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Medicare Coverage of Amyloid PET: Implications for Clinical Practice

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Medicare Coverage of Amyloid PET: Implications for Clinical Practice

On July 17, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a memo proposing to permit Medicare coverage determinations for beta amyloid ($A\beta$)-targeted PET to be made by Medicare Administrative Contractors. As neuroradiologists, neurologists, and nuclear medicine physicians, we highlight the relevance of this decision to our clinical practice.

Alzheimer disease (AD) is the leading cause of dementia, affecting more than 6 million patients in the United States, with health care costs expected to exceed \$1 trillion by 2050.¹ $A\beta$ plaques are a widely accepted AD biomarker, as well as a promising therapeutic target, despite recent studies questioning the pathophysiologic significance of $A\beta$ in AD.²

The Imaging Dementia: Evidence for Amyloid Scanning (IDEAS) study enrolled more than 18,000 Medicare beneficiaries 65 years of age or older, aiming to answer 2 central questions: “Does $A\beta$ -targeted PET change management?” and “Does $A\beta$ -targeted PET improve outcomes?”³ While the first question was answered affirmatively, providing the strongest evidence supporting the clinical utility of $A\beta$ -targeted PET to date,³ and evaluation of the second question is ongoing because the IDEAS study had important limitations. Most notably, Black and Hispanic/Latino patients were markedly underrepresented, despite well-documented racial disparities in AD risk, diagnosis, and outcomes.¹ The ongoing New IDEAS study seeks to address these disparities by emphasizing an accrual of patients from underrepresented groups.

Recently, $A\beta$ -targeted therapies have been approved by the FDA, including aducanumab and lecanemab. While there are important adverse events to consider, including amyloid-related imaging abnormalities,¹ this approval represents the most promising therapeutic option for AD to date, with understandably strong interest from both patients and referring neurologists. Eligibility for $A\beta$ -targeted therapies requires a positive $A\beta$ -targeted PET or CSF analysis. Any emerging and future AD therapies are likely to include $A\beta$ -targeted PET as part of their inclusion criteria. Even as serologic and CSF assays of $A\beta$ show the promise of approximating levels of overall brain $A\beta$, no other technology allows the assessment of its geographic distribution. Furthermore, $A\beta$ -PET is much preferred to CSF testing from the patients’ and caregivers’ perspective, due to its noninvasive nature.

Clinicians and scientists at our major academic urban medical center are collaborating closely in studying $A\beta$ -targeted PET in the clinical and research settings, participating in the IDEAS/New IDEAS studies, developing imaging-centered clinical trials evaluating different aspects of AD pathophysiology, and optimizing quan-

titative analysis methods of $A\beta$ -targeted PET.⁴ Access to $A\beta$ -PET will improve clinical trial accrual and will increase our understanding of the geographic distribution of brain $A\beta$ levels and how they are affected by emerging disease-modifying therapies. We therefore applaud this decision by CMS to commence reimbursement of $A\beta$ -targeted PET studies in the clinical setting. We further encourage increased training opportunities for practicing radiologists and radiology residents and fellows in the interpretation of $A\beta$ -targeted PET, along with educational opportunities for neurologists and other dementia specialists, and the incorporation of $A\beta$ -targeted PET into national clinical guidelines for imaging of patients with cognitive impairment. It is important for our community to ensure the availability of $A\beta$ -targeted PET, particularly in underserved populations.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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