CANCER LEADERSHIP COUNCIL

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

July 11, 2002

Thomas A. Scully
Administrator, Centers for Medicare & Medicaid Services
Department of Health & Human Services
200 Independence Avenue, S.W.
Room 443-G -- HHH Building
Washington, D.C. 20201

Dear Mr. Scully:

The undersigned cancer patient, provider and research organizations are writing to register their strong concerns regarding the recent Program Memorandum (AB-02-072) offering guidance on a provision of the Benefits Improvement and Protection Act of 2000 (BIPA) that is of critical importance to people with cancer. Section 112 of BIPA requires the Medicare program to continue covering drugs that are "not usually self-administered by the patient." The Program Memorandum is inconsistent with both the letter and the intent of BIPA and therefore we urge that it be replaced prior to its effective date of August 1, 2002, with guidance that ensures continued coverage of these life-saving drugs.

## Importance to People with Cancer

The BIPA provision and the accompanying Program Memorandum are of supreme significance to cancer patients because they determine the terms of Medicare coverage for products that are unquestionably necessary for quality cancer care. Among the universe of products that can theoretically be self-administered but are "not usually self-administered" are various biological growth factors-for red blood cells, white blood cells and platelets-that are administered to cancer patients whose blood cells are at risk of depletion because of cancer chemotherapy. These products have consistently been covered by Medicare because they are usually administered to Medicare beneficiaries with cancer by providers, rather than by self-administration.

## Congressional Intent

Section 112 was a response to a 1997 program guidance from the Centers for Medicare & Medicaid Services, or CMS (the then Health Care Financing Administration, or HCFA), to contractors that they could exercise discretion to cease coverage of these and other products that could theoretically be self-administered, despite the fact that the products had been covered by Medicare since their introduction as provider-administered drugs "incident to" covered provider services. At the urging of advocates for cancer patients, Congress first acted, on an emergency basis, through an appropriations measure for the Department of Health and Human Services (HHS) for fiscal year 2000, prohibiting any implementation of such guidance. This prohibition, however, was limited to the fiscal year associated with the appropriation.

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As the advocates continued to express concerns about potential CMS action following the lapse of the appropriations restriction, Congress subsequently recognized that permanent legislation was required in order reliably to maintain the coverage status quo. Section 112 was the result, reflecting the strong resolve of Congress to continue coverage of products that are usually administered by providers, regardless of whether they might theoretically be administered by patients themselves, and, as clearly demonstrated by the legislative history, to continue coverage of drugs that had been covered prior to the 1997 CMS guidance.

The Committee Report accompanying the House-passed version of BIPA, which includes the self-injectable drug provision that was incorporated in the final BIPA package, states that Medicare "should assume, as it did for many years, that Medicare patients do not usually self-administer injections or infusions to themselves." Moreover, according to the Committee Report, Congress "anticipate[d] that [Medicare would] instruct its contractors not to rely on this section to exclude a drug or biological without making an explicit finding supported by evidence that it is usually administered to themselves by Medicare patients." The legislative history thus leaves little doubt that Congress sought to preserve coverage of those drugs that had been historically covered by the Medicare program and that it placed substantial evidentiary burdens on any effort by the program or its contractors to diminish that coverage.

## The Recent Program Memorandum

Given both the plain language of the BIPA provision and its legislative history, the position reflected in the recent Program Memorandum is disturbing. Instead of following the strong Congressional directive assuming continued coverage, the Program Memorandum establishes a series of presumptions that undermine continued coverage. Most significant among these presumptions is that "[a]bsent evidence to the contrary, drugs delivered by subcutaneous injection should be presumed to be self-administered by the patient." This presumption, unsupported by any evidence and contrary to Congressional intent in BIPA, is devastating to cancer patients because most injections of growth factors are administered subcutaneously, albeit by providers rather than self-administration. Thus, CMS has not only ignored the Congressional instruction to assume continued coverage of these important products, but has, in effect, created the opposite presumption-i.e., of non-coverage.

As a result of this presumption, contractors essentially have a green light to deny coverage for products that Congress clearly intended to protect because they "are not usually self-administered" to Medicare cancer patients. Other presumptions in the Program Memorandum are also inconsistent with the letter and spirit of BIPA, including the presumption that the more frequently a particular drug is injected, the more likely it is to be self-administered. Congress plainly wanted CMS to look solely to whether the drug was or was not "usually self-administered by the patient." In the absence of supporting evidence, CMS was to presume that currently covered drugs were covered because they were not "usually self-administered."

## Contractor Discretion

While BIPA and its legislative history are less clear on this point, the Program Memorandum is also problematic because of its encouragement of carrier discretion, apparently unfettered except for the invalid presumptions posited by CMS. This issue was precipitated in the first instance by random carrier denials of coverage, encouraged by CMS in the 1997 guidance document. Although Congress did not explicitly ban individualized carrier coverage decisions, they are against the logic of BIPA, which is to establish a nationwide coverage standard depending on whether a given drug is "usually self-administered by the patient." The legislative history does make clear that Medicare "should only consider whether a majority of Medicare patients with the disease or condition actually administer the drug to themselves." The coverage decision is thus intended to be made on a national basis, and there is no room for individualized contractor decisions on a state or regional basis.

## Oral v. Injectable Drugs

CMS also inexplicably took the opportunity in the Program Memorandum to make a policy change wholly unrelated to BIPA in changing the standard for coverage of drugs available in both an oral and injectable form. The Program Memorandum states that "if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form." Congress enacted the current provisions for oral cancer drugs (both active anti-cancer agents and anti-emetics) in order to expand treatment options, not to constrict them. In many instances, there will be clinical reasons to choose one form of administration over the other, depending on medical judgment and patient preference-the decision should not be made by Medicare contractors on the basis of fiscal considerations.

## Conclusion

The Program Memorandum violates both the letter and spirit of Section 112 of BIPA. The terms of BIPA are clear and do not require elaboration by CMS. Instead, contractors should be notified of the standard for coverage-whether drugs are not "usually self-administered by patients" who are Medicare beneficiaries-and informed of the presumption of continued coverage of existing drugs like the growth factors necessary for quality cancer care for beneficiaries. We urge that the Program Memorandum be withdrawn prior to its effective date and replaced, if at all, only with a straightforward reporting of the BIPA provision and its presumption of continued coverage.

Sincerely,

**Cancer Leadership Council**

American Cancer Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research Foundation of America
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
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
The Susan G. Komen Breast Cancer Foundation
Us Too! International - Prostate Cancer Education and Support
Y-ME National Breast Cancer Organization

cc: The Honorable Max Baucus
The Honorable Charles E. Grassley
The Honorable John D. Rockefeller
The Honorable Olympia J. Snowe
The Honorable William M. Thomas
The Honorable Charles B. Rangel
The Honorable Nancy L. Johnson
The Honorable Fortney H. "Pete" Stark
The Honorable W.J. "Billy" Tauzin
The Honorable John D. Dingell
The Honorable Michael Bilirakis
The Honorable Sherrod Brown