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Filed via E-mail

Mark A. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 314-G – HHH Bldg.
Washington, D.C. 20201

RE: Draft Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Making a Determination of Coverage with Evidence Development

Dear Dr. McClellan:

The undersigned organizations in the Cancer Leadership Council (CLC) represent cancer patients, providers and research organizations. Both the CLC and our individual organizations have been engaged in advocacy on Medicare coverage issues for a number of years and have welcomed a newly collaborative approach to those issues on the part of the Centers for Medicare & Medicaid Services (CMS). We regard the draft Guidance on “Factors CMS Considers in Making a Determination of Coverage with Evidence Development” as a continuation of several promising trends in CMS policy: first, a willingness to assume a more expansive approach to coverage of new or unproven technologies; and second, a new emphasis on the collection of data as part of a move toward measurement of quality in treatment of cancer and other serious or life-threatening diseases.

The draft Guidance will raise questions for some, including providers who may be called upon to collect data without mechanisms for reimbursement for their efforts, as well as device manufacturers who may doubt that coverage is in fact being expanded. For cancer patients, the primary concern is whether the new coverage with evidence development (CED) policy will interfere in any way with the strong coverage protections for cancer drugs set forth in the current Medicare law.
Under § 1861(t)(2)(B) of the Social Security Act, Medicare coverage for cancer drugs specifically includes "any use which has been approved by the Food and Drug Administration," as well as those additional uses not approved by FDA but cited in certain medical compendia. These assurances of coverage were prompted more than a decade ago by patient and physician outcry over inconsistent coverage decisions by Medicare contractors and are now considered by the entire cancer community to be vital to quality cancer care for Medicare beneficiaries. The failure to recognize that the new CED policy in no way affects this statutorily mandated coverage has generated some understandable anxiety, which we believe would be dispelled by CMS clarification on the point.

The current leadership of CMS has been very progressive with respect to coverage issues, and we support this additional incremental step toward expanded coverage and enhanced evidence development while encouraging clarification of the matters discussed herein. Thanks to CMS and its coverage staff for their responsiveness to the needs of people with cancer.

Sincerely,

Cancer Leadership Council

American Cancer Society  
American Psychosocial Oncology Society  
American Society of Clinical Oncology  
American Society for Therapeutic Radiology & Oncology  
Cancer Care, Inc.  
Cancer Research and Prevention Foundation  
The Children's Cause for Cancer Advocacy  
Fertile Hope  
International Myeloma Foundation  
Kidney Cancer Association  
Lance Armstrong Foundation  
Leukemia & Lymphoma Society  
Lymphoma Research Foundation  
Marti Nelson Cancer Foundation  
Multiple Myeloma Research Foundation  
National Coalition for Cancer Survivorship  
National Prostate Cancer Coalition  
North American Brain Tumor Coalition  
Ovarian Cancer National Alliance  
Pancreatic Cancer Action Network  
Sarcoma Foundation of America  
Us TOO International Prostate Cancer Education and Support Network  
Y-ME National Breast Cancer Organization