September 12, 2002

Thomas A. Scully  
Administrator, Centers for Medicare and Medicaid Services  
200 Independence Avenue, S.W.  
Room 314-G — HHH Bldg.  
Washington, D.C. 20201

Dear Mr. Scully:

The Cancer Leadership Council, including cancer patient, provider, and research organizations, is writing to urge action to ensure proper and adequate reimbursement for high-dose interleukin-2 (IL-2) therapy. For patients with metastatic renal cell carcinoma and metastatic melanoma, high-dose IL-2 therapy represents the only possibility of long-term survival, but limits on current Medicare reimbursement for this inpatient therapy are severely restricting patient access.

As you know, high-dose IL-2 therapy must be administered on an inpatient basis. Hospital stays of five to seven days, with intensive nursing support, are required for IL-2 treatment, and often the therapy is administered in a bone marrow transplant unit or an intensive care unit due to potentially severe side effects. Because of the wide range and intensity of services that are demanded for safe use of IL-2, the treatment costs are significant. The cost of each admission for IL-2 treatment is estimated at approximately $30,000, but the average Medicare reimbursement ranges from $5,000 to $6,000.

A number of institutions have determined that they cannot bear the costs associated with IL-2 use in light of the limited rate of Medicare reimbursement and no longer provide this treatment, and additional institutions have indicated that they may discontinue this service. As a result, patient access to IL-2 has suffered, and the availability of this therapy may become even more restricted. Although it is estimated that this treatment may be an appropriate option for only 1,300 Medicare patients annually, for those patients it may be the sole effective treatment.

We strongly urge that the Centers for Medicare and Medicaid Services (CMS) take action to assign IL-2 therapy to a DRG that would ensure appropriate payment for the treatment. It has been suggested that there are inadequate data on which to base a reassignment of IL-2 to a different DRG. Even if Medicare claims data do not provide sufficient data for movement of IL-2 code into a higher-paying DRG, we believe that reliable non-Medicare data will support such a decision.
In the Conference Report accompanying the Balanced Budget Act of 1997, Congress directed the Health Care Financing Administration (HCFA) to consider reliable, validated data other than Medicare data in the annual recalibration and reclassification of DRGs. Congress directed this change “in order to ensure that Medicare beneficiaries have access to innovative new drug therapies.” In the Final Rule updating the FY 2000 Inpatient Prospective Payment Rates, CMS (at that time HCFA) stated that it remained open to considering non-Medicare data in the DRG process, as long as those data are reliable and validated.

On many occasions since the enactment of the Balanced Budget Act of 1997, Congress has reiterated its intention that Medicare beneficiaries have access to promising drug therapies. Recently, several Members of Congress expressed this specific opinion with regard to IL-2. They share the concern of the cancer community that patients with only one promising treatment option be ensured access to that therapy.

We urge your prompt attention to this matter of great importance to individuals with metastatic kidney cancer and metastatic melanoma and to the entire cancer community. We look forward to hearing from you soon.

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
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 Coalition for Cancer Survivorship
National Patient Advocate Foundation
National Prostate Cancer Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
The Wellness Community
Y-ME National Breast Cancer Organization