



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

August 28, 2001

Thomas A. Scully
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
200 Independence Ave., S.W.
Room 314-G HHH Bldg.
Washington, D.C. 20201

Dear Mr. Scully:

We are writing to bring to your attention potential noncompliance of some Medicare contractors with a provision of the Benefits Improvement and Protection Act of 2000 (BIPA) that requires payment for drugs that are “not usually self-administered.” As you may know, this provision was the culmination of a multi-year debate among patient advocates, Congress and Medicare officials regarding the circumstances under which Medicare would cover drugs that could conceivably be self-administered but were in fact usually administered by a provider. Efforts by some Medicare officials to deny reimbursement for these drugs were initially blocked on a one-year basis through an Appropriations limitation, and then last year the policy of covering the drugs was made permanent through BIPA. If there was ever any doubt about the coverage status of these drugs, it has clearly been resolved by the 2000 legislation.

Now, however, it appears that individual carriers and intermediaries may not be apprised of the impact of the legislation. We understand that some contractors have asserted that coverage should be determined by reference to instructions for self-administration in labeling approved by the Food and Drug Administration (FDA). These contractors have sought to deny coverage for drugs that could possibly be, but are not usually, self-administered. It is absolutely clear that the content of FDA-approved labeling does not establish or deny Medicare coverage; rather, under BIPA, coverage depends on how the drug is usually administered to patients. We strongly encourage you to inform the carriers and intermediaries that they lack discretion to second-guess coverage of these drugs on the basis of FDA-approved labeling.

Another issue that has been raised is whether Medicare coverage could be determined beneficiary-by-beneficiary based on the individual patient’s inability to self-administer a drug. Such coverage on an individual basis of otherwise non-covered drugs is currently recognized in the Medicare Carriers Manual in the case of certain emergencies, such as a diabetic coma, and an expansion of this policy may well be warranted. However, such an expansion would be additive to the coverage guaranteed by BIPA for all drugs that are not usually self-administered.

Thomas A. Scully
August 28, 2001
Page 2

Congress clearly intended a strong presumption of Medicare coverage of injectable drugs. The legislative history accompanying the BIPA provision states the drafters' intention that the Department assume "that Medicare patients do not usually self-administer injections or infusions to themselves." It further anticipates that Medicare will instruct the contractors that they may not deny Medicare coverage of a drug without "an explicit finding supported by evidence that it is usually administered to themselves by a majority of Medicare patients." (H.R. Rep. No. 106-1019, Part I, page 37.)

In light of apparent lack of appreciation of the BIPA provision by some Medicare contractors, we urge you to communicate its terms promptly to the carriers and fiscal intermediaries. Thank you for your attention to this issue of great importance to people with cancer, and we look forward to working with you on this and other matters in the future.

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.
Cancer Care, Inc.
Cancer Research Foundation of America
The Children's Cause, Inc.
Coalition of National Cancer Cooperative Groups
Colorectal Cancer Network
Cure For Lymphoma Foundation
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
North American Brain Tumor Coalition
Oncology Nursing Society
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
US TOO! International, Inc.
Y-ME National Breast Cancer Organization

cc: The Honorable William Thomas The Honorable Michael Bilirakis
 The Honorable Charles Rangel The Honorable Thomas Daschle
 The Honorable W.J. "Billy" Tauzin The Honorable Edward Kennedy
 The Honorable John Dingell The Honorable Orrin Hatch
 The Honorable Nancy Johnson The Honorable Max Baucus
 The Honorable Pete Stark The Honorable Charles Grassley