



A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

August 9, 2006

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Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Ave., S.W.
Room 314-G - HHH Bldg.
Washington, DC 20201

RE: Clinical Trial Policy (CAG-00071R)

Dear Dr. McClellan:

The undersigned cancer patient, provider, and research organizations are writing regarding the reconsideration of the Medicare coverage policy on clinical trials. Many of us were involved in the decade-long legislative effort that ended with the issuance in June 2000 of an Executive Memorandum directing Medicare to pay for routine patient care costs in clinical trials. We applauded that action and the National Coverage Decision that implemented the policy.

We welcome the reconsideration of the clinical trials coverage decision if it presents the opportunity to refine the policy. However, we do not support any movement to restrict or reduce the current scope of coverage of clinical trials.

Impact of National Coverage Decision

Prior to the National Coverage Decision, Medicare beneficiaries were clearly underrepresented in clinical trials. A study of the clinical trials in one large cancer cooperative group concluded that only 25% of the patients enrolled in those trials were patients age 65 or older, even though that population represented 63% of all patients with cancer. This study confirmed anecdotal reports regarding the limited participation of seniors in clinical trials.¹

A follow-up study in that same cancer cooperative group found older patient population in trials had increased to 38% of trial enrollees in the period from 2001 to 2003, from the pre-coverage

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).

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policy level of 25%.² This is an important but inadequate improvement, and it suggests that additional efforts must be made to boost clinical trials participation by seniors. With the reimbursement issue for seniors significantly addressed by the National Coverage Decision, cancer organizations are attempting to address other barriers to trials enrollment by educating providers and patients regarding participation of seniors in trials and enhancing overall consumer awareness of the benefits of participation in trials.³ Any retrenchment in the coverage standards would threaten the progress that has been made to date and undermine our additional efforts to enhance senior participation.

Refinements in the National Coverage Decision

Although participation by seniors overall has been enhanced since the coverage decision, one population of seniors has not benefited as significantly. The cancer cooperative group study identifies those seniors without supplemental insurance policies as a population that participates in trials at a less robust rate than seniors overall. This population most likely includes seniors who are enrolled in Medicare managed care plans and who do not ordinarily purchase supplemental coverage. Those beneficiaries' claims for clinical trials are processed as fee-for-service claims subject to 20% coinsurance. Because these managed care enrollees do not routinely have supplemental coverage and are probably unable to pay the coinsurance for their clinical trial care out-of-pocket, they must forego clinical trials enrollment. The conclusions of the study authors regarding the experience of Medicare managed care enrollees are consistent with reports from other clinical trial sponsors regarding the lack of participation of this group of seniors due to economic barriers.

We understand that the Centers for Medicare & Medicaid Services (CMS) has the ability to adjust payments to managed care plans to reflect the costs that may be 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. We urge CMS to address this issue immediately. This will only become a more significant issue if efforts to boost enrollment in Medicare managed care plans is successful.

We appreciate the opportunity to comment on the initiation of the process for reconsidering the coverage decision on clinical trials, and we look forward to the issuance of a decision memo in early 2007. We consider the Medicare clinical trials policy a work-in-progress and recommend that no major changes be made in the scope of the policy. The coverage policy has addressed the

² 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)

³ We believe the "Medicare and You" handbook might be used more effectively to educate Medicare beneficiaries regarding Medicare policy on clinical trials coverage and clinical trials enrollment opportunities, and we would like to collaborate with the agency in exploring this idea.

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reimbursement obstacle to clinical trials for many Medicare beneficiaries, and cancer organizations have redoubled their efforts to remove additional barriers to clinical trials participation. We urge CMS to use the reconsideration process to address implementation issues related to the coverage policy but not as an opportunity to restrict Medicare beneficiaries' payment for routine patient care costs in trials.

Sincerely,

Cancer Leadership Council

American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology &
Oncology
Association of American Cancer Institutes
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
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
Us TOO International Prostate Cancer Education
and Support Network
Y-ME National Breast Cancer Organization

cc: Leslye K. Fitterman, Ph.D.