

August 16, 2023

Joseph Chin, M.D.
Medical Officer for Coverage and Analysis
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services, mailstop: S3-02-01
7500 Security Blvd.
Baltimore, MD 21244

RE: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (CAG00431R)

Dear Dr. Chin:

The 35 undersigned organizations resolutely support the Centers for Medicare & Medicaid Services (CMS) proposal to end the 10-year coverage with evidence development (CED) requirements for Beta Amyloid (A β) Positron Emission Tomography (PET) imaging in dementia and neurodegenerative disease. We similarly support CMS' proposal to cover more than one scan per patient's lifetime and allow A β PET scan use outside the context of a CED CMS-approved study. Collectively, our organizations represent people living with Alzheimer's disease and related dementias (ADRD); family caregivers; healthcare providers; researchers; coalitions and advocacy organizations focused on chronic disease, aging, and minority and women's health; private-sector leaders; and clinical trial sites. **Together, we strongly urge CMS to maintain and update the existing National Coverage Determination (NCD) to clearly cover A β PET (without CED or other conditions of coverage), rather than providing coverage at the discretion of Medicare Administrative Contractors (MACs) and Medicare Advantage (MA) plans. We are concerned that the transition from national to local coverage discretion would put beneficiaries at risk of coverage gaps.**

Additionally, while we appreciate CMS' proposal to increase timely and equitable Medicare access to A β PET scans, we oppose the agency's simultaneous CED restrictions to beneficiary access for the entire class of FDA-approved monoclonal antibody (mAb) disease-modifying therapies for the treatment of early Alzheimer's (CAG-00460N) and the precedent established by the decision.^[i] In 2013, Medicare decided to limit coverage of A β PET scans under CED, citing insufficient evidence that the imaging findings would make a difference for patients with Alzheimer's disease due to the lack of a disease-modifying therapy and limited symptomatic treatment. ^[ii] Today, there are two FDA-approved Alzheimer's disease-modifying therapies, one on-label symptomatic treatment, and several other treatments in development. The painful irony of this contradictory policymaking will become increasingly apparent as more beneficiaries are accurately diagnosed with early Alzheimer's by A β PET scans but will be unable to realize the benefits of FDA-approved therapies to delay their decline or address neuropsychiatric symptoms that significantly impact their quality of life.

Statement of Interest

Many of the organizations listed here will present their own responses to CMS and will actively advocate for those positions. These comments are not intended to impact adversely the ability of individual organizations, alone or in combination, to pursue separate comments with respect to the proposed NCD for A β PET in dementia and neurodegenerative disease.

We Urge National Coverage Without CED or Other Conditions of Coverage

Under its current 10-year coverage policy, CMS' NCD under CED limits Medicare coverage for A β PET to a single scan per lifetime that occurs within the context of a clinical trial.[iii] Medicare beneficiaries who need a scan today have three flawed options : (1) pay for the scan out-of-pocket, (2) forgo the test, or (3) be forced into limited clinical trials under CED (however, there are currently no active trials). Published appropriate use criteria, which CMS adopted in its two designated CED studies, required that knowledge of A β PET results was expected to change diagnosis and management and whether A β PET is associated with improved clinical outcomes.

Extensive CED data collected on 18,000 Medicare beneficiaries validated the FDA's original assessment of the therapeutic value of A β PET imaging. The CMS-approved CED study, Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) data analysis, published in JAMA in April 2019, found that PET imaging has significantly helped in the diagnosis and monitoring the progression of AD as well as in identifying which patients are likely to benefit from a potential treatment.[iv] Just as importantly, a negative PET result rules the disease out—the study found approximately 36 percent of patients clinically diagnosed with AD were negative for amyloid plaque confirmed by an amyloid PET scan.[v] Overall, the data demonstrate that use of A β PET scan resulted in changes in clinical management for more than 60 percent of patients who participated—most notably in the starting, stopping, or modification of AD drug therapy, but also in the use of other drug therapies and/or counseling about safety and future planning.[vi]

However, due to low participation among Medicare beneficiaries of color in the first CMS-approved CED trial, CMS required a second CED confirmatory study in 2020 to gather additional information. The New IDEAS study[vii] was a limited extension of the original IDEAS study for underserved populations, but CMS' proposed decision memo states that, "One study (New IDEAS) has not been completed due to enrollment issues and is not active." [viii]

National coverage and the removal of CED requirements for A β PET imaging will be particularly significant for underserved communities who were not well-represented in CMS-approved clinical studies. A 2022 secondary cohort analysis of the original IDEAS study found lower odds of amyloid PET positivity in older Asian, Black, and Hispanic adults with MCI and dementia compared with non-Hispanic White individuals.[ix] These results have important implications for the diagnosis, treatment, and prevention of ADRD in groups that are at the highest risk of dementia, which further supports the proposed elimination of the CED restriction and CMS' finding that these tests are reasonable and necessary.

