



The Council on Radionuclides and Radiopharmaceuticals, Inc.

Michael J. Guastella, MS, MBA
Executive Director

500 North Capitol Street, NW
Suite 210
Washington, DC 20001-7407
(202) 547-6582
Fax: (202) 547-4658
michael.guastella@corar.org

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VIA ELECTRONIC SUBMISSION

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Attention: CAG-00431R
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Beta Amyloid Positron Emission Tomography in Dementia and
Neurodegenerative Disease (CAG-00431R)**

Dear Ms. Chiquita Brooks-LaSure:

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the above referenced proposed decision memorandum to remove the national coverage determination (NCD) at § 220.6.20. CORAR represents the developers and manufacturers of diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine and research, and also includes firms that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in healthcare facilities.

This proposed decision memorandum would end Medicare Coverage with Evidence Development (CED) requirements as well as remove the coverage limitation of one-lifetime limit on positron emission tomography (PET) beta amyloid imaging. Regarding the proposed decision memorandum you previously stated, *“We know there is significant interest in the medical community about new treatments that may be effective in slowing the development of Alzheimer's disease. PET scans are an important part of diagnosis and treatment of Alzheimer's disease, and this decision is an important part of CMS' mission to help improve the lives of Americans we serve.”*

Evidence continues to build over the last few years supporting the clinical utility of PET beta amyloid imaging to aid in diagnosis and treatment of disease and assist in the early identification of patients eligible for newly approved anti-amyloid monoclonal antibody treatment. For example, a recent study demonstrated the clinical value of identifying the amyloid status of patients to better inform clinical decision-making, including patient management, improved diagnostic accuracy, and reduced risk of adverse events¹. CORAR acknowledges the important step that CMS is taking as stated in the proposed decision memorandum, *“We believe removal of NCD 220.6.20 will allow appropriate coverage of amyloid PET scans and will greatly reduce provider and patient burden from the existing requirements and test limitation.”*

¹ E.g., Hattori N, et al. J Alzheimer Dis Rep. 2020. Ceccaldi M, Jonveaux T, Verger A, et al. Alzheimers Dement. 2018;14(3):293-305. doi:10.1016/j.jalz.2017.09.009.

However, this proposed decision memorandum would permit Medicare coverage determinations to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act (the Act). This provides the MACs with a Local Coverage Determination (LCD) for PET beta amyloid imaging. CORAR believes a further step is needed to reduce the risk of delays and avoid the potential for a patchwork of PET beta amyloid imaging coverage policies for Medicare beneficiaries. CORAR strongly recommends that CMS issue a National Coverage Determination (NCD) versus coverage at the discretion of MACs and Medicare Advantage (MA) plans. An NCD would provide clear and consistent national coverage immediately for PET beta amyloid imaging to benefit all eligible Medicare beneficiaries.

However, in the case that CMS finalizes an LCD policy for PET beta amyloid imaging, CORAR urges CMS to quickly coordinate its implementation through all the MACs. This to ensure clear and seamless coverage while also supporting immediate beneficiary access to PET beta amyloid imaging once the current NCD is removed. This is especially important for those beneficiaries under consideration for anti-amyloid therapy.

CORAR appreciates CMS's consideration of our comments. I would be happy to answer any questions you may have and can be reached at (202) 547-6582 or michael.guastella@corar.org.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Guastella".

Michael J. Guastella, MS, MBA
Executive Director