

CANCER LEADERSHIP COUNCIL

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

July 30, 2010

Louis B. Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: National Coverage Analysis for Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer (CAG-00422N)

Dear Dr. Jacques:

The undersigned organizations, members of the Cancer Leadership Council, represent cancer patients, providers and research entities. Our common interest is to ensure access to quality care for people who have been diagnosed with cancer or who are at risk of cancer. We are deeply troubled by the recent action of the Centers for Medicare & Medicaid Services (CMS) initiating a national coverage analysis (NCA) for an immunotherapy product, sipuleucel-T or PROVENGE, approved by the Food and Drug Administration (FDA) in April 2010 for the treatment of hormone refractory prostate cancer.

According to the NCA Tracking Sheet, CMS intends to conduct its own independent review of whether this immunotherapy is reasonable and necessary for the treatment of prostate cancer, as indicated in the FDA-approved labeling. In this undertaking, CMS proposes to contract with “an external entity” to perform a technology assessment and then to consult with the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) before making a coverage determination. It is anticipated that this process will take a year to reach conclusion.

This proposed course of action is wasteful, needlessly dilatory and expensive, and inconsistent with the Medicare statute. There is no legal or medical basis to deny Medicare coverage for this product as approved by FDA. Moreover, aside from the impact on Medicare beneficiaries, this action by CMS will cast a pall over decisions by private insurers to extend coverage to this new immunotherapy, so that men of all ages with prostate cancer may find themselves denied access to potentially life-extending treatment.

Since 1993, section 1861(t)(2) of the Medicare statute has provided specific definition of drugs covered by the program for use "in an anticancer 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 certain unapproved uses reflected in medical compendia. The statute thus clearly envisions that Medicare coverage for cancer drugs will flow from approval by FDA, and CMS has historically followed this practice.

In this instance, CMS suggests deviation from this normal practice on the basis of a potential determination under section 1862(a)(1)(A) of the Act that the FDA-approved product is "not reasonable and necessary for the . . . treatment of illness. . . ." Given the extensive review of the clinical trial data by FDA, the Department's leading scientific and medical component, as well as the demonstrated survival advantage conveyed by the product, it is difficult to envision a basis for CMS and its outside consultants to make such a determination on the basis of anything other than cost, which we do not believe is permissible, even under section 1862 (a)(1)(A).

We strongly urge that CMS act promptly to withdraw the NCA in order to remove the cloud of uncertainty that has been inappropriately placed over this product.

Sincerely,

Cancer Leadership Council

C3: Colorectal Cancer Coalition
Cancer Support Community
Coalition of Cancer Cooperative Groups
Education Network to Advance Cancer Clinical Trials (ENACCT)
International Myeloma Foundation
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
National Comprehensive Cancer Network
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network