May 29, 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 Reconsideration of National Coverage Determination on Positron Emission Tomography (FDG) as to Cervical Cancer (CAG-00181R2)

Dear Acting Director Jensen:

We are writing in response to the Centers for Medicare & Medicaid Services' (CMS) request for comments on the Reconsideration of the NCD on Positron Emission Tomography (FDG), CAG-00181R2, regarding the request to remove the current Coverage with Evidence Development (CED) requirements for FDG-PET (PET) imaging for the initial staging of cervical cancer contained in Section 220.17 of the NCD Manual. For the reasons stated below, we strongly support this request, and encourage CMS to act favorably in response.

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

Under the new omnibus NCD, CAG-00181R, Medicare covers PET imaging as medically necessary for the "subsequent treatment strategy" of cervical cancer.

However, as CMS is aware, coverage for PET imaging for the "initial treatment strategy" is currently dualistic, and is predicated on the results of a previously-performed CT or MRI. If conventional imaging is negative for extrapelvic metastatic disease, then PET imaging is covered by Medicare for the initial phase of management. Other uses of PET during the "initial treatment strategy," however — including PET in the absence of prior CT or MRI — are only covered under CED. We note that the additional step of requiring CT or MRI prior to routine coverage for PET is unique to cervical cancer. No similar prerequisites exist for obtaining Medicare coverage for the use of PET for initial staging of other covered cancers under the omnibus NCD.

We concur with the requestors that the existing literature, the data from the NOPR, and the University of Alberta technology assessment offer strong clinical evidence for the utility of PET for initial staging of cervical cancer.[1] 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, PET will generally be necessary to enable a treating physician to assess the supraclavicular nodes when CT or MRI does show para-aortic nodal involvement (the most common site of extrapelvic metastatic disease). Moreover, as the requestors note, 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 also agree with the requestors that the data collected by the NOPR over the previous two years provides additional supporting clinical evidence for removing the CED requirements in this instance. 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] Finally, we would reiterate 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. As we — and our members — are continually seeking to reduce the inconvenience, radiation exposure, and expense related to imaging, we believe that it cannot be in the interest of patients, providers, or CMS to perpetuate a policy that increases inconvenience, exposure, and expense by requiring both CT/MRI and PET.

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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.

In light of this evidence, we strongly encourage CMS to amend NCD CAG-00181R and adopt a manual policy providing PET coverage for the initial staging of cervical cancer without restriction. By removing this additional and unnecessary barrier to the use of PET for the initial staging of cervical cancer, CMS will 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 further agree — as do the requestors — with the conclusion reached by CMS in CAG-00181R that cervical cancer is diagnosed primarily via biopsy, as the cervix is readily accessible and directly visualized with optical instruments and without specialized imaging technologies. As such, we would support a decision by CMS to non-cover the use of PET for the *diagnosis* of cervical cancer.

We appreciate the opportunity to provide comments to CMS in this regard, and look forward to working with CMS to provide any additional information that you would find valuable in your decision making process.

Sincerely,

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