



July 15, 2022

*Comments submitted electronically via the comment platform on CMS.gov.*

David Dolan  
Lead Analyst  
Centers for Medicare and Medicaid Services

Joseph Hutter, MD  
Lead Medical Officer  
Centers for Medicare and Medicaid Services

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

Dear Dr. Hutter and Mr. Dolan:

The Society for Women's Health Research (SWHR) appreciates the opportunity to provide feedback in response to the Centers for Medicare & Medicaid Services (CMS) call for public comment on the National Coverage Analysis (NCA) for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease.

SWHR is a more than 30-year-old education and advocacy nonprofit organization dedicated to promoting research on biological differences in disease and improving women's health through science, policy, and education. Given Alzheimer's disease's (AD) disproportionate impact on women, SWHR has engaged with its AD Network to raise awareness about biological sex differences in AD and has created recommendations for future research and policies in this field.<sup>1</sup>

SWHR appreciates that CMS has initiated this NCA to determine whether its current policy of one beta-amyloid PET scan per patient per lifetime should be revised and supports the removal of this lifetime limit. Furthermore, given the Coverage with Evidence Determination (CED) requirement that, in order for PET scans of patients seeking to participate in monoclonal antibody trials be covered by Medicare, that they must enroll in the trial could deter the participation of patients, who either may wish to partake in a new CED-sponsored trial in the future or may wish to get another scan independently. Given the rapidly growing AD crisis and its disproportionate impact on women, both as patients and caregivers, improving access to diagnostic tools, and subsequently, to diagnoses that can inform treatment and care management, will be critical.

As the only FDA-approved diagnostic tools that allow health care providers to visualize when a patient experiencing a mild cognitive impairment has beta-amyloid neurotic plaques, a hallmark pathology of AD, PET scans serve an important diagnostic role. SWHR is not aware of any

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<sup>1</sup> Waters, A, Society for Women's Health Research Alzheimer's Disease Network, Laitner, MH. Biological sex differences in Alzheimer's preclinical research: A call to action. *Alzheimer's*

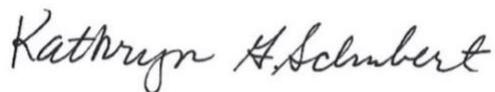
scientific benefit of limiting these scans to one per patient. Enhancing access to these scans could help clinicians have greater assurance of a patient's diagnosis and their treatment recommendations.

Research has already shown that beta-amyloid PET influences clinical decision-making. The Imaging Dementia—Evidence for Amyloid Scanning, or IDEAS, study which included 11,409 participants with progressive, unexplained mild cognitive impairment (MCI) or dementia of uncertain cause, demonstrated that a patient receiving an amyloid PET scan had a change in treatment more than 60% of the time, and a change in diagnosis for 35% of patients based on their individual results.<sup>2</sup>

When it comes to progressive neurological disorders, timely and accurate diagnosis is critical to inform treatment and management and to improve outcomes. While SWHR recognizes that CMS, as part of its policymaking process, must maintain costs, there are long-term cost and health implications associated with AD. Removing the once per lifetime per patient limit on beta-amyloid PET scans for those with cognitive impairments, which can change and develop over time, represents one step that places greater decision-making authority in the hands of clinicians and could yield positive results for patients and their families.

SWHR appreciates the opportunity to comment on the NCD reconsideration for beta-amyloid PET scans and stands ready to assist CMS to establish policies that best support individuals affected by AD. If you have questions about these comments or require additional information, please do not hesitate to contact me at [kathryn@swhr.org](mailto:kathryn@swhr.org) or 202.297.5122.

Sincerely,



Kathryn G. Schubert, MPP  
President and Chief Executive Officer  
Society for Women's Health Research

cc: Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services  
Tamara Syrek Jensen, JD, Director, Coverage and Analysis Group, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services

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<sup>2</sup> Rabinovici GD, Gatsonis C, Apgar C, et al. Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia. JAMA. 2019;321(13):1286-1294. doi:10.1001/jama.2019.2000