February 3, 2009

Steve Phurrough, MD, MPA
Director
Coverage and Analysis Group
Centers for Medicare & Medicaid
7500 Security Blvd, Mail Stop
Baltimore, MD 21244 C1-09-06

Re: Proposed Decision Memo for Positron Emission Tomography (FDG) for Solid Tumors (CAG 00181R)

Dear Dr. Phurrough:

We are writing in response to the Centers for Medicare & Medicaid Services' (CMS) request for comments on its proposed decision memorandum revising the current coverage determinations for oncologic FDG-PET imaging.

This letter is submitted jointly on behalf of the National Oncologic PET Registry (NOPR) Investigators, the American College of Radiology (ACR), the Academy of Molecular Imaging (AMI), the American Society for Radiation Oncology (ASTRO), the American College of Nuclear Physicians (ACNP), and the Society of Nuclear Medicine (SNM). These groups collectively are composed of clinicians, academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including integrated positron emission tomography/computed tomography (PET/CT). We represent tens of thousands of physicians, providers, and patients with regard to this technology, and have worked closely with CMS over the past three years to increase beneficiary access to PET/CT through the development of the National Oncologic PET Registry (NOPR).

We wish primarily to voice our collective and strong support for the proposed decision overall. The articulation of a new, streamlined coverage framework (distinguishing the categories of "initial treatment" and "subsequent treatment") is a significant improvement upon the previous four-category coverage framework, and we appreciate the efforts of CMS to develop a comprehensive omnibus framework that will minimize the need to seek indication-by-indication coverage decisions in the future. We are also supportive of

the decision of CMS to provide coverage for initial treatment for nearly all oncologic indications that were covered previously only under the coverage with evidence development (CED) rubric. Additionally, we support the decision to maintain coverage for nine oncologic indications (breast, cervix, colorectal, esophagus, head and neck (non-CNS/thyroid), lymphoma, melanoma, non-small cell lung, and thyroid cancers) that, although not included in the NOPR, were covered under prior individual decisions.

While we applaud the proposed decision in general, there are several aspects of the proposed memorandum that we believe would benefit from clarification and revision by CMS in its final decision.

First, while we support the expanded PET coverage proposed by CMS, we continue to believe that the research data and existing literature supports full coverage for PET for all oncologic indications in the new category of "subsequent treatment," and encourage CMS to expand coverage in this regard in the final rule. In particular, we note that in the case of ovarian cancer, both the CMS Technology Assessment and the data from the NOPR indicated the significant clinical value of PET. Indeed, use of PET in ovarian carcinoma for detection of suspected recurrence, treatment monitoring, and restaging represented the three most frequent indications for PET under the NOPR program. For suspected recurrence and restaging, PET led to a change in intended management (treatment to non-treatment or vice versa) in 44.5% and 37.7% of cases, respectively When used for treatment monitoring, PET led to a planned adjustment in the dose or duration of therapy, change to another therapy, or switching to supportive care in 53.5% of cases. We therefore encourage CMS, at a minimum, to extend non-CED coverage to subsequent treatment evaluations of ovarian cancer.

Second, if the final decision does continue CED for certain cancers and indications, we strongly encourage CMS to ensure that beneficiaries continue receiving uninterrupted access to PET during the implementation of the new NCD. We understand that once the final decision becomes effective, new CED studies—accommodating the additional AHRQ requirements—will be required. We also understand that it is highly unlikely that such studies will be operational at the time the final decision becomes effective. Thus, while we support the efforts to expand data collection regarding the impact of PET on health outcomes, we also believe it is crucial to avoid creating an abrupt "coverage gap" for cancer patients in the process. The existing NOPR study meets many, but not all, of the new AHRQ requirements, and we believe that the NOPR could be expanded to fulfill the outcomes-based requirements of the proposed decision. We are actively examining various design options (such as linking CED data to Medicare claims data in order to measure and evaluate outcomes) that would help achieve this objective. We welcome the opportunity to work closely with CMS, AHRQ and other stakeholders both to establish a transitional mechanism that would ensure uninterrupted PET access, and to develop a robust CED framework that meets the specifications of the final decision.

