

June 13, 2007

Steve E. Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, Maryland 21244

RE: National Coverage Analysis for Erythropoiesis Stimulating Agents (ESAs)
For Non-Renal Disease Indications (CAG-00383N)

Dear Dr. Phurrough:

The undersigned organizations represent cancer patients, providers and researchers in connection with responsible coverage policies for cancer therapies, among other issues. We are writing to express concern about the proposed decision memo for the use of erythropoiesis stimulating agents (ESAs) in cancer and related neoplastic conditions. We take no position as to whether Medicare officials have identified appropriate limits on the use of these products because we believe that determination should not be made prior to a determination on that issue by the Food and Drug Administration (FDA). Absent action by FDA, Medicare's proposal is premature and should be withdrawn.

The ESA controversy is under active review by FDA, which has primary responsibility for determining the limits that are set forth in the proposed decision memo. As Medicare officials are no doubt aware, the FDA's Oncologic Drugs Advisory Committee (ODAC) intensively reviewed the available data in a meeting on May 10. Even prior to the ODAC meeting, FDA had taken action to require "black box" warnings for the products. FDA is currently considering the recommendations from ODAC, but the agency is not compelled to follow them. Until FDA has made a decision to change the existing labeling of ESAs, Medicare should follow the labeling as it is currently configured, certainly taking into account the warnings required by FDA.

This result is necessary, not just as a matter of medical evidence and bureaucratic prudence but also because it is compelled by the laws that govern Medicare coverage policies. In 1993 Congress enacted legislation that was intended to resolve questions about the discretion of Medicare officials and contractors to limit coverage of medically appropriate cancer therapies. Accordingly, in §1861(t)(2) of the Social Security Act (42 U.S.C. §1395x(t)(2)), the term "drugs" is specifically defined to include "any drugs or biologicals used in an anticancer

Steve E. Phurrough, MD, MPA

June 13, 2007

Page 2

chemotherapeutic regimen for a medically accepted indication,” which is further defined to include “any use which has been approved by the Food and Drug Administration” as well as any compendia-supported use that has not been found by the Secretary to be medically inappropriate.

In light of these legal requirements, Medicare does not have discretion to restrict coverage to be inconsistent with the FDA-approved labeling. In addition, if off-label coverage is to be restricted in a manner that conflicts with compendia references, there must be a specific determination by the Secretary that the restricted uses are medically inappropriate.

The proposed decision memo should be withdrawn to await the decision by FDA as to the medically appropriate uses of ESAs, and any future coverage determination by Medicare should be made in strict conformity with the terms of §1861(t)(2) of the Act.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Psychosocial Oncology Society
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
C3: Colorectal Cancer Coalition
Cancer Care
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Coalition of Cancer Cooperative Groups
International Myeloma Foundation
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
The Lung Cancer Alliance

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
Susan G. Komen for the Cure
Us TOO International Prostate Cancer
Education and Support Network
The Wellness Community
Y-ME National Breast Cancer Organization