August 27, 2009

Tamara Syrek Jensen, J.D.
Acting Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd., Mail Stop C1-09-06
Baltimore, MD 21244

Re: Comments on Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Cervical Cancer (CAG-00181R2)

Dear Acting Director Jensen:

We are writing in strong support of the Centers for Medicare & Medicaid Services' (CMS) Proposed Decision Memorandum for Positron Emission Tomography (FDG) for Cervical Cancer, CAG-00181R2, which proposes to cover FDG PET (PET) for staging in beneficiaries who have biopsy-proven cervical cancer, and to remove the current Coverage with Evidence Development (CED) limitations on the use of PET for the initial staging of cervical cancer.

This letter is submitted jointly on behalf of the Academy of Molecular Imaging (AMI), the American College of Nuclear Physicians (ACNP), the American College of Radiology (ACR), the American Society of Clinical Oncology (ASCO), the American Society for Radiation Oncology (ASTRO), 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 several years to increase beneficiary access to PET/CT through the development of the National Oncologic PET Registry (NOPR).

We applaud the proposal to align coverage of PET for cervical cancer with the new omnibus PET National Coverage Decision (NCD) CAG-00181R, released earlier this year. As we noted in our initial May 29, 2009 comments in support of this request, coverage for PET imaging for cervical cancer is currently predicated on a prior CT or MRI that is negative for extrapelvic metastatic disease. This additional step of requiring a prior CT or MRI before authorizing PET coverage is unique to cervical cancer — indeed, we noted that no similar prerequisites exist for obtaining Medicare coverage for the use of PET for initial staging of other

covered cancers under the omnibus NCD. Moreover, we observed that requiring CT or MRI prior to PET for cervical cancer initial treatment ignores the fact that the vast majority of PET studies performed in the United States are PET/CT studies The proposed decision would eliminate this anomaly in coverage, affording beneficiaries easier access to this important imaging technique without the imposition of additional inconvenience, unnecessary radiation exposure, and further expense.

We are also pleased to learn from the proposed decision that the CMS internal technology assessment confirms that the existing literature, the data from the NOPR, and the University of Alberta technology assessment all offer strong clinical evidence for the utility of PET for initial staging of cervical cancer.[1] As we stated in our initial comments, this literature indicates that almost all patients who receive a CT or MRI of the pelvis that shows no extrapelvic metastatic disease will still require PET in order to develop an initial treatment plan. Additionally, it indicates that PET will generally be necessary to enable a treating physician to assess the supraclavicular nodes when CT or MRI shows para-aortic nodal involvement (the most common site of extrapelvic metastatic disease). Moreover, it indicates that relying on negative conventional imaging as the basis for performing PET ignores the fact that PET is both more sensitive and more specific than CT or MRI for detecting pelvic and para-aortic nodal metastasis. We believe that the proposed decision accurately reflects the acknowledged limitations of the current PET coverage for cervical cancer (as identified in the literature), and that the proposed coverage determination responds appropriately to these limitations by authorizing PET coverage for initial staging purposes.

Besides eliminating the requirement for a prior CT or MRI, the proposed decision also takes the additional positive step of removing the CED requirement. As we noted in our initial comments, the data collected by the NOPR over the past two years provides strong supporting clinical evidence for this proposal. In specific, the NOPR data indicate that the percentage of the 341 cervical cancer patients who saw a "change in management" due to the use of PET was 36.1%, a similar percentage as the overall "change in management" percentage (39.8%) for all initial staging studies included in the NOPR.[2] Having served its intended purpose — providing quantifiable data to inform the proposed coverage decision — we now believe that the proposal to terminate the CED requirement as to cervical cancer is eminently justifiable.

Finally, we continue to agree with the conclusion reached by CMS in the omnibus NCD CAG-00181R (and again in this proposed decision) that, as cervical cancer is diagnosed primarily via biopsy, a decision to nationally non-cover the use of PET for the *diagnosis* of cervical cancer is appropriate.

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[1] *See, e.g.*, Grigsby PW. The contribution of new imaging techniques in staging cervical cancer. *Gynecol Oncol.* 2007;107(1, Supplement 1):S10-S12; Grigsby PW, Siegel BA, Dehdashti F. Lymph node staging by positron emission tomography in patients with carcinoma of the cervix. *J Clin Oncol.* Sep 1 2001;19(17):3745-3749; Tran BN, Grigsby PW, Dehdashti F, Herzog TJ, Siegel BA. Occult supraclavicular lymph node metastasis identified by FDG-PET in patients with carcinoma of the uterine cervix. *Gynecol Oncol.* 2003/9 2003;90(3):572-576.

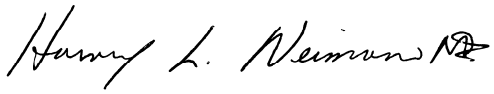
[2] Hillner BE, Siegel BA, Shields AF, et al. Relationship between cancer type and impact of PET and PET/CT on intended patient management: findings of the National Oncologic PET Registry. *J Nucl Med* 2008; 49:1928-1935.

The proposed decision will provide numerous benefits to patients and providers alike. It will remove an additional and unnecessary barrier to the use of PET for the initial staging of cervical cancer, enable CMS to harmonize the omnibus coverage policy for the use of PET across all covered cancers, accelerate the initial staging (and thus subsequent treatment planning) processes for patients, simplify the data collection burden of the NOPR, and streamline the reimbursement of providers for PET services rendered. We strongly support the proposed decision, and appreciate the opportunity to provide comments to CMS in this regard. We look forward to working with CMS to provide any additional information that you would find valuable in your decision making process.

Sincerely,

Timothy J. McCarthy, PhD
President, AMI

Jay A. Harolds, MD, FACNP
President, ACNP



Harvey L. Neiman, MD, FACR
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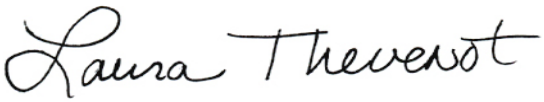

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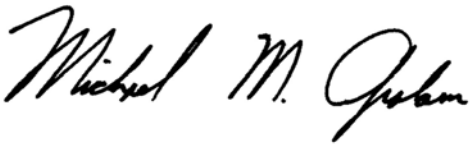

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