



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

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December 23, 2004

Mark A. McClellan, M.D., Ph.D.  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
200 Independence Avenue, S.W.  
Room 314-G – HHH Bldg.  
Washington, D.C. 20201

Re: Draft Decision Memo for Anticancer Chemotherapy for Colorectal Cancer  
[CAG-00179N]

Dear Dr. McClellan:

The undersigned organizations representing cancer patients, providers and research organizations are writing to offer comment on the above-referenced coverage determination. While we support efforts by the Centers for Medicare & Medicaid Services (CMS) to collect more data on the effectiveness of cancer therapies, it is important to do so within the context of existing statutory, regulatory and other frameworks. We would suggest a reconsideration of the proposed coverage determination to take into account current law and practices and to focus more narrowly on the areas of unmet need with respect to coverage, mostly in the arena of relatively rare “orphan” cancers where clinical trials are very difficult to organize, initiate and bring to closure.

#### Background

Since 1993, the Medicare statute has recognized the importance of so-called “off-label” uses of cancer drugs and has set forth mechanisms to facilitate their coverage by Medicare. This coverage is based on references in recognized medical compendia and on reports of effectiveness in certain peer-reviewed medical journals. In recent years, the system established by Congress in 1993 has not functioned with optimal efficiency, in

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part because the compendia process has slowed unacceptably and CMS has not updated the list of appropriate peer-reviewed journals. We urge CMS to take all possible steps to remedy these deficiencies so as to return the coverage process to the efficiency that was formerly in place.

In addition, it is important to recognize the role of clinical trials both in the treatment of individual cancer patients and as the engine for progress against cancer in the future. CMS embraced the significance of cancer clinical trials in 2000 through the issuance of a National Coverage Decision (NCD) requiring coverage of all routine patient care costs in clinical trials. As CMS considers coverage decisions now and in the future, the 2000 NCD should be part of the landscape. Nothing in CMS's current coverage decisions should challenge the fundamental validity of the 2000 decision.

#### CMS Proposal

The general concept underlying the current proposal is commendable—i.e., that Medicare will cover as-yet-unproven therapies in the context of clinical trials—and there are undoubtedly situations where such an approach is warranted. However, we have grave concerns about limiting the coverage-triggering trials to those sponsored by the National Cancer Institute (NCI). As we understand it, those trials will customarily feature patient access to the investigational drugs free of charge. If this is the case, there would seem to be no purpose to Medicare coverage of the drugs in the context of NCI-sponsored trials.

However, we do believe that there will be other circumstances where quality clinical trials may be underway before the existing statutory and other mechanisms would mandate coverage, and in that setting CMS coverage of the off-label uses would be welcome, but only if the pharmaceutical sponsor is not providing the drug without charge. In other situations, particularly those involving rare “orphan” cancers where there is little commercial incentive to initiate clinical trials, we would endorse the concept of submission of data to a central registry to enable collection of information about effectiveness.

#### Summary

Our organizations support CMS efforts to collect more data, through clinical trials or data registries, regarding the effectiveness of anticancer drugs. However, CMS must recognize, endorse and enhance existing statutory and other mechanisms for Medicare

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coverage of cancer drugs for both approved and off-label uses. The cancer community looks forward to working with CMS to optimize the uses of anticancer chemotherapy for the benefit of beneficiaries with cancer.

Sincerely,

**Cancer Leadership Council**

American Cancer Society  
American Society of Clinical Oncology  
American Society for Therapeutic  
Radiology & Oncology, Inc.  
Cancer Research and Prevention Foundation  
International Myeloma Foundation  
Kidney Cancer Association  
The Leukemia & Lymphoma Society  
Lymphoma Research Foundation

Multiple Myeloma Research Foundation  
National Coalition for Cancer Survivorship  
North American Brain Tumor Coalition  
Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
The Susan G. Komen Breast Cancer  
Foundation  
Us Too International Prostate Cancer  
Education and Support Network  
Y-ME National Breast Cancer Organization