PARTNERSHIP TO FIGHT CHRONIC DISEASE

A VISION FOR A HEALTHIER FUTURE

August 7, 2026

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: *Agency Information Collection Activities: Proposed Collection; Comment Request — Medicare Coverage of Items and Services for Coverage with Evidence Development (CMS-10697; Docket No. CMS-2026-2179)*

To Whom It May Concern:

The Partnership to Fight Chronic Disease (PFCD) submits this comment in response to CMS's proposed reinstatement of its information collection for Coverage with Evidence Development (CED). We write to urge CMS to use this opportunity to critically examine the real-world burden imposed by its CED requirements, particularly as they apply to CED coverage limitations on FDA-approved anti-amyloid monoclonal antibody therapies (ATTs) for early-stage Alzheimer's disease. Multiple clinical trials address the questions CMS raised with respect to ATTs. We urge you to reconsider the CED and facilitate broader Medicare coverage for these therapies.

CED Registry Requirements Create Significant Access Barriers for People Living with Alzheimer's

CMS's CED framework conditions Medicare coverage of ATTs on patient enrollment in a qualifying clinical registry or trial. In practice, these requirements impose onerous administrative complexity on physicians, infusion centers, and patients alike and limit the providers available to treat the growing population living with Alzheimer's disease in America.

A survey of infusion centers found considerable confusion and logistical challenges with CED compliance: scheduling difficulties, high out-of-pocket costs, and unclear guidance that complicates patient management and resource allocation.[1] For a single patient to access treatment, providers must verify eligibility, coordinate across billing, infusion, imaging, and registry systems, conduct multiple specialist visits, and submit patient data to a registry every six months — a cumbersome process that is particularly challenging for small and rural practices to implement.[2] Adding CED registry requirements means less time providers have available to see patients. That burden exacerbates existing dementia provider shortages that delay patient access to care.

[1] Medicare's Patient Registry is Slowing Alzheimer's Treatment Access. *Real Clear Health*. November 22, 2024. https://www.realclearhealth.com/articles/2024/11/22/medicares_patient_registry_is_slowing_alzheimers_treatment_access_1074126.html
[2] The Partnership to Fight Chronic Disease. *A Cumbersome Path to Treatment: Is This the New Norm?* https://9b387f1b-9183-4728-bc19-e2eef317a0ca.filesusr.com/ugd/666885_f09f541f01a24cb6ab10a2ba5b315881.pdf

These are not hypothetical burdens. The administrative weight of CED registry compliance has created a structural access barrier that falls hardest on underserved communities. Registries are concentrated in large urban centers, leaving rural patients — who already face disproportionate Alzheimer's burdens — with fewer qualifying sites and greater logistical obstacles to care. Every day of delay carries irreversible consequences: an estimated 2,000 people a day with Alzheimer's disease progress from the mild stage to moderate disease and beyond the range of FDA-approved, disease-modifying therapies.[3]

The Evidence Is In: CED Questions Answered

Soon, PFCD will publish a white paper making the affirmative case for reconsideration of the NCD for amyloid-targeting therapies. We invite CMS to consider that analysis as a resource in its ongoing work.

The scientific record has materially advanced since CMS issued its 2022 CED determination. In the four years since, the FDA has approved two new ATTs. Nearly a dozen peer-reviewed clinical trial studies involving more than 5,300 participants across three continents have documented the safety and efficacy of these therapies. These trials include a range of community clinical practice settings and extend across multiple years documenting long-term benefits and a manageable risk profile. Clinical experts in Alzheimer's and dementia treatment have published Appropriate Use Recommendations for each medication to aid physicians within community practice settings. The collective body of evidence directly and sufficiently answers the three questions that CMS identified as prerequisites for lifting the CED requirement.

The Paperwork Reduction Act asks agencies to consider the necessity and utility of information collections. PFCD respectfully submits that the CED information collection for ATTs no longer serves a necessary evidentiary function. Continuing to require registry participation imposes an unjustified burden on providers and patients while unduly limiting access to life-changing treatment for a fatal, progressive disease.

CMS should reconsider and remove the CED requirement for all ATTs for early-stage Alzheimer's disease and provide Medicare beneficiaries with coverage to label for disease-modifying therapies.

Respectfully submitted,

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[3] Milliman. *Alzheimer's Disease Severity Progression: Prevalent Population Estimates Over Time*. June 2023. https://edge.sitecorecloud.io/millimaninc5660-milliman6442-prod27d5-0001/media/Milliman/PDFs/2023-Articles/6-5-23_AD-Severity-Progression-Population-Estimates.pdf?la=en&hash=D0C2DC7D20AFE3C8E5DA8678FE0B1A07