

December 29, 2009

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BY ELECTRONIC DELIVERY

Louis B. Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, Maryland 21244

**Re: Proposed Coverage Decision Memorandum for Positron
Emission Tomography (NaF-18) to Identify Bone Metastasis of
Cancer (CAG-00065R and CAG-00065R1)**

Dear Dr. Jacques:

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 (PET) (NaF-18) to identify bone metastasis of cancer.¹ 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 the importance of advanced imaging technologies, such as Na-F18 PET, to decisions about patient care and improving health outcomes.

In the Proposed Decision Memorandum, CMS describes its intent to cover NaF-18 PET imaging when "the beneficiary's treating physician determines that the NaF-18 PET study is needed to inform

¹ The proposed decision is available at:
<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=233> (hereinafter "Proposed Decision Memorandum").

the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment, and when the beneficiary is enrolled in, and the NaF-18 PET provider is participating in,” a prospective clinical study “that is designed to collect additional information at the time of the scan to assist in initial treatment planning and in identification of symptomatic bone metastases.”² CMS makes this proposal after concluding that NaF-18 PET is “promising,” but “the evidence of clinical benefit is not yet conclusive and is not generalizable to the Medicare patient population.”³ In particular, CMS states, “there is inconsistent evidence that the results of NaF-18 PET scans are used to alter recommended treatment strategy.”⁴ CMS also reports that it found “no conclusive evidence of improved patient oriented health outcomes related to NaF-18 PET studies for routine follow-up or monitoring of suspected bone metastases, except for the diagnosis of bone metastases in patients with symptomatic evidence of bone pain and with no other imaging findings of bone metastasis.”⁵

We agree that NaF-18 PET is promising, and we appreciate CMS’s recognition that beneficiaries should have access to this service. We believe that the evidence is sufficient to cover the test as prescribed by physicians, however, without coverage with evidence development (CED). As described in the National Institutes of Health literature review cited in the Proposed Decision Memorandum, there is evidence that NaF-18 PET is “more sensitive and selective than conventional bone scans for diagnosis and treatment of bone metastases.”⁶ This conclusion is supported by the Evan-Sapir (2006) study CMS cites in the Proposed Decision Memorandum that found that, “compared with bone scans, NaF-18 PET/CT is highly sensitive and specific for detecting bone metastases in patients with high-risk prostate cancer, and has the potential to change patient management.”⁷ NaF-18 PET also offers advantages to patients, such as a shorter wait between injection and imaging, compared to other bone scan methods. In addition, unlike bone scans using 99mTc, there have been no shortages of the resources needed to perform NaF-18 PET. ACCC believes that Medicare should allow patients and physicians to select the most appropriate imaging methods for each patient, and we encourage CMS to cover NaF-18 PET to ensure that patients have a choice of effective imaging modalities.

Moreover, although ACCC generally supports efforts to expand the body of evidence supporting clinical decision-making, we are concerned that limiting access

² Id. at 1.

³ Id. at 11-12.

⁴ Id. at 11.

⁵ Id.

⁶ Id. at 4-5.

⁷ Id. at 8.

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to NaF-18 PET to beneficiaries who are enrolled in clinical trials would be overly restrictive. CMS notes that three clinical trials currently are recruiting participants to study oncologic uses of NaF-18 PET for detecting metastases,⁸ but it is not clear how many beneficiaries could participate in those trials or whether other studies would meet the requirements outlined in the Proposed Decision Memorandum. Because Medicare beneficiaries often are excluded from clinical trials due to co-morbidities or do not have access to providers who participate in trials because of where they live, the proposed decision could deny access to NaF-18 PET for a large number of beneficiaries. Rather than limiting coverage to beneficiaries who participate in a study, we recommend that CMS encourage beneficiaries and providers to participate in studies but not require participation for coverage of NaF-18 PET.

ACCC is grateful for CMS for its continuing efforts to expand coverage of diagnostic imaging for beneficiaries fighting cancer. Our members constantly search for tools to appropriately diagnose, treat, and manage cancer, and ACCC looks forward to continuing to work with CMS to establish coverage decisions that allow beneficiaries to access important technologies.

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 NaF-18 PET.

Sincerely,



Luana R. Lamkin, RN, MPH

President

Association of Community Cancer Centers

cc: Tamara Syrek Jensen, JD
Stuart Caplan, RN, MAS
Jeffrey Roche, MD, MPH

⁸ Id. at 11.