of their routine costs, including scientific support, credible and capable sponsorship and protection of participating patients.

Some clinical trials are "deemed" to be qualified and do not have to go through this process. These include trials that are funded by the National Institutes of Health (including those centers and cooperative groups funded by NIH), the Centers for Disease Control and Prevention, HCFA, the Agency for Healthcare Research and Quality, the Department of Defense, the Department of Veterans Affairs, and trials conducted under an Investigational New Drug application approved by the Food and Drug Administration, or those drug trials that are exempt from having an Investigational New Drug application under FDA regulations. These IND-exempt trials will have to certify that they meet the qualifying criteria once the criteria are established.

The policy is posted on HCFA's web site at <http://www.hcfa.gov/quality/8d.htm>.

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