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February 4, 2009

BY ELECTRONIC DELIVERY

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

**Re: Proposed Decision Memorandum for Positron Emission
Tomography (FDG) for Solid Tumors (CAG-00181R).**

Dear Dr. Phurrough:

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) for solid tumors.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 solid tumors that are biopsy proven or strongly suspected based on other diagnostic testing. Further, we believe that CMS also should finalize its proposal to cover the use of FDG PET, without Coverage with Evidence Development (CED), in the determination of subsequent treatment strategy for patients with breast, cervix, colorectal, esophagus, head and neck, lymphoma, melanoma, non-small cell lung, and thyroid² cancer.

ACCC appreciates CMS's new two-part coverage framework to replace the four-part diagnosis, staging, restaging, and monitoring framework. CMS also proposes to use CED to study the use of FDG PET in the subsequent treatment strategy for treating other cancer types, and ACCC believes this is a reasonable approach that the

¹ The proposed decision is available at:

<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=218>.

² With respect to thyroid cancer, CMS proposes to cover FDG PET for restaging of follicular cell types.

agency should finalize. In finalizing this proposal, however, ACCC asks the agency to provide greater detail regarding its plans to implement CED in a way that preserves continuity of care. ACCC believes that the NCD proposed coverage framework affords physicians and patients with another state-of-the-art tool to fight cancer more effectively.

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 membership, ACCC represents the facilities and providers responsible for treating over 60% of all U.S. cancer patients. 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 PET. Some of the results of this study were published in a March 2008 issue of the

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.

Journal of Clinical Oncology.⁴ ACCC appreciates the efforts of the NOPR Working Group in synthesizing the data collected through the registry. Our members are committed to increasing the clinical data available for use in treatment decisions through expanded clinical research and believe that the efforts of the NOPR Working Group have achieved that goal.

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, leading to the possibility of 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 proposals.

We fully recognize, however, the limitations of the NOPR data in linking the use of FDG PET to patients' long-term clinical outcomes. The authors state that a major limitation of the data is the inability to determine if the change in intended management led to better clinical outcomes for Medicare beneficiaries. The NOPR, however, deliberately was designed to measure change in intended patient management strategy, not actual change in management or long-term patient survival. Second, as a result of the inherent weakness of the NOPR, the authors could not address whether FDG PET should be used in lieu of other imaging techniques or instead as a complement to the current standard of care. ACCC agrees with these limitations, but nonetheless believes that this diagnostic tool has significant benefits in determining the right course of treatment for many cancer patients.

ACCC is committed to ensuring that cancer patients have access to the entire continuum of quality care and all available clinical information about their disease. As such, in addition to finalizing these coverage proposals, we urge the agency to clarify in its final decision how it plans to ensure that patients who require FDG PET to guide "subsequent treatment strategies" under the CED requirement will receive uninterrupted access to this state-of-the art care. Under the proposed decision, CMS would provide coverage for FDG PET to guide "subsequent treatment strategies" only if the beneficiary is enrolled in a clinical study pursuant to a CED framework that meets certain listed criteria. ACCC urges CMS to detail in its final decision a clear pathway for Medicare beneficiaries to

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.

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continue to access FDG PET. This pathway should include practical and specific information to guide beneficiaries and their physicians to access these clinical trials and obtain Medicare coverage.

ACCC is grateful for CMS and the NOPR Working Group's hard work and dedication in collecting and analyzing the clinical data associated with FDG PET. As a result, our members now have a clearer understanding of the value that FDG PET adds to physician's treatment decisions for certain types of cancer. We urge CMS to carefully monitor the results of the upcoming CED on the use of FDG PET for the subsequent treatment strategy for brain, ovary, pancreas, prostate, small cell lung, soft tissue sarcoma, testes, and all other solid tumors. 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 act quickly to remove the CED coverage restrictions to 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,



Ernest Anderson, Jr., MS, RPh

President

Association of Community Cancer Centers (ACCC)

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