CANCER LEADERSHIP COUNCIL

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

April 26, 2004

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

Dear Dr. McClellan:

The undersigned organizations are writing to express their concern regarding the proposed criteria recently announced to implement the demonstration project under § 641 of the Medicare Modernization Act (MMA) of 2003. While we appreciate that the limitations imposed by Congress on both the number of participants and the amount of expenditure create difficult implementation issues, we believe that the Centers for Medicare & Medicaid Services (CMS) has imposed some restrictions that are inconsistent with Congressional intent. In addition to specifying those inappropriate restrictions, we will offer several suggestions to make the implementation of the demonstration project more equitable and efficient.

Coverage of Off-Label Indications

CMS has stated its intention to limit drug coverage to indications approved by the Food & Drug Administration (FDA). This limitation is inconsistent with the terms of the statute and with sound oncology principles. The cancer patient advocates who worked for years on coverage of oral drugs insisted that the compromise reflected in § 641 create "a demonstration project under Part B" in order to ensure that the special provisions for coverage of off-label uses of cancer drugs in 42 U.S.C. § 1395x(t)(2)(B) would apply to drugs in the demonstration project. This is the only possible reason for the reference to Part B, as § 641 separately references the statutory bases for coverage of the drugs designed to be "replaced" in the demonstration project.

The statutory provisions requiring Medicare to cover medically appropriate off-label uses of cancer drugs were enacted in recognition of the central role of such uses in modern cancer care. FDA approvals, in most cases, fall short of capturing the standard of care in cancer, which typically involves combinations of cancer drugs not specifically reviewed or approved by FDA. It is for this reason that Medicare now routinely covers off-label, or unapproved, uses of cancer drugs if they are referenced in standard medical compendia. To restrict coverage under § 641 to approved indications is to render the coverage criteria inconsistent with Part B.

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The effect of this decision is to automatically deprive beneficiaries with multiple myeloma access to one of the most effective potential therapies that might otherwise have been made available under the demonstration project, not as a result of Congressional action but rather through administrative line-drawing. The oral drug at issue, thalidomide, is used for both primary therapy and for progressive disease following primary therapy. It is also a less toxic and often more effective alternative to high-dose chemotherapy with stem cell transplant, and probably a more cost-effective option for Medicare. Unquestionably, it should be part of the demonstration project.

Inclusion of Oral Hormonal Agents

Exclusion of tamoxifen and other oral hormonal agents is also clearly inconsistent with Congressional intent. The legislative history of the various bills preceding § 641 is replete with mentions of tamoxifen as an oral cancer drug that should be covered by Medicare for patients with breast cancer. Like breast cancer, prostate cancer is also heavily dependent on oral hormonal agents. CMS should not be relying on an overly technical interpretation of the statute's reference to "replacement" to restrict coverage of a class of drugs that was clearly in the minds of legislators as they enacted the demonstration project.

Coverage of New Drugs

Depending on how the coverage criteria are finalized, there may be relatively few cancer drugs that are included in the demonstration project. For this reason and for reasons of clinical benefit to patients with orphan cancers, CMS should permit coverage of new oral cancer drugs that are approved by FDA during 2005 and perhaps the early part of 2006, assuming they otherwise satisfy the final coverage criteria.

Selection of Beneficiaries

In this circumstance, where Congress has imposed significant limits on the number of participants, we have no objection to the use of random selection as a means of identifying those who may participate in the demonstration project. However, we would suggest that there may also be a role for "means testing" at the extremes of financial hardship. Thus, while most beneficiaries could be randomly selected for participation in the program, we urge that a certain number of slots be reserved for those who can demonstrate, in a relatively non-burdensome fashion, extreme financial need that would permit avoidance of the uncertainty of the random selection process.

Coordination with Patient Assistance Programs

Some of the pharmaceutical companies whose drugs would be included in the demonstration project have ongoing patient assistance programs that provide generous support for needy patients. We would not want to see those programs disrupted or displaced by the demonstration

project, as the goal should be to maximize overall access to these life-extending products. CMS should consider carefully suggestions from these companies regarding accommodations that would permit existing patient assistance programs to continue unabated.

Expenditure Limits

We applaud CMS recognition of the Congressional intent with respect to oral cancer drugs, as reflected in the Conference Report, which indicates that "[n]o less than 40 percent" of the available funds shall be dedicated to cancer therapies. Thus, CMS has determined that 40% of the designated $500,000,000, or $200,000,000, will be allocated to cancer. It is important to note, however, that the Conference Report establishes a floor of 40%, not a ceiling. Therefore, on the merits, we would encourage CMS to consider a greater than 40% allocation of funding to cancer, based on the fact that the cancer drugs that would be covered under the demonstration project add therapeutic benefit beyond the drugs they replace. In other words, the oral cancer drugs for which we seek -- and Congress granted -- coverage do not merely offer a more convenient form of administration but also arguably a more effective clinical result. Surely, this argues for more than the minimum coverage of these life-extending drugs.

CONCLUSION

As you know, we have the greatest respect for your ability and your instincts as Administrator of both the Medicare program generally and the § 641 demonstration project specifically. We know that you are sensitive to issues of central importance to the cancer community, such as the role of medically appropriate off-label uses of cancer drugs, as well as to the other aspirations of cancer patient advocates. After years of intense effort on behalf of cancer patients, Congress was able to come forward with only a limited transitional benefit; within those limits, we trust you to make decisions that will maximize to the fullest extent possible access to life-extending cancer drugs pending introduction of a comprehensive drug benefit in January 2006.

Sincerely,

Cancer Leadership Council

Alliance for Lung Cancer
American Cancer Society
American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology, Inc.
Cancer Care, Inc.
Cancer Research and Prevention Foundation
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
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
The Wellness Community
Y-ME National Breast Cancer Organization