

April 8, 2015

Tamara Syrek Jensen, J.D.
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: National Coverage Analysis (NCA) Tracking Sheet for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (CAG-00065R2)

Ms. Jensen,

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), The American College of Nuclear Medicine (ACNM) and the American College of Radiology (ACR) appreciate the opportunity to comment on the request submitted by the National Oncologic PET Registry (NOPR) Working Group to reconsider the national coverage policy for Positron Emission Tomography (^{18}F -NaF PET) to Identify Bone Metastasis of Cancer (CAG-00065R2). We support NOPR's request to end the prospective data collection requirements under CED for use of ^{18}F -NaF PET imaging in intended patient management.

SNMMI is an international scientific and professional organization that promotes the science, technology and practical application of nuclear medicine. SNMMI's more than 18,000 members set the standard for nuclear medicine and molecular imaging by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues.

ACNM is a professional academy composed of physicians and other nuclear medicine professionals dedicated to enhancing the practice of nuclear medicine through the study, education and improvement of clinical practice. The organization is a strong advocate for nuclear medicine professionals and provides access to activities encompassing the business and socioeconomics of nuclear medicine before the legislative and regulatory bodies, other medical organizations, the media and the general public.

ACR is a professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science and professions of radiological care. The ACR represents over 36,000 members, drawn from radiologists, radiation oncologists, medical physicists, interventional radiologists, and nuclear medicine physicians. For over three quarters of a century, the ACR has devoted its resources to making imaging safe, effective and accessible to those who need it.

In February 2010, CMS issued its NaF PET Decision Memorandum, which stated that the existing evidence was not yet sufficient to determine whether the results of NaF PET imaging to identify bone metastases improved health outcomes of beneficiaries. However, over the past three years, the NOPR conducted a large-scale CED study for NaF PET. As a result of that study, the NOPR investigators now believe that they have demonstrated through their published research that NaF PET is both reasonable and a necessary procedure. SNMMI, ACNM strongly agree with NOPR's findings that the purpose for data collection requirements under CED for NaF PET for bone metastasis has been fulfilled and that data collection is no longer necessary.

NOPR studies showed the value of NaF PET regarding the management of patients with osseous metastases, including assessment of systemic therapy. The overall change in management associated with NaF PET in breast and prostate cancer was 40%. These findings on the impact of NaF PET are comparable to those previously reported for ¹⁸F-FDG PET used in treatment monitoring of chemotherapy. For comparison, continuing current therapy was planned in 79% of patients with prior NaF PET scans when scans showed no change or a decrease/absence of osseous metastasis. Treating physicians planned to switch therapy in 59% of patients after scans showed evidence of new or progressive metastases. When estimated prognosis was worse, changing therapy was even more common (76%). Hence, the impact of NaF PET in this setting is greatest in patients who were found to have evidence of progressive disease. Most of these patients had plans of switching to a new active cancer-directed therapy rather than to supportive care¹.

NaF PET/CT is also useful in many benign bone, joint and other conditions such as:

- Detection of bone remodeling in early-stage osteoarthritis of the temporomandibular and hip joints²
- Ankylosing spondylitis^{3 4}
- Patellofemoral compartment pain⁵
- Spontaneous osteonecrosis of the knee⁶
- Characterization of bone mineralization around joint arthroplasties⁷
- Early detection of aseptic loosening of total knee arthroplasty⁸
- Differentiation of septic from aseptic loosening of total hip arthroplasty^{9 10}
- Determination of treatment efficacy of bone active agents in patients with diminished bone mineral density¹¹

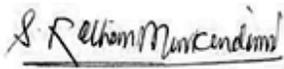
Additionally, NaF PET/CT appears to be the most accurate imaging modality and is advantageous over contrast-enhanced MRI and cone beam CT in the assessment of the bisphosphonate-induced osteonecrosis of the jaw¹².

In conclusion, we ask that CMS finalize the request to end the prospective data collection requirements under CED for use of ¹⁸F-NaF PET PET imaging in intended patient management. We believe that the evidence-based conclusions from NOPR's analysis of their extensive NaF PET data set strongly support this reconsideration request. As always, SNMMI is ready to discuss any of its comments with CMS. In this regard, please contact Susan Bunning, Director, Health Policy and Regulatory Affairs, by email at sbunning@snmmi.org or by phone at 703-326-1182.

Respectfully Submitted,



Virginia Pappas, CAE
CEO, SNMMI



Rathan M. Subramaniam, MD, PhD, MPH, FACNM
President, ACNM



William T. Thorwarth, Jr, MD, FACR
CEO, ACR

¹ Hillner BE, Siegel BA, Hanna L, et al. ¹⁸F-fluoride PET used for treatment monitoring of systemic cancer therapy: results from the National Oncologic PET Registry. J Nucl Med 2015;56:222-228

² Kobayashi N, InabaY, TateishiU, et al: New application of ¹⁸F-fluoride PET for the detection of bone remodeling in early stage osteoarthritis of the hip. Clin Nucl Med 2013; 38: e379-e383

³ StrobelK, FischerDR, TamborriniG, et al: ¹⁸F-fluoride PET/CT for detection of sacroiliitis of ankylosing spondylitis. J Nucl Med Mol Imaging 2010; 37: 1760-1765

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- ⁴ FischerDR, PfirrmannCW, ZublerV, et al: High bone turnover assessed by 18F-fluoride PET/CT in the spine and sacroiliac joints of patients with ankylosing spondylitis: Comparison with inflammatory lesions detected by whole body MRI. *EJ NM MI Res* 2012; 2: 38
- ⁵ DraperCE, QuonA, FredericsonM, et al: Comparison of MRI and 18F-NaF PET/CT inpatients with patellofemoral pain. *J Magn Reson Imaging* 2012; 36: 928-932
- ⁶ AratakeM, YoshifumiT, TakahashiA, et al: Evaluation of lesion in a spontaneous osteonecrosis of the knee using 18F-fluoride positron emission tomography. *Knee Surg Sports Trauma tol Arthrosc* 2009; 17: 53-59
- ⁷ UllmarkG, NilssonO, MaripuuE, et al: Analysis of bone mineralization on uncemented femoral stems by [18F]-fluoride-PET: A randomized clinical study of 16 hips in 8 patients. *Acta Orthop* 2013; 84: 138-144
- ⁸ Sterner T, PinkR, FreudenbergL, et al: The role of [18F] fluoride positron emission tomography in the early detection of aseptic loosening of total knee arthroplasty. *Int J Surg* 2007; 5: 99-104
- ⁹ KobayashiN, InabaY, ChoeH, et al: Use of F-18 fluoride PET to differentiate septic from aseptic loosening in total hip arthroplasty patients. *Clin Nucl Med* 2011; 36: e156-e161
- ¹⁰ ChoeH, InabaY, KobayashiN, et al: Use of 18F-fluoride PET to determine the appropriate tissue sampling region for improved sensitivity of tissue examinations in cases of suspected periprosthetic infection after total hip arthroplasty. *Acta Orthop* 2011; 82: 427-432
- ¹¹ FrostML, MooreAE, SiddiqueM, et al: 18F-fluoride PET as a noninvasive imaging biomarker for determining treatment efficacy of bone active agents at the hip: A prospective, randomized, controlled clinical study. *J Bone Miner Res* 2013; 28:1337-1347
- ¹² GuggenbergerR, FischerDR, MetzlerP, et al: Bisphosphonate-induced osteonecrosis of the jaw: Comparison of disease extent on contrast-enhanced MR imaging, [18F] fluoride PET/CT, and cone beam CT imaging. *Am J Neuroradiol* 2013; 34: 1242-1247