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June 5, 2009

BY ELECTRONIC DELIVERY

Tamara Syrek Jensen
Acting Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mailstop: C1-09-06
7500 Security Blvd.
Baltimore, MD 21244

**Re: NCA Tracking Sheet for Positron Emission Tomography (FDG) for
Cervical Cancer (CAG-00181R2)**

Dear Ms. Jensen:

The Association for Community Cancer Centers (ACCC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) National Coverage Analysis (NCA) Tracking Sheet for Positron Emission Tomography (FDG) for Cervical Cancer (CAG-00181R2).¹ ACCC is committed to ensuring that cancer patients have broad access to the entire continuum of quality care and that coverage with evidence development (CED) requirements be removed as soon as they no longer are necessary. We therefore write in support of the recommended expansion of coverage of FDG² Positron Emission Tomography (FDG PET) imaging for the initial staging of cervical cancer.

ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 700 member institutions and organizations treat 45% of all U.S. cancer patients. Combined with our physician

¹ NCA Tracking Sheet for Positron Emission Tomography (FDG) for Cervical Cancer (CAG-00181R2), May 8, 2009, <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=232>.

² FDG refers to 2-deoxy-2-[F-18] fluoro-D-glucose, also known as F-18 fluorodeoxyglucose, the radioisotope commonly used in oncologic positron emission tomography (PET) imaging procedures.

membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients. We are committed to ensuring that patients have broad access to the most effective tools available in their battle against cancer.

ACCC applauds CMS's recent decision to cover FDG PET without restriction for the subsequent management of cervical cancer in women who have undergone anticancer treatment.³ With regard to initial staging, however, CMS limited coverage to beneficiaries who have conventional imaging that is negative for extra-pelvic metastasis or who are enrolled in a prospective clinical study under CED. We believe that the benefit of FDG PET in the clinical decision-making process for treatment of cervical cancer supports the unrestricted coverage of FDG PET for initial staging purposes as well.

There are more than 11,000 new cases of cervical cancer each year, and more than 4000 women die from the disease annually. Treatment recommendations for cervical cancer depend on the stage of the cancer. FDG PET is a non-invasive imaging procedure used to assess metabolic activity and perfusion in human organs and tissues. Images are obtained by processing of emissions from positron-emitting radioisotopes, FDG in the oncology setting, that usually are administered intravenously. The rate of FDG decay provides information on glucose metabolism of tissues being studied. As malignancies can cause abnormalities of glucose metabolism, FDG evaluation can indicate the probable presence or absence of malignancy based upon observed differences in biologic activity of adjacent tissues. FDG PET is both more sensitive and more specific than other imaging technologies for detecting metastasis in cervical cancer patients.⁴ Accordingly, FDG PET is an invaluable tool in allowing physicians to determine the initial staging of cervical cancer and to ensure that the proper treatment strategy is pursued.

ACCC agrees with the requestors that CED no longer is necessary for FDG PET for the initial treatment strategy for cervical cancer.⁵ CMS lifted the CED requirements on a number of solid tumors types in its April 2009 decision in part because data collected and analyzed by the National Oncologic FDG PET Registry (NOPR) showed that FDG PET utilization was associated with a 36.5% change in intended management.⁶ Of the 341 patients who underwent initial staging of cervical cancer under NOPR, there was a 36.1% change in management

³ Decision Memorandum for FDG PET for Solid Tumors (CAG-00181R) (Apr. 3, 2009).

⁴ Letter from Peter W. Grigsby and Barry A. Siegel to Tamara Syrek Jensen, April 14, 2009, at 2-3.

⁵ *Id.* at 1-2.

⁶ Hillner BE, Siegel BA, Liu D, et al. Impact of PET/CT and PET alone on expected management of patients with cancer: initial results from the National Oncologic PET Registry. *J Clin Oncol* 2008; Decision Memorandum for FDG PET for Solid Tumors (CAG-00181R) (Apr. 3, 2009).

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due to the FDG PET results.⁷ As these data demonstrate, FDG PET for the initial staging of cervical cancer has been shown to have the same significant benefits in determining the proper course of treatment as FDG PET for other solid tumors. ACCC encourages CMS to harmonize its coverage policy for the use of FDG PET across all covered cancers by removing the CED restrictions currently in place for the initial staging of cervical cancer.

ACCC greatly appreciates the efforts of CMS to provide appropriate coverage for FDG PET in the oncology setting. We believe that FDG PET has been proven as an important tool in determining the initial staging of cervical cancer and the proper treatment of cervical cancer patients and encourage CMS to cover its use for that purpose without CED restriction. We would be pleased to answer any questions regarding these comments. Please contact Matthew Farber, Manager, Provider Economics and Public Policy, at 301-984-9496 ext. 221 if ACCC can be of any assistance as CMS continues to evaluate FDG PET.

Sincerely,



Luana Lamkin, RN, MPH

President

Association of Community Cancer Centers (ACCC)

cc: Stuart Caplan, RN, MAS
Jeffrey Roche, MD, MPH
Katherine Tillman, RN, MA

⁷ Letter from Peter W. Grigsby and Barry A. Siegel, *supra* at 3 (citing 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).