



November 30, 2006

Filed Via E-Mail

Kimberly Long
Medicare Coverage Advisory Committee
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality,
Coverage and Analysis Group
7500 Security Blvd. – C1-09-06
Baltimore, Maryland 21233

Dear Ms. Long:

The undersigned cancer patient, provider and research organizations are pleased to have the opportunity to comment on the reconsideration of the Medicare clinical trials policy. Most of us have a longstanding involvement in clinical trials, ranging from advocacy for adequate reimbursement for clinical trials to engagement in trials design initiatives to ongoing education and outreach to increase patient participation in cancer clinical trials.

We write to urge that the reconsideration of the clinical trials policy be viewed as an opportunity for refinement of the policy and its implementation and not a chance to impose limits on the current scope of coverage.

Benefits of National Coverage Decision

Clinical trials are an important option for cancer patients, particularly those with limited treatment choices. The National Coverage Decision has made clinical trials more accessible to patients. For example, one of the large cancer cooperative groups has undertaken an analysis of participation by patients age 65 or older in the group's trials and has observed an increase in participation by seniors since the National Coverage Decision. Prior to the release of the coverage policy, only 25% of the patients enrolled in the cooperative group's trials were age 65 or older, even though seniors accounted for 63% of all patients with cancer. From 2001 to 2003, a period of time after the National Coverage Decision, seniors represented 38% of trial enrollees.¹

¹ Laura F. Hutchins, et al., *Underrepresentation of Patients 65 Years of Age or Older in Cancer-Treatment Trials*, 341 N. Eng. J. Med. 2061 (1999), Joseph M. Unger, et al., *Impact of the Year 2000 Medicare Policy Change on Older Patient Enrollment to Cancer Clinical Trials*, 24 J. Clin. Onc. 141 (2006).

This improvement, while important, is clearly insufficient, and cancer organizations are engaged in efforts to address obstacles, other than reimbursement issues, that hinder seniors' participation in clinical trials. However, any retrenchment in the Medicare coverage policy would likely threaten the progress in boosting senior participation in trials that has been made to date.

Definition of "Routine" Costs

We understand that one of the challenges in implementing the clinical trials policy has been the lack of a reliable and consistent definition of "routine costs" in clinical trials. Uncertainty about what will be considered a routine cost contributes to a compliance burden for trial sponsors and participating physicians and can cause concerns among Medicare beneficiaries about reimbursement for the care they receive in a trial. Because trials answer important questions about treatment and may trim utilization of unnecessary or ineffective therapies, we urge the Centers for Medicare & Medicaid Services (CMS) to apply a more expansive policy to coverage of care that will facilitate efficient completion of trials and conclusive information about cancer treatments.

Prior to the National Coverage Policy, seniors reported that uncertainty about reimbursement contributed to their reluctance to participate in trials. A lack of clarity about routine care costs – and resulting confusion among trial sponsors – may have a similar effect on participation.

Beneficiaries in Medicare Managed Care Plans

One population of seniors that has not benefited from the clinical trials coverage policy is Medicare beneficiaries enrolled in Medicare managed care plans. Managed care enrollees have reported since implementation of the coverage policy that they cannot participate in trials because they are subject to coinsurance requirements for expenses of the trial. This population of beneficiaries do not ordinarily purchase supplemental coverage policies. However, their claims for care in clinical trials are processed as fee-for-service claims subject to 20% coinsurance. Because these beneficiaries do not have supplemental coverage and cannot afford to pay out-of-pocket for coinsurance amounts, they forego clinical trials participation. The cancer cooperative group study identified seniors without supplemental insurance policies – most likely managed care enrollees – as a group that participates in trials at a less robust rate than seniors overall.

We urge CMS to adjust payments to managed care plans to reflect the costs that have been associated with the National Coverage Decision on routine patient care costs in clinical trials. This adjustment is necessary to ensure that beneficiaries will have access to clinical trials according to the terms of their managed care plans and not as fee-for-service claims with 20% copayment. If efforts to boost enrollment in managed care plans are successful, this will become an even more serious problem. Therefore, we urge immediate action to address it.

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We appreciate the opportunity to comment on the reconsideration of the Medicare clinical trials policy. We strongly urge that this process be utilized to improve the implementation of the policy and not to limit or restrict the current policy.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic
Radiology & Oncology
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society

The Lung Cancer Alliance
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer
Foundation
Y-ME National Breast Cancer Organization

cc: Janet Brock, Executive Secretary