However, given the operational capacity of the existing NOPR, we do not believe that it is possible for the NOPR itself to fully transition to the requirements of the new CED

long-term outcomes study within the available timeframe between the proposed and final decisions. We are not aware of any other organization or entity that has the capacity to develop and implement a fully-compliant CED study within this timeframe. Thus, in order to avoid inadvertently creating a PET "coverage gap" between the finalization of the NCD and the full implementation of any new CED study, we propose to work with CMS and AHRQ to amend the existing NOPR protocol in a manner that would enable beneficiaries to continue receiving PET coverage under a transitional study vehicle while a long-term outcomes study is being finalized.

Third, we request that CMS clarify whether it considers multiple myeloma to be a "solid tumor" for purpose of this NCD. The literature points to excellent sensitivity for detection of both osseous and soft-tissue lesions of myeloma, and the NOPR data demonstrate that PET frequently influences intended patient management in myeloma. We urge CMS to treat myeloma as a solid tumor (analogous to its classification of other lymphomas, to which it is closely related), rather than a "liquid" hematologic neoplasm.

Fourth, although the streamlining of the coverage framework into "initial" and "subsequent" treatment is a positive development, we encourage CMS to recognize in the final decision that—in certain clinical situations—the one-time-only availability of PET for "initial" treatment evaluation (for each new cancer diagnosis) may hamper good clinical practice. Two practical scenarios illustrate this general concern. First, where PET is used for diagnosis or initial staging purposes, the result may indicate that radiation therapy, rather than surgery, is the appropriate method of treatment. In such situations, a second (initial) PET scan, often a limited study done under technically different conditions, may be needed for radiation therapy planning (e.g., for PET-based simulation). Second, in a small fraction of patients, PET used to evaluate a suspicious lesion (e.g., a pulmonary nodule) for cancer diagnosis can produce a false-negative result. If such patients are subsequently diagnosed with cancer, however, the prevailing standard of care is to use PET for initial staging prior to surgery, in order to exclude unresectable disease (because of the interval development of metastatic disease). In both of these illustrations, a literal interpretation of the proposed coverage framework prohibits coverage for this second scan, despite the fact that failure to perform a scan in these circumstances would be contrary to good clinical practice.

Scenarios such as those described above, in which more than one PET study is performed for either diagnosis or initial staging in a given subject, occurred quite infrequently for those cancers covered under the NOPR. Based on fully-consented NOPR data from May 2007 through December 2008, a total of 97,043 PET scans were performed. Of these, 16,766 were done for diagnosis and 21,134 for initial staging (total = 37,900), in a total of 36,959 patients. Thus, only 754 patients (1614 scans)—or 2.0%—had more than one scan during this interval for initial treatment evaluation (diagnosis and/or initial staging).

We therefore recommend that the final rule accommodate and cover clinically necessary "second initial" scans in situations such as those described above. One way to accomplish this objective would be through the use of HCPCS codes for these specific services. Providers currently use the CPT level I HCPCS codes to report all covered

indications of PET/CT procedures. As one approach, for example, we recommend that CMS expand coverage and track utilization of second radiation planning scans by developing a HCPCS Level II temporary G code G02xx *PET/CT Imaging, radiation therapy planning, subsequent to initial PET or PET/CT study*.

Again, we wish to reiterate our support for the new framework developed by CMS, and to express our appreciation for the efforts CMS has made to expand oncologic PET coverage to its Medicare beneficiaries. We appreciate the opportunity to comment on this proposed decision memorandum, and look forward to providing CMS with any additional information that would be of value in this regard.

Sincerely,

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Chair, NOPR Working Group

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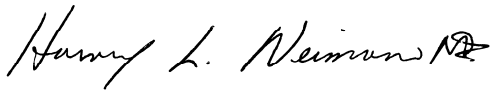

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