United States Senate
WASHINGTON, DC 20510

February 17, 2023

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

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

Dear Secretary Becerra and Administrator Brooks-LaSure:

We write to ask for your assistance with improving access to treatment for the more than six million Americans living with Alzheimer's disease and their families. Given the progressive nature of this terminal disease, we encourage you to take steps now to ensure patients have immediate access to FDA-approved treatments if the patient and clinician decide it is right for the patient. Specifically, we ask, as the Centers for Medicare & Medicaid Services (CMS) examines additional information in light of the recent lecanemab decision and considers reviewing its current coverage policy, that CMS reconsider the requirements for Coverage with Evidence Development (CED) for Food and Drug Administration (FDA)-approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease.

By 2050, nearly 13 million Americans are projected to live with Alzheimer's disease. In 2022 alone, Alzheimer's and other dementia will cost the nation $321 billion. Medicare and Medicaid bear much of this financial weight, as the programs are expected to cover about $239 billion, or 67 percent, of these costs in 2021. Unless a treatment to slow, stop, or prevent the disease is approved and accessible to people, Alzheimer's is projected to reach a total cost of $1 trillion by 2050.

In November 2022, positive results from the Phase 3 trial of lecanemab, a mAb for the treatment of mild cognitive impairment due to early stage Alzheimer's disease, were reported by the trial's sponsors Eisai and Biogen.[1] Fortunately, the data demonstrate that this mAb therapy slows cognitive and functional decline over 18 months and results in positive effects on biological markers of Alzheimer's disease. In a study of 1,800 individuals in the early stages of Alzheimer's, lecanemab reduced the rate of cognitive decline by 27 percent. The peer-reviewed, published results show lecanemab will provide patients with more time to participate in daily life and live independently. It could mean many more months of being able to interact with loved ones. Lecanemab received accelerated approval by the FDA on January 6, 2023, and other mAbs directed against amyloid for the treatment of Alzheimer's disease are currently under FDA review.

Under the current national coverage determination (NCD), CMS will only cover mAbs treating Alzheimer's and other dementia approved through the accelerated approval pathway for individuals enrolled in randomized clinical trials. This decision creates a barrier to care for older Americans, especially individuals living in rural and underserved areas. It is an enormous physical and financial burden for Medicare beneficiaries to spend countless hours traveling to the few research institutions that host the trials. Unless CMS reconsiders the April 2022 NCD, access to disease-modifying therapy for Alzheimer's disease will be extremely limited or nearly nonexistent due to the agency's CED requirements.

Processes that may delay coverage decisions by several months can impose significant access delays, resulting in irreversible disease progression and added burdens for caregivers and loved ones. Based on projections from the Alzheimer's Association, more than 2,000 individuals aged 65 or older transition per day from mild dementia due to Alzheimer's disease to moderate dementia due to Alzheimer's disease, and therefore outside the anticipated indicated population of lecanemab. Given the progressive nature of this terminal disease and absence of treatment alternatives, delays would deny these Medicare beneficiaries the opportunity to benefit from this treatment.[2]

We encourage CMS to reconsider the CED requirements for FDA-approved monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease. Our request reflects that of the patient community and is consistent with a request the Alzheimer's Association submitted to CMS on December 19, 2022. That reconsideration request included a letter signed by more than 200 Alzheimer's disease researchers and experts expressing their confidence in the lecanemab data, saying there should be "no barriers" to accessing the drug if it is approved. This overdue CMS action will ensure Medicare beneficiaries living with mild cognitive impairment due to Alzheimer's disease and early stage Alzheimer's disease have immediate access to FDA-approved treatments if the patient and clinician decide it is right for them.

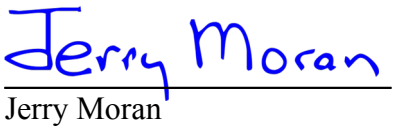
Sincerely,

Susan M. Collins
United States Senator

Shelley Moore Capito
United States Senator

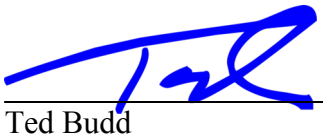
John Barrasso, M.D.
United States Senator

James Lankford
United States Senator



Jerry Moran
United States Senator

Kevin Cramer
United States Senator



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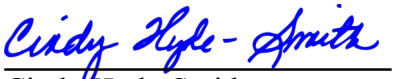
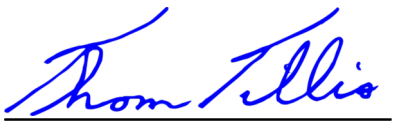


Cindy Hyde-Smith
United States Senator



Thom Tillis
United States Senator

Amy Klobuchar
United States Senator

John Hoeven
United States Senator

M. Michael Rounds
United States Senator

John Boozman
United States Senator

[1] Van Dyck, C. H., Swanson, C. J., Aisen, P., Bateman, R. J., Chen, C., Gee, M., Kanekiyo, M., Li, D., Reyderman, L., Cohen, S., Froelich, L., Katayama, S., Sabbagh, M., Vellas, B., Watson, D., Dhadda, S., Irizarry, M., Kramer, L. D., & Iwatsubo, T. (2023). Lecanemab in Early Alzheimer's Disease. New England Journal of Medicine, 388(1), 9–21. https://doi.org/10.1056/nejmoa2212948

[2] To determine this number, the Alzheimer's Association started with prevalence estimates of individuals age 65 and older with Alzheimer's dementia (Rajan 2021) and mild cognitive impairment (Petersen 2018). They adjusted the Alzheimer's dementia estimate using Graham 1997 to estimate the number of those in the mild stage and used Petersen 2013 to estimate the number of those with MCI who are amyloid positive, resulting in the number of those who would be eligible for an Alzheimer's treatment. They then applied annual transition rates of amyloid positive individuals reported by Potashman 2021 and annual transition rates of people with all-cause MCI from Mitchell 2009 to determine the number of people with mild Alzheimer's dementia and the number of people with MCI due to Alzheimer's disease who progress to the more severe stages of dementia for which the treatments are not indicated.