August 16, 2023

VIA ELECTRONIC DELIVERY

David Dolan and Joseph Hutter, M.D.
Center for Clinical Standards and Quality
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CAG-00431R
P.O. Box 8013
Baltimore, MD 21244–1850

Re: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease Proposed Decision Memorandum and National Coverage Analysis [CAG-00431R]

Dear Mr. Dolan and Dr. Hutter:

The Society of Nuclear Medicine & Molecular Imaging (SNMMI) appreciates the opportunity to comment on the Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease Decision Memorandum (CAG-00431R) posted on July 17, 2023. SNMMI and its more than 15,000 members set the standard for the practice of nuclear medicine and molecular imaging by creating guidelines, sharing information through journals and meetings, and advocating on key issues that affect molecular imaging and therapy, research, and practice.

We appreciate the decision by the Centers for Medicare & Medicaid Services (CMS) to open a national coverage analysis (NCA) and reconsider NCD 220.6.20. SNMMI agrees with the agency’s proposal to remove the NCD, ending coverage with evidence development (CED) for PET beta amyloid imaging and permitting Medicare Administrative Contractors to make determinations about coverage under section 1862(a)(1)(A) of the Social Security Act. That is an appropriate action given the importance of Medicare beneficiary access to this minimally invasive, essential procedure and the significance of dementia and neurogenerative disease in the Medicare population.

SNMMI has been concerned about elements of the current NCD. Specifically, we believe that maintaining patients to a single lifetime scan and solely under CED will only serve to hamper access. Indeed, NCD 220.6.20 is longstanding, and the clinical studies approved under the NCD have not expanded since 2016. And yet, as CMS acknowledges, other studies have been conducted outside the NCD, generating additional evidence, and obviating the need to maintain CED.

In addition, a single scan per lifetime is neither reasonable nor supported by evidence. Given that amyloid presence in the brain may change over time and accurate measurements of beta amyloid are important, Medicare should cover more than one amyloid PET scan in a patient’s lifetime. Accordingly, SNMMI agrees with CMS in its proposed assessment that “removal of NCD
220.6.20 will allow appropriate coverage of amyloid PET scans and will greatly reduce provider and patient burden from existing requirements and test limitation.”

SNMMI also shares CMS’ view that more recent and advanced treatments directed against amyloid, which require the confirmation of the presence of amyloid in the brain, make tests like amyloid PET even more critical to medical treatment and further justify the removal of NCD 220.6.20. PET scans provide crucial information that may affect the course of treatment. Anti-amyloid drug treatments for Alzheimer’s Disease are examples of interventions where diagnostic tests such as amyloid PET ensure that such therapies are used with appropriate patients, thereby reducing unnecessary exposure to potential harmful side effects. Removal of NCD 220.6.20 will ensure that such treatments can effectively be used and widen the options for diagnosis and assessment of disease progression.

Finally, we are pleased that CMS proposes in the decision memorandum to remove NCD and we urge the agency to retire or remove the other PET NCDs that inappropriately limit coverage. We believe that such NCDs are outdated and do not reflect current clinical evidence and practice. In particular, we recommend that CMS retire NCD 220.6.19 which essentially non-covers NaF-18 PET nationally. We believe that coverage of such scans should be left to contractor discretion.

Thank you for your consideration of our comments. Please feel free to contact Julia Bellinger, JBellinger@SNMMI.org if the Agency has additional questions about the topics discussed in our comments.

Sincerely,

Helen Nadel, MD FRCPC (Diag Rad) (Nuc Med), ABR (Ped Rad), ABNM, FACNM, FSNMMI
President, SNMMI