Support for national Medicare coverage of Aβ PET scans was outlined in July 2022, when 20 of our organizations joined together in a comment letter to CMS.[x] In December 2022, 53 organizations shared a letter with President Biden urging him to direct the Secretary of the U.S. Department of Health and Human Services to reopen the Aβ PET NCD for a full reconsideration.[xi]

While we greatly appreciate CMS' proposal to expand coverage of Aβ PET scans and end the one scan per beneficiary lifetime limit, we are concerned that leaving coverage to the discretion of local contractors could result in variability of coverage and beneficiary access delays to early diagnosis and intervention. **An NCD finding the tests reasonable and necessary without CED or other conditions of coverage would provide consistent and clear coverage immediately once such a policy was finalized.**

Our concern with claim-by-claim coverage is that Medicare Advantage (MA) plans frequently assert that, under chapter 4 sections 90.3 and 90.4 of the Medicare Managed Care Manual, they are not required to cover items and services in the absence of an NCD or Local Coverage Decision (LCD).[xii] If MA plans attempt to assert that coverage is not required for Aβ PET scans, there would likely be access issues that would disproportionately impact beneficiaries in lower-income communities who are more likely to have MA. A recent paper by Harvard Medical School and Inovalon found that MA enrollees are 50% more likely than FFS enrollees to be enrolled in a health maintenance organization (HMO). The same study found that MA enrollees have a lower average income are less likely to have attained a higher education degree or own a home or car.[xiii]

Conclusion

To ensure equitable access to Aβ PET scans, we support the CMS proposal to end CED restrictions for Aβ PET scans. We further urge CMS to modify the existing Aβ PET NCD to end the lifetime scan coverage limit and provide national coverage without any other coverage requirements so that all Medicare beneficiaries with ADRD can access the tests they need and deserve.

Thank you for considering our views and for CMS' commitment to improved detection and quality care for people with Alzheimer's disease. If you have questions, please contact Sue Peschin, President and CEO of the Alliance for Aging Research, at speschin@agingresearch.org or the Alliance's Vice President of Public Policy and Government Relations, Michael Ward, at mward@agingresearch.org.

Sincerely,

ADvancing States
Alliance for Aging Research
Alliance for Patient Access
Alzheimer's Drug Discovery Foundation

Alzheimer's Los Angeles
Alzheimer's New Jersey
Alzheimer's Orange County
American Senior Alliance

American Society of Consultant Pharmacists (ASCP)
BrightFocus Foundation
Caregiver Action Network
CaringKind, The Heart of Alzheimer's Caregiving
Chronic Care Policy Alliance
Cleveland Clinic Lou Ruvo Center for Brain Health Nevada
Family Caregiver Alliance
Global Alzheimer's Platform Foundation
Global CEO Initiative on Alzheimer's Disease
Global Coalition on Aging Alliance for Health Innovation
HealthyWomen
Infusion Providers Alliance
Livpact

Lupus and Allied Diseases Association, Inc.
National Alliance for Caregiving
National Brain Health Center for African Americans
National Consumers League
National Minority Quality Forum
National Task Group on Intellectual Disabilities and Dementia Practices
Nevada Chronic Care Collaborative
NTM Info & Research
Partnership to Fight Chronic Disease
Patients Rising
RetireSafe
Society for Women's Health Research
UsAgainstAlzheimer's
Voices of Alzheimer's

[i] Centers for Medicare and Medicaid Services. "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease." 06 Jul 2023. <https://www.cms.gov/medicare/coverage-evidence-development/monoclonal-antibodies-directed-against-amyloid-treatment-alzheimers-disease-ad>.

[ii] Centers for Medicare and Medicaid Services. "Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease." 27 Sep 2013. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=265>.

[iii] Ibid.

[iv] Gil Rabinovici 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):1286-129., <https://jamanetwork.com/journals/jama/fullarticle/2729371>.

[v] Ibid.

[vi] Ibid.

[vii] American College of Radiology Bulletin. "A new trial is recruiting patients for its dementia imaging study focusing on underrepresented populations." <https://www.acr.org/Practice-Management-Quality-Informatics/ACR-Bulletin/Articles/March-2021/New-IDEAS>.

[viii] Centers for Medicare and Medicaid Services. “Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease.” 17 Jul 2023. <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=308>.

[ix] Consuelo H. Wilkins et al. “Racial and Ethnic Differences in Amyloid PET Positivity in Individuals With Mild Cognitive Impairment or Dementia: A Secondary Analysis of the Imaging Dementia—Evidence for Amyloid Scanning (IDEAS) Cohort Study.” JAMA Neurol. 2022;79(11):1139-1147. <https://jamanetwork.com/journals/jamaneurology/fullarticle/2796653#noi220059r63>.

[x] Alliance for Aging Research. “Twenty Organizations Ask Medicare to End Coverage Restrictions for Alzheimer’s Disease Diagnostics.” 15 Jul 2022. <https://www.agingresearch.org/news/twenty-organizations-ask-medicare-to-end-coverage-restrictions-for-alzheimers-disease-diagnostics/>.

[xi] Alliance for Aging Research. “Alliance Leads More Than 50 Organizations Urging President Biden to Reevaluate Decision on Alzheimer’s Diagnostics.” 13 Dec 2022. <https://www.agingresearch.org/news/alliance-leads-more-than-50-organizations-urging-president-biden-to-reevaluate-decision-on-alzheimers-diagnostics/>.

[xii] Centers for Medicare and Medicaid Services. “Medicare Managed Care Manual Chapter 4 Benefits and Beneficiary Protections.” 22 Apr 2016. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>.

[xiii] Scott Builder et al. “Harvard-Inovalon Medicare Study: Who Enrolls in Medicare Advantage vs. Medicare Fee-for-Service.” Inovalon. https://www.inovalon.com/resource/harvard-inovalon-medicare-study-who-enrolls-in-medicare-advantage-vs-medicare-fee-for-service/?utm_medium=email&utm_source=GranID20461-&utm_campaign=RH231334-&utm_content=harvard-inovalon-medicare-study.