United States Senate

WASHINGTON, DC 20510

December 9, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Secretary Becerra and Administrator Brooks-LaSure,

In September 2013, the Center for Medicare and Medicaid Services (CMS) issued a national coverage determination (NCD) that limits Medicare coverage of certain brain imaging in connection with diagnosing Alzheimer's disease. That decision limits the imaging to a single scan during a person's lifetime, under Medicare coverage that requires enrollment in a clinical trial. In light of new research showing the effectiveness of this imaging technology, we support reconsideration of the NCD and urge CMS to update it to improve access to this evidence-based diagnostic tool.

CMS's 2013 NCD limited imaging known as "positron emission tomography beta amyloid" ("amyloid PET" or "PET Aβ") imaging to one lifetime scan, through "coverage with evidence development" in clinical studies that meet CMS criteria.[1] The PET Aβ scan is a "minimally-invasive diagnostic imaging procedure used to distinguish normal from diseased tissue" that can "detect levels of amyloid [a protein associated with Alzheimer's disease][2] in the human brain."[3] When CMS issued the 2013 NCD, it noted that amyloid PET imaging was a promising technology that could "exclude Alzheimer's disease in narrowly defined and clinically difficult differential diagnoses."[4] But due to limited findings regarding the relationship between amyloid disposition and Alzheimer's disease, CMS decided to limit Medicare coverage of amyloid PET imaging to once per lifetime and only while enrolled in a clinical trial.[5]

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[1] *See* Decision Memo: Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease from Louis Jacques et al. to Administrative File CAG-00431N (Sept. 27, 2013), https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=265.
[2] Jorge Sepulcre, *Hallmarks of Alzheimer's Found Well before Diagnosis*, The Harvard Gazette (May 2, 2022), https://news.harvard.edu/gazette/story/2022/05/hallmarks-of-dementia-found-well-before-diagnosis/.
[3] Amyloid PET, Centers for Medicare and Medicaid Services, https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Amyloid-PET.
[4] Decision Memo, *supra* note 1.
[5] *See id*.

Since CMS issued the NCD, there has been significant progress in Alzheimer's and related dementia research. Specifically, studies conducted on the use of amyloid PET scans for patients with dementia have demonstrated the benefits of this diagnostic tool, including improved diagnosis accuracy and better clinical management. Reviews of research on diagnostic management related to PET found consistent "increase[s] in diagnostic confidence or diagnostic certainty after [amyloid PET]."[6] Studies have also found that, although some variation across demographics may exist[7], PET Aβ imaging can exclude Alzheimer's disease, prevent potential misdiagnosis, and monitor the impact of therapeutic interventions for patients presenting with symptoms of dementia.[8] The research has also demonstrated other amyloid PET Aβ benefits, including "changes in clinical management" such as adjusting medication and "counseling about safety and future planning."[9] And the science shows that amyloid PET imaging may provide a needed tool in emerging treatments to combat amyloid plaques.[10]

Despite the new evidence that amyloid PET imaging is effective, current Medicare coverage restrictions create access barriers for patients and providers may be discouraged from including amyloid PET scans "as part of standard clinical practice."[11] Amyloid PET scans cost thousands of dollars out of pocket,[12] so even if a health care provider who specializes in dementia determines that a patient's accurate diagnosis requires a scan, only those who can afford it or can enroll in a clinical trial will get one.

Requiring access to clinical trials also disproportionately and negatively impacts populations that are less likely to enroll in those trials because of barriers including cost, stigma, travel, discrimination, and lack of awareness.[13] Indeed, the clinical-trial requirement runs contrary to

