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May 2, 2008

Steve 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 Positron Emission Tomography (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181R)

Dear Dr. Phurrough:

The American Society of Clinical Oncology (ASCO) is the leading organization representing physicians engaged in cancer research and care. We are writing to support the request submitted by the National Oncologic PET Registry (NOPR) Working Group for coverage of Positron Emission Tomography (PET) across all oncologic indications except for monitoring response to treatment.

The NOPR Working Group has reported data primarily related to the use of PET for brain, cervical, ovarian, pancreatic, small cell lung, and testicular cancers that support Medicare coverage for diagnosis, staging, and restaging purposes. The principal finding from the NOPR is that PET usage is associated with a 36.5% change in the treatment or no-treatment decision. Within this group for whom the treatment decision is changed, PET findings prompted a change from a non-treatment to a treatment plan three times more frequently than they prompted a shift from treatment to non-treatment. The PET findings also resulted in changes in the goal of treatment. These data suggest that use of PET results in clinically important changes in cancer treatment and that Medicare beneficiaries will benefit from coverage of PET. The NOPR data set and findings are reported in detail in the *Journal of Clinical Oncology*.<sup>1</sup> The evidence from the NOPR supports a decision for Medicare coverage of PET in cancer diagnosis, staging, and restaging/suspected recurrence. As the NOPR has actually collected data on all cancers that are not already covered by Medicare, we believe that it is appropriate to extend this coverage to all cancer indications.

We believe the PET Registry serves as an example of how the Coverage with Evidence Development process may be effectively applied for diagnostic and treatment methods that would not otherwise meet Medicare coverage standards. We look forward to a prompt decision by CMS to extend Medicare coverage to PET

<sup>1</sup> Hillner BE, Siegel BA, Liu D, et al: Impact of Positron Emission Tomography/Computed Tomography and Positron Emission Tomography (PET) Alone on Expected Management of Patients with Cancer: Initial Results From the National Oncologic PET Registry. *J Clin Oncol* 26:1-7, 2008.

across all oncologic indications except for monitoring treatment. We understand that the NOPR Working Group will continue to collect data regarding use of PET in treatment monitoring.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, slightly slanted style.

Joseph S. Bailes, MD  
Chair, ASCO Government Relations Council

cc: Stuart Caplan, RN, MAS  
Katherine Tillman, RN, MA