

Submitted Electronically: CAGinquiries@cms.hhs.gov

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April 17, 2008

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

Dear Mr. Caplan:

We are writing in response to the reconsideration of Positron Emission Tomography (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181R). The Society of Nuclear Medicine (SNM), representing more than 16,000 physicians, scientists, pharmacists, and nuclear medicine technologists, appreciates the opportunity to provide comments to assist the Centers for Medicare and Medicaid Services (CMS) in making a decision regarding this reconsideration of the NCD on PET.

The SNM supports expanding Medicare coverage for PET (FDG) for all oncologic indications. Based on the data recently released by the National Oncologic PET Registry (NOPR), the SNM requests that CMS end the data collection requirements for diagnosis, staging and restaging/suspected recurrence for PET across all cancer types and provide coverage for these services for Medicare beneficiaries. With overwhelming and rapidly increasing evidence showing the clinical effectiveness of PET, coverage should be defined by the prevailing literature.

The SNM has been a staunch supporter of NOPR since its inception nearly two years ago. Many SNM members have taken part in the study and have known for some time that diagnosis, staging, restaging and monitoring therapy is a powerful tool in diagnosing, treating, and monitoring disease and is capable of dramatically changing the course of patient care.


While we believe the NOPR to be a uniquely representative sample of the Medicare population, we are also aware that not all PET facilities participate because of the additional administrative burden on these facilities and their referring physicians, along with the added financial impact of the Deficit Reduction Act (DRA) implementation. Additionally, we are aware that some third-party payers have policies for coverage of PET for these Medicare non-covered or CED-only-covered indications on a

regular or case-by-case basis. These gaps in coverage for Medicare beneficiaries are concerning, and we strongly encourage CMS to eliminate administrative barriers to patient care for Medicare beneficiaries.

As you well know, the principal purpose of Coverage with Evidence Development (CED) is to provide the data necessary for CMS to make well-informed payment decisions. This has been the NOPR Working Group's goal since May, 2006 and led to the release of the NOPR study in March 2008. In this study, the data showed that PET is associated with a 36.5% change in the treatment or no-treatment decision, and these changes encompassed the full range of potential oncologic uses of PET (diagnosis, initial staging, restaging, and detection of suspected recurrence). Also, the 36.5% number does not fully explain the impact of PET imaging has in the clinical arena because it only takes into account full changes between non-treatment and treatment. Thus, PET was connected with management change in almost three-quarters of patients when considering the inclusion of different modes of therapy, and alterations in the recommended type of non-treatment care. We believe this important study, especially when viewed in light of the other published literature, is more than sufficient evidence for CMS to expand coverage for PET studies.

The SNM appreciates the opportunity to comment on this reconsideration of Positron Emission Tomography (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and Testicular Cancers (CAG-00181R). The SNM is more than willing to discuss our comments or work with CMS to address the above issues. Please contact the Society of Nuclear Medicine technical advisor, Denise A. Merlino at dmerlino@snm.org, or at 781-435-1124. You may also contact the SNM Economics Coordinator, Zachary Hochstetler at zhochstetler@snm.org, or at 703-652-6760.

Respectfully Submitted,



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President, SNM (Society of Nuclear Medicine)