



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

June 6, 2005

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Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 314-G – HHH Bldg.
Washington, D.C. 20201

RE: Draft Guidance for the Public, Industry and CMS Staff:
Factors CMS Considers in Making a Determination of
Coverage with Evidence Development

Dear Dr. McClellan:

The undersigned organizations in the Cancer Leadership Council (CLC) represent cancer patients, providers and research organizations. Both the CLC and our individual organizations have been engaged in advocacy on Medicare coverage issues for a number of years and have welcomed a newly collaborative approach to those issues on the part of the Centers for Medicare & Medicaid Services (CMS). We regard the draft Guidance on “Factors CMS Considers in Making a Determination of Coverage with Evidence Development” as a continuation of several promising trends in CMS policy: first, a willingness to assume a more expansive approach to coverage of new or unproven technologies; and second, a new emphasis on the collection of data as part of a move toward measurement of quality in treatment of cancer and other serious or life-threatening diseases.

The draft Guidance will raise questions for some, including providers who may be called upon to collect data without mechanisms for reimbursement for their efforts, as well as device manufacturers who may doubt that coverage is in fact being expanded. For cancer patients, the primary concern is whether the new coverage with evidence development (CED) policy will interfere in any way with the strong coverage protections for cancer drugs set forth in the current Medicare law.

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Under § 1861(t)(2)(B) of the Social Security Act, Medicare coverage for cancer drugs specifically includes “any use which has been approved by the Food and Drug Administration,” as well as those additional uses not approved by FDA but cited in certain medical compendia. These assurances of coverage were prompted more than a decade ago by patient and physician outcry over inconsistent coverage decisions by Medicare contractors and are now considered by the entire cancer community to be vital to quality cancer care for Medicare beneficiaries. The failure to recognize that the new CED policy in no way affects this statutorily mandated coverage has generated some understandable anxiety, which we believe would be dispelled by CMS clarification on the point.

The current leadership of CMS has been very progressive with respect to coverage issues, and we support this additional incremental step toward expanded coverage and enhanced evidence development while encouraging clarification of the matters discussed herein. Thanks to CMS and its coverage staff for their responsiveness to the needs of people with cancer.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology &
Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Fertile Hope
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
Leukemia & Lymphoma Society

Lymphoma Research Foundation
Marti Nelson Cancer 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
Us TOO International Prostate Cancer Education
and Support Network
Y-ME National Breast Cancer Organization