Congress of the United States
Washington, DC 20515

October 28, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Secretary Becerra and Administrator Brooks-LaSure,

We write to express our strong support of the Center for Medicare and Medicaid Services (CMS)'s reconsideration process for the national coverage determination (NCD) for Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease (hereafter referred to as "PET beta amyloid imaging") issued on June 16, 2022. We urge you to not only swiftly reconsider the one scan per patient per lifetime restriction but to also reconsider the coverage with evidence development (CED) for PET beta amyloid imaging (NCD 220.6.20) all together. Further, we request that when CMS re-proposes or revises the NCD, it does not reinforce current barriers in accessing this critical diagnostic tool.

Currently, the coverage with evidence development (CED) framework for this NCD has significantly limited access to this diagnostic tool for Medicare beneficiaries for nearly a decade. There is robust literature demonstrating the importance of early and accurate diagnosis both to Alzheimer's patients and their caregivers. Consistent and credible evidence accumulated over the past decade demonstrates that PET beta amyloid imaging is a critical step forward in improving the lives of those impacted by this devastating illness.

Since 2013, CMS has worked with a range of stakeholders to generate evidence to demonstrate that these tests should be covered by Medicare. The data generated by the CMS-approved CED trials, as well as outside of those trials, across the Medicare patient population, in clinical settings, and in non-clinical settings is overwhelming. For example, one study involving more than 11,000 patients showed that 90 days after PET beta amyloid imaging, patient care plans changed in 60.2% of patients initially characterized as having mild cognitive impairment and 63.5% of patients initially characterized as having dementia. Hence, imaging was associated with significant alterations in how a patient's disease was managed. That is in addition to the significant comfort to individuals who learn they do not have Alzheimer's as a result of

diagnostic tools. In that same study, the diagnosis changed from Alzheimer disease to non–Alzheimer disease in 25.1% of patients. [1]

By CMS' own definition, the intention of CED is to support evidence development for technologies that are "likely to show benefit for the Medicare population, where the available evidence base does not provide a sufficiently persuasive basis for coverage outside the context of a clinical study."[2] If over the past ten years, CMS has not found a way to generate the evidence necessary to determine that PET beta amyloid imaging should be covered, it calls into question the premise of CED. It also robs individuals with Alzheimer's, and their loved ones, of the hope for timely access to forthcoming disease-modifying treatments.

Requiring patients to enroll in clinical trials to access PET beta amyloid imaging also contradicts CMS' stated goal of improving health equity, particularly for patients in rural and urban underserved areas. For example, as CMS is aware, Latino Americans are 1.5 times as likely and Black Americans are twice as likely to develop Alzheimer's.[3] Despite this, Black participants in Alzheimer's disease research studies were 35% less likely to be diagnosed with Alzheimer's and related dementias than white participants.[4]

Additionally, patients in rural communities are more likely to face access challenges to academic medical centers, and other providers offering clinical trials. Continuing to force disadvantaged, rural, and minority communities to participate in clinical trials to access important diagnostic tools will only compound existing health disparities in Alzheimer's disease, continue to limit access for patients, and raise healthcare costs.

Furthermore, the restriction to one PET scan per patient per lifetime will likely negatively impact participation in trials under CMS' NCD for monoclonal antibodies (mAB) directed against amyloid for the treatment of Alzheimer's disease. Due to this restriction, any additional PET scans during the trials will not be covered and those costs will likely fall on the beneficiaries. This unnecessarily raises barriers for low-income beneficiaries and will limit trial participation. It is critical that beneficiaries have access to PET scans so that shared decisions between physicians, patients, and caregivers about whether to initiate this treatment are fully informed. Beneficiaries should not be denied access to innovative therapies because of outdated restrictions on the number of PET scans covered.

Since CMS' NCD regarding PET beta amyloid imaging was first issued in 2013, evidence demonstrating its clinical utility has grown substantially. Millions of Americans and their families are relying on you to improve the quality of their lives in the face of this devastating

[1] Rabinovici GD, Gatsonis C, Apgar C, et al. JAMA 2019;321:1286-94.
[2] https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27
[3] Aranda, Maria P., Vega, William A., Richardson, Jason R., Resendez, Jason. "Priorities for Optimizing Brain Health Interventions Across the Life Course in Socially Disadvantaged Groups." Florida International University and UsAgainstAlzheimer's. (2019)
[4] National Institute on Aging. https://www.nia.nih.gov/news/data-shows-racial-disparities-alzheimers-disease-diagnosis-between-black-and-white-research#:~:text=Black%20participants%20in%20Alzheimer's%20disease,to%20develop%20dementias%20than%20whites.

illness. With that in mind, and within all relevant rules and regulations, we urge you to swiftly reconsider the NCD for this important diagnostic tool.

Sincerely,

Paul D. Tonko
Member of Congress

Darin LaHood
Member of Congress

Nanette Diaz Barragán
Member of Congress

Fred Upton
Member of Congress