December 1, 2004

Submitted Electronically to CMS

Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G – HHH Bldg.
Washington, D.C. 20201

Re: Draft Decision Memo for Positron Emission Tomography (FDG) for Brain Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181N)

Dear Dr. McClellan:

The undersigned organizations, representing cancer patients, providers, and researchers, are writing to express their support for the draft decision memo for coverage of PET scans as a diagnostic tool for several cancers. We applaud the Centers for Medicare & Medicaid Services (CMS) plan to cover PET scans in brain, ovarian, pancreatic, and small cell lung cancers while at the same time collecting data that may establish the benefits of the technology in these cancers.

We note that CMS concluded that the evidence was sufficient to support coverage of PET for cervical cancer diagnosis and staging without requiring enrollment in a trial or registry, while the agency issued a non-coverage decision for use of PET in testicular cancer. Because the CMS-requested technology assessment concluded there is some evidence of the utility of PET in testicular cancer and in light of the most recent recommendations from the National Comprehensive Cancer Network that PET scans be used in cases of recurrent or residual testicular cancer, we would encourage the agency, instead of establishing a non-coverage policy, to cover the technology for testicular cancer if patients are enrolled in a high-quality clinical trial. This approach is responsive to the conclusion of the technology assessment that more studies are necessary to establish the effectiveness of PET in testicular cancer.
We urge CMS to clarify that coverage for PET scans will be available in the context of clinical trials for those cancers for which a non-coverage decision has not been issued. Such a policy is especially important for use of PET scan in multiple myeloma, a PET scan use which is not included in this coverage analysis but which may show promise in this orphan cancer. Coverage in clinical trials will facilitate the collection of data about the appropriate use of PET in multiple myeloma.

This innovative plan for coverage will likely encounter some implementation obstacles, and we are encouraged that CMS is consulting with the professional and research organizations whose members will be utilizing PET in cancer diagnosis and staging and analyzing the clinical trials and registry data.

We appreciate the opportunity to comment on this proposal and look forward to working with CMS on other cancer care coverage and reimbursement issues.

Sincerely,

Cancer Leadership Council

American Cancer Society
American Society of Clinical Oncology
Cancer Care, Inc.
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Coalition of National Cancer Cooperative Groups
Fertile Hope
Kidney Cancer Association
Lance Armstrong Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
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
The Wellness Community
Y-ME National Breast Cancer Organization