C L C CANCER LEADERSHIP COUNCIL

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

December 16, 2002

Thomas A. Scully
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Hubert Humphrey Building - Room 433-G
Washington, D.C. 20201

Dear Mr. Scully:

The undersigned organizations, representing cancer patients, providers and researchers, are writing to express their serious concern about a new Medicare coverage policy announced in the preamble to the final rule on the Hospital Outpatient Prospective Payment System (HOPPS), 67 Federal Register 66755-56 (Nov. 1, 2002). In an abrupt and unjustified change of policy, the Centers for Medicare & Medicaid Services (CMS) indicated it would no longer defer to the expertise of the Food and Drug Administration (FDA) in determining whether to cover drugs for their labeled indications. This change is inconsistent with longstanding administrative interpretations of the Medicare statute, as well as the terms of the statute itself, and should not be implemented.

Under the new policy announced by CMS without benefit of prior notice or opportunity for public comment, CMS may deny coverage of new drugs for a number of reasons that have no basis in the Medicare statute, including characterization of the drug as "novel, complex, or controversial," "costly to the Medicare program," or "receiv[ing] marketing approval based on the use of surrogate outcomes." These non-statutory criteria represent a severe threat to cancer treatment for Medicare beneficiaries.

If coverage can be denied because a new drug is "novel" or "complex," cancer patients will likely be refused access to cutting-edge therapy. Even if there were a basis in the statute for such denials of coverage, it would represent bad public policy given our Nation's investment in biomedical research funding that supports development of "novel" and "complex" new drugs.

Similarly, the fact that a new therapy may be "costly to the Medicare program" is not a reason for non-coverage under the Medicare statute. Indeed, cancer care generally is more costly that many other diseases because it involves patients who are very ill and require aggressive treatment for their condition. Congress has never authorized CMS to deny coverage based on the cost of therapy, and it has not been the practice of the Medicare program to do so.

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Further, many new cancer drugs are approved on the basis of surrogate endpoints like "response rates" or "time to progression," rather than the more difficult and time-consuming endpoint of survival. These surrogates have been identified by medical experts at FDA as indicative of clinical benefit. In fact, it is not correct to suggest, as CMS does, that FDA does not make its decisions based on "clinical effectiveness." FDA is widely regarded as one of the premier health regulatory bodies in the world, and CMS has no basis upon which to challenge the thoroughness or correctness of its decision-making.

The potential refusal of CMS to cover new drugs consistently with the indications approved by FDA is particularly unsupportable with respect to cancer drugs. Motivated by excessive denials of coverage for medically appropriate uses of cancer drugs, Congress in 1993 restricted the discretion of CMS and its contractors to deny coverage for such uses. Specifically, for purposes of coverage, the term "drugs" is defined to include "any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication," including "any use which has been approved by the Food and Drug Administration." 42 U.S.C. §1395x (t)(2)(A and B).

FDA approval is viewed as the gold standard of safety, effectiveness and clinical benefit. We question whether CMS has the medical expertise to second-guess the science-based decisions of FDA. Moreover, if the policy is implemented by CMS, many beneficiaries with cancer may be denied access to life-extending therapies. We urge CMS not to implement the newly articulated coverage policy in the absence of specific authorization by Congress.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer Advocacy, Support, and Education
American Cancer Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology, Inc.
Association of American Cancer Institutes
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Childhood Cancer Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Pancreatic Cancer Action Network
Us Too! International – Prostate Cancer Education and Support
Y-ME National Breast Cancer Organization

cc: The Honorable Tommy Thompson, Secretary, DHHS
Mark McClellan, Commissioner, FDA
The Honorable Charles Grassley
The Honorable Max Baucus
The Honorable Deborah Pryce
The Honorable William Thomas
The Honorable Charles Rangel
The Honorable Nancy Johnson
The Honorable Pete Stark
The Honorable Billy Tauzin
The Honorable John Dingell
The Honorable Michael Bilirakis
The Honorable Sherrod Brown
Alex Azar, General Counsel, DHHS
Sheree Kanner, Chief Counsel, DHHS
Troy Daniel, Chief Counsel, FDA