

February 12, 2018

Tamara Syrek Jensen, Esq.
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

RE: Reconsideration of NCD for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer

Dear Director Syrek Jensen:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), the World Molecular Imaging Society (WMIS), and the American College of Radiology (ACR) write in support of the reconsideration of the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) on Positron Emission Tomography ¹⁸F-sodium fluoride (NaF) (CAG00065R2).¹ We believe that the results of the confirmatory analyses performed by the National Oncologic PET Registry (NOPR) fulfill the requirements in the CMS Decision Memorandum of December 15, 2015,² and demonstrate that the use of NaF PET to assess bone metastasis of cancer informs the selection of more appropriate curative or palliative care for patients. These studies were published in the *Journal of Nuclear Medicine* in November and December 2017, and validate that NaF PET is reasonable and necessary for Medicare beneficiaries. We urge CMS to accept the NOPR's reconsideration request to provide Medicare coverage for NaF imaging.

NaF PET Testing Demonstrates Clinical Utility in Changing Cancer Patient Management

As CMS has recognized since 2015, the NOPR's NaF PET registry has produced evidence that NaF PET impacts clinical decision making by physicians when used to identify bone metastasis in oncology. In its December 15, 2015 Decision Memorandum, the agency acknowledged that the data collected by the NOPR from 2011 through 2014 "produced evidence on clinical validity and change in intended patient management." The agency, however, elected to extend Coverage with Evidence Development to "confirm actual changes in patient management" in accordance with physician intentions.

¹ National Coverage Analysis (NCD) for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (CAG-00065R2), available at <https://www.cms.gov/medicare-coverage-database/details/ncadetails.aspx?NCAId=279&NCDId=336&ncdver=1&IsPopup=y&>.

² Decision Memo for Positron Emission Tomography (NaF-18) to Identify Bone Metastasis of Cancer (CAG00065R2), Dec. 15, 2015, available at <https://www.cms.gov/medicare-coverage-database/details/nca-decisionmemo.aspx?NCAId=279&NCDId=336&ncdver=1&IsPopup=y&bc=AAAAAAAAACAQAAA%3d%3d&>.

This extension of CED was specifically to enable the conduct and publication of confirmatory analyses to answer whether the addition of NaF-18 PET imaging leads to:

- A change in patient management to more appropriate palliative care; or
- A change in patient management to more appropriate curative care; or
- Improved quality of life; or
- Improved survival

In 2016 and 2017, the NOPR conducted two confirmatory analyses in accordance with the 2015 NCD. In the first study, the NOPR analyzed the concordance between intended patient management as reported on post-NaF PET treatment plans provided to the NOPR and actual patient management based on Medicare claims data. This study was published online in the *Journal of Nuclear Medicine* on November 30, 2017, and is attached as Appendix A. This study reveals substantial concordance between intended and claims-inferred post-NaF treatment plans. Importantly, these concordance levels are similar to those that CMS found adequate to support coverage for ¹⁸F-fluorodeoxyglucose positron emission tomography (FDG PET).

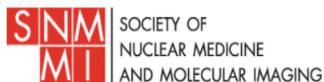
In the second study, the NOPR reviewed the correlation between NaF PET results, hospice admission, and survival. This study's results were published online in the *Journal of Nuclear Medicine* on December 28, 2017, and are attached as Appendix B. The results of this study confirm a high correlation between NaF PET results and both survival and hospice admission, with the effect increasing further along in the disease progression.

Recommend Reconsideration of NaF PET NCD

The data compiled by the NOPR and published in the two recent studies demonstrate a clear link between NaF PET and changes in actual patient management to more appropriate curative or palliative care. SNMMI, WMIS, and ACR believe that these data establish clinical utility for NaF PET for osseous metastasis for all oncologic indications. Moreover, these utility data underscore the importance of NaF PET in day-to-day oncology practice. Since the closure of the NOPR NaF PET registry to patient accrual on December 14, 2017, Medicare beneficiaries no longer have access to this vital service. It is imperative that the agency begin the reconsideration process for NaF PET to restore coverage.

We recommend that CMS initiate the reconsideration process for the NCD on Positron Emission Tomography (NaF-18) with a solicitation for public comment. We strongly support covering NaF-18 PET imaging to identify bone metastases for all oncologic uses when the beneficiary's treating physician determines that the NaF-18 PET study is needed to inform the initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after the completion of initial treatment.

We appreciate your consideration this important issue.



Sincerely,

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