

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group  
Center for Clinical Standards and Quality  
Centers for Medicare & Medicaid Services  
7500 Security Blvd.  
Baltimore, MD 21244-1850

September 11, 2020

Dear Ms. Jensen:

The undersigned applaud the Coverage and Analysis Group (CAG) at the Centers for Medicare & Medicaid Services (CMS) for their important role in ensuring that Medicare beneficiaries have access to innovative medical advancements that are reasonable and necessary. We are grateful for the time and effort you have already dedicated to learning about the clinical care pathway—including the role of beta amyloid (A $\beta$ ) PET scans—for individuals with a potential Alzheimer’s disease diagnosis. It is in this spirit that we share with you our principles for coverage of A $\beta$  PET scans that have been collaboratively developed by the undersigned organizations.

Alzheimer’s disease is a growing public health crisis with a significant societal impact.<sup>1</sup> Approximately 5.8 million Americans are living with Alzheimer’s disease and this number is projected to double in 20 years. Eighty percent of these patients are 75 years old or older.<sup>2</sup> As a result, many organizations are involved today in Alzheimer’s disease advocacy and policy development. We maintain a keen interest in ensuring patient access to safe and effective diagnostic tests and potential future therapies.

A $\beta$  PET scans are approved by the Food and Drug Administration (FDA) to estimate A $\beta$  neuritic plaque density in adults with cognitive impairment who are being evaluated for Alzheimer’s disease and other causes of cognitive decline. Through A $\beta$  PET scans, physicians have access to reliable and accurate diagnostic information to inform care of patients living with Alzheimer’s disease. Furthermore, numerous anti-amyloid targeting Alzheimer’s disease therapies are in development today.<sup>3</sup> If these therapeutics are approved by FDA and become available to patients with Alzheimer’s disease, A $\beta$  PET scans will play an increasingly critical role in identifying patients most likely to benefit from treatment and allow them to better plan for the future. We are concerned that the existing National Coverage Determination (NCD) for A $\beta$  PET scans, which only allows coverage in the context of coverage with evidence development (CED), creates a barrier for Medicare beneficiary access to potential future Alzheimer’s disease therapies.

The undersigned conclude that the following coverage principles for A $\beta$  PET scans can enable appropriate Medicare beneficiary access:

---

<sup>1</sup> Alzheimer’s Association, Centers for Disease and Control Prevention, and Emory Rollins School of Public Health. *A Public Health Approach to Alzheimer’s and Other Dementias*. <https://www.cdc.gov/aging/aginginfo/pdfs/Module1-Alzheimers-Disease-Public-Health-Crisis.pdf>.

<sup>2</sup> Alzheimer’s Association. *2020 Alzheimer’s Disease Facts and Figures*. <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>.

<sup>3</sup> Cummings, et al. Alzheimer’s disease drug development pipeline: 2019. *Alzheimer’s & Dementia: Translational Research & Clinical Interventions*. 2019; 272-293. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6617248/>.

1. Access to A $\beta$  PET scans is supported by evidence and should be covered when the diagnostic will be used to inform patient management or the decision to use an FDA-approved therapeutic. Access may be achieved most expeditiously through a reconsideration of the non-coverage language in the existing amyloid PET NCD.
2. At a minimum, A $\beta$  PET scans meet the “reasonable and necessary” standard for an NCD when A $\beta$  confirmation is included in the labeling of an FDA-approved therapeutic.
3. A CMS A $\beta$  PET scan coverage reconsideration should be informed by available Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Study<sup>4</sup> data and all other published data on the clinical utility of A $\beta$  imaging to broadly support patient management and appropriate care planning decisions for patients with cognitive impairment who are being evaluated for Alzheimer’s disease and other causes of cognitive decline.

New therapies and innovation in Alzheimer’s disease will change care pathways for patients. We know the CAG will play a critical role in evaluating appropriate coverage for new innovations and in establishing access to future treatment for Medicare beneficiaries across the country. We are grateful for your work and we welcome continued discussion on this important issue. Thank you for your consideration on this matter.

Sincerely,

Aging Life Care Association®  
Alliance for Aging Research  
Alzheimer’s Foundation of America  
Alzheimer’s Los Angeles  
American Brain Coalition  
Biogen  
Biotechnology Innovation Organization  
BrightFocus Foundation  
Council on Radionuclides and Radiopharmaceuticals, Inc.  
Dementia Alliance International  
Eisai, Inc.  
Eli Lilly and Company  
GE Healthcare  
Genentech, A Member of the Roche Group  
The Gerontological Society of America  
Global Alzheimer’s Platform Foundation  
LEAD Coalition  
Livpact  
Life Molecular Imaging  
Medical Imaging & Technology Alliance  
National Certification Council for Activity Professionals  
Society of Nuclear Medicine and Molecular Imaging  
UsAgainstAlzheimer’s

---

<sup>4</sup> IDEAS, Imaging Dementia—Evidence for Amyloid Scanning. <https://www.ideas-study.org/>