Congress of the United States

Washington, DC 20515

January 30, 2023

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 thank you for your leadership on issues important to Americans living with Alzheimer's and other dementia, as well as their caregivers. On behalf of the more than 6 million Americans living with Alzheimer's disease and their families, we are encouraged that the Centers for Medicare & Medicaid Services' (CMS) door is open to reconsidering the National Coverage Determination (NCD) of monoclonal antibodies treating Alzheimer's and other dementia. We ask that CMS reconsider the Coverage with Evidence Development (CED) requirements for Food and Drug Administration (FDA)-approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease (AD).

Alzheimer's disease is a progressive brain disorder that damages and eventually destroys brain cells, leading to a loss of memory, thinking, and other brain functions, and, by 2050, nearly 13 million Americans are projected to live with the disease. In addition, in 2022 alone, Alzheimer's and other dementia will cost the nation $321 billion. In fact, the U.S. taxpayer-funded federal health care programs 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, by 2050, Alzheimer's is projected to reach a total cost of $1 trillion (in 2022 dollars).

In November, positive results from the Phase 3 trial of lecanemab were reported, a mAb for the treatment of mild cognitive impairment due to Alzheimer's disease and early-stage Alzheimer's disease. Fortunately, the data demonstrates that this therapy slows cognitive and functional decline over 18 months and results in significant positive effects on biological markers of Alzheimer's disease. Additionally, studies show the new treatment reduced the rate of cognitive decline by 27 percent for patients within the early stages of Alzheimer's, which will allow patients more time to participate in daily life and live independently. It could mean many more months of recognizing their spouse, children, and grandchildren. This is the second treatment to receive accelerated approval by the FDA for this drug class, and we anticipate further decisions by the FDA on additional drugs in the class.

As you know, last year CMS evaluated a different mAb treatment and issued a NCD for not just that product, but all future mAb therapies. Under this NCD CMS would only cover monoclonal antibodies treating Alzheimer's and other dementia approved through the accelerated approval pathway for individuals enrolled in randomized clinical trials and treatments approved through the traditional approval pathway when patients are enrolled in prospective comparative studