

CANCER LEADERSHIP COUNCIL

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

March 6, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4159-P, Contract Year 2015 Policy and Technical Changes to the
Medicare Advantage and the Medicare Prescription Drug Benefit
Programs

Dear Administrator Tavenner:

The Cancer Leadership Council, including the undersigned cancer patient, health professional, and research organizations, urges that the Centers for Medicare & Medicaid Services (CMS) reconsider the new policy on classes of clinical concern that has been proposed for Medicare Part D beginning in contract year 2015. Removing three classes of drugs from “protected classes” status in 2015 and following years is not in the best interest of individuals with cancer or other serious illnesses who depend on ready access to prescription drugs.

From the initial implementation of Medicare Part D, the Cancer Leadership Council has recommended in the strongest possible terms that cancer patients have access to all drugs in the class of antineoplastic agents. Cancer drugs are not readily interchangeable, and decisions about appropriate therapy for a cancer patient may be driven by information about the specific mutation associated with an individual’s cancer. In addition, cancer patients may require access to combination therapies, combining two or more cancer drugs in a drug regimen, and may require access to several different chemotherapy agents over the

course of their disease. Anything less than access to “all or substantially all” cancer drugs would threaten the quality of care provided to Medicare beneficiaries. This has always been true, but access to all cancer drugs is even more important as we move toward “targeted” or “personalized” cancer treatment. The protected classes policy that has been in place in Medicare Part D, which requires that all or substantially all drugs in a class be covered, has generally ensured Medicare beneficiaries diagnosed with cancer access to the drug therapies they need.

CMS has concluded that antineoplastics meet the two criteria for a class of drugs to be considered a class of clinical concern. The agency would require that: 1) hospitalization, disability, or death is likely to result if administration of a drug in the class does not occur in less than seven days, and 2) more specific formulary standards cannot address the matter of access to drugs in the class “due to the diversity of disease or condition manifestations and associated specificity or variability of drug therapies necessary to treat such manifestations.” The first criterion is dangerously restrictive, and we are concerned that its application in future contract years would result in the elimination of protected status for antineoplastics.

In addition, as advocates for cancer patients, we have concerns about the elimination of protected status for other drug classes. Cancer patients often have serious and significant co-morbidities that require treatment, and the protected classes policy has helped to ensure that they have appropriate access not only to antineoplastics but also to supportive care medications. For example, many cancer patients are prescribed antidepressants, and proper care requires access to all of the drugs in that class to protect against dangerous drug interactions.

We understand that the decision to reconsider the protected classes of drugs was driven in part by a desire to increase the ability of plan issuers to negotiate lower drug prices. We offer a caution about attempting to achieve program savings through this policy change. We believe that there will be a financial burden for patients and also for plan issuers associated with the appeals that will be pursued if the protected classes are limited, in addition to the significant personal burden that will be placed on Medicare beneficiaries who find coverage appeals processes sometimes unresponsive and lengthy. In addition, delay in access to appropriate therapy may result in increased utilization of other health care services, undermining any attempt to save money through more restricted formularies in Medicare Part D.

We strongly recommend that CMS abandon its decision to eliminate the protected classes of antidepressants, immunosuppressants, and antipsychotics and also reconsider the criteria for establishing a class of clinical concern.

Sincerely,

Cancer Leadership Council

American Cancer Society Cancer Action Network
American Society of Clinical Oncology
Association for Molecular Pathology
Bladder Cancer Advocacy Network
CancerCare
Cancer Support Community
The Children's Cause for Cancer Advocacy
Free to Breathe
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
LIVE**STRONG** Foundation
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen
Us TOO International Prostate Cancer Education and Support Network