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[6] Yejin Kim et al., *A Review of Diagnostic Impact of Amyloid Positron Emission Tomography Imaging in Clinical Practice*, Dementia Geriatric Cognitive Disorders (Sept. 10, 2018), https://pubmed.ncbi.nlm.nih.gov/30199882/.
[7] Consuelo H. Wilkins et al., *Racial and Ethnic Differences in Amyloid PET Positivity in Individuals with Mild Cognitive Impairment or Dementia*, JAMA Neurology (Oct. 3, 2022), https://jamanetwork.com/journals/jamaneurology/fullarticle/2796653?widget=personalizedcontent&previousarticle=2795399.
[8] *See* Shailendra Mohan Tripathi and Alison D. Murray, *Alzheimer's Dementia: The Emerging Role of Positron Emission Tomography*, Neuroscientist (Mar. 4, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9449436/.
[9] Gil D. Rabinovici et al., *Association of Amyloid Positron Emission Tomography with Subsequent Chance in Clinical Management Among Medicare Beneficiaries with Mild Cognitive Impairment or Dementia*, JAMA (Apr. 2, 2019), https://jamanetwork.com/journals/jama/fullarticle/2729371.
[10] *See* Katherine W. Turk et al., *Amyloid PET Ordering Practices in a Memory Disorders Clinic*, Alzheimer's & Dementia (Aug. 17, 2022), https://alz-journals.onlinelibrary.wiley.com/doi/10.1002/trc2.12333; ; *see also* Alzheimer's Association Statement on Lecanemab Phase 3 Topline Data Release, Alzheimer's Association (Sep. 27, 2022), https://www.alz.org/news/2022/alzheimers-association-statement-on-lecanemab-phas.
[11] *Id*.
[12] For Healthcare Professionals: Frequently Asked Questions about Beta-Amyloid Imaging, Alzheimer's Association, https://www.alz.org/media/Documents/health-care-pros-faqs-beta-amyloid-imaging.pdf.
[13] Ash B. Alpert et al., *Addressing Barriers to Clinical Trial Participation for Transgender People with Cancer to Improve Access and Generate Data*, J. of Clinical Oncology, 1, 2 (Nov. 10, 2022), https://ascopubs.org/doi/pdf/10.1200/JCO.22.01174?role=tab; Adil E. Bharucha et al., *Participation of Rural Patients in Clinical Trials at a Multisite Academic Medical Center*, J. Clinical and Translational Science (July 12, 2021), https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/article/participation-of-rural-patients-in-clinical-trials-at-a-multisite-academic-medical-center/F360013CC25C8406FAADE3A7FE703FA3; Karen M. Winkfield et al., *Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement*, 36 J. Clinical Oncology 3331, 3332 (Nov. 20, 2018),

both the National Institutes of Health and Food and Drug Administration established goals for increasing representative populations in clinical trials.[14] Those who have studied the issue have concluded that, in the context of amyloid PET imaging, lack of diversity in clinical trials "may exacerbate existing racial and ethnic disparities in dementia care," demonstrating ongoing and significant barriers to amyloid PET imaging.[15] While we are grateful for CMS support for the New IDEAS study that aims to further demonstrate the value of amyloid PET scans across race, gender, and age,[16] the out-of-pocket cost for PET Aβ imaging and other barriers to participation in clinical trials under the current NCD unfairly limit patient access to this diagnostic tool. Patients who need it based on their provider's clinical judgment should be able to get it.

Alzheimer's disease and related dementia are difficult to manage without facing financial and clinical trial barriers. As one caregiver described, amyloid PET imaging can be a helpful tool to address the "gnawing uncertainty of not knowing" why people with Alzheimer's and related dementia are experiencing memory loss or what the best medical options might be to treat their disease or "develop[] coping strategies to better manage [the] disease."[17] We must make every effort to grant equitable access to tools that can help individuals and their loved ones treat and manage this disease.

We ask that CMS update its NCD to improve equitable access to amyloid PET imaging for people managing Alzheimer's disease and other dementias.

Sincerely,

Edward J. Markey	Shelley Moore Capito	Martin Heinrich
United States Senator	United States Senator	United States Senator

https://ascopubs.org/doi/pdf/10.1200/JCO.18.01132?role=tab.

[14] FDA News Release: FDA Takes Important Steps to Increase Racial and Ethnic Diversity in Clinical Trials (Apr. 13, 2022), https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-increase-racial-and-ethnic-diversity-clinical-trials; Minority Health and Health Disparities Strategic Plan 2021-2025, National Institutes of Health (Mar. 2021), https://www.nimhd.nih.gov/about/strategic-plan/.

[15] Wilkins, *supra* note 7.

[16] Frequently Asked Questions, The New IDEAS Study, https://www.ideas-study.org/About-Us/FAQ.

[17] Jim Taylor, *Medicare: Cover Amyloid PET Scans and Stop Keeping People with Dementia in the Dark*, STAT (May 25, 2021), https://www.statnews.com/2021/05/25/medicare-cover-pet-scans-dementia/.

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