The Centers for Medicare & Medicaid Services and Amyloid-β Positron Emission Tomography for Alzheimer Disease

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Amyloid-β (Aβ) positron emission tomography (PET) has attracted great interest for its potential role as a diagnostic test for Alzheimer disease (AD) and other neurodegenerative diseases. At present, the Centers for Medicare & Medicaid Services (CMS) does not cover Aβ PET imaging.

In July 2013, the CMS issued a draft decision for public comment about the use of Aβ PET, proposing “that the evidence is insufficient to conclude that the use of [Aβ PET] imaging improves health outcomes for Medicare beneficiaries with dementia or neurodegenerative disease.” In this issue of *JAMA Internal Medicine*, Pearson and colleagues at the Institute for Clinical and Economic Review summarize their review of the evidence for the imaging in the diagnostic evaluation of AD. They found that “the medical literature provides extremely limited data with which to evaluate the clinical utility of Aβ PET.” Their review was part of the background material for CMS’s technology assessment of the current status of the scans.

Despite the limited overall evidence about Aβ PET, CMS found “sufficient evidence” that its use “could be promising in 2 scenarios.” The first scenario is excluding AD “in narrowly defined and clinically difficult differential diagnoses, such as AD vs frontotemporal dementia.” The second scenario is in clinical trials seeking better treatment or prevention strategies for AD. Thus, CMS has proposed to cover 1 Aβ PET scan per patient through “coverage with evidence development” in approved clinical studies. Coverage with evidence development is the mechanism through which CMS offers broader coverage of a promising technology despite major gaps in the evidence and requires that the broader coverage facilitate the collection of additional data. As of September 2013, CMS had not issued a final national coverage determination.

Clearly, more data are needed about the role of Aβ PET in the prevention, diagnosis, and treatment of patients with AD. At present, the evidence tells us that the role of the scans is uncertain in many situations. The test could aid diagnosis and management in some circumstances, but it could also be harmful in other circumstances; for example, if a positive scan result leads to labeling a person as having a dread and incurable disease and that potential diagnosis turns out to be wrong.

The CMS has proposed a courageous and innovative approach—to pay for Aβ PET as part of coverage with evidence development. Thus, meaningful data should be gathered that could potentially help to improve the lives of millions of Medicare beneficiaries. This approach serves the public interest. It would be irresponsible for the CMS to cover Aβ PET imaging without adequate evidence about its role in AD or other neurodegenerative diseases.

Conflict of Interest Disclosures: Dr Steinbrook was a member of the Medicare Evidence Development and Coverage Advisory Committee from 2010 to 2012.

Correction: This article was corrected on October 9, 2013, for a typographical error.