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BY ELECTRONIC DELIVERY

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**Re: Proposed Coverage Decision Memorandum for FDG
Positron Emission Tomography to Guide Initial Management
of Cervical Cancer (CAG-00181R2)**

Dear Ms. Jensen:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed national coverage decision (NCD) on positron emission tomography (FDG PET) to guide initial management of cervical cancer.¹ We urge the agency to finalize its proposal to cover the use of FDG PET to help determine the appropriate initial treatment strategy for beneficiaries who have biopsy proven cervical cancer.

ACCC believes that the proposal to cover FDG PET only for biopsy proven cervical cancer is a valid proposal and agrees that this procedure can be effective in the following areas:

- To determine whether or not the beneficiary is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or

¹ The proposed decision is available at:

<https://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=232&> (hereinafter "Proposed Decision Memorandum")

- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.²

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 900 member institutions and organizations treat 60 percent of all U.S. cancer patients when combined with our physician membership. We are often at the front line in fighting cancer and therefore have a unique perspective on how FDG PET affects patient care and often improves health outcomes.

FDG PET is a non-invasive imaging procedure used to assess metabolic activity and perfusion in various organs or tissues in the human body. Images are obtained by processing of emissions from positron-emitting radioisotopes 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. In January of 2005, CMS instituted a CED requirement for the use of FDG PET in certain cancer types. The purpose of the CED was to develop evidence on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; and c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.

Various stakeholders, with the support of CMS, established and maintained the National Oncologic FDG PET Registry (NOPR) to study the effect of FDG PET on clinical decision-making as part of an April 18, 2005 NCD.³ CMS required providers to submit data to a registry as a condition of coverage of the FDG

² Proposed Decision Memorandum at 1.

³ The NCD is available at:

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=220.6.14&ncd_version=1&basket=ncd%3A220%2E6%2E14%3A1%3APET+%28FDG%29+for+Brain%7C%7C+Cervical%7C%7C+Ovarian%7C%7C+Pancreatic%7C%7C+Small+Cell+Lung%7C%7C+and+Testicular+Cancers.

PET. Some of the results of this study were published in a March 2008 issue of the *Journal of Clinical Oncology*.⁴

The *Journal of Clinical Oncology* study shows that FDG PET utilization was associated with a 36.5% change in the treatment or no-treatment decision of the physician. This includes the full scope of potential uses of FDG PET in the diagnosis and treatment of a particular cancer. Further, the data demonstrate that physicians stated that they often changed their intended management of the respective cancer based on the FDG PET results. Additionally, where the pre-PET treatment plan was biopsy, FDG PET led to a decision to avoid surgical intervention 75% of the time, a dramatic improvement in patient care. Due to the affect that FDG PET had in enhancing the clinical-decision making process, we believe that CMS should finalize its proposal.

ACCC is grateful for CMS for its continuing efforts to allow access to FDG PET for an expanded list of cancers. Our members constantly search for tools to appropriately treat and manage cancer and should the clinical benefits of FDG PET continue to evolve, we hope the agency would continue to act quickly afford broader access to this important technology.

We would be pleased to answer any questions regarding these comments. Please contact Matt Farber at 301-984-9496 ext. 221 if ACCC can be of any assistance as CMS continues to evaluate FDG PET.

Sincerely,



Luana R. Lamkin, RN, MPH
President
Association of Community Cancer Centers

cc: Louis Jacques, MD
Stuart Caplan, RN, MAS
Jeffrey Roche, MD, MPH

⁴ Hillner BE, Siegel BA, Liu D, et al. Impact of Positron Emission Tomography/Computed Tomography and Positron Emission Tomography Alone on Expected Management of Patients with Cancer: Initial Results from the National Oncologic PET Registry. *J.Clin Oncol* 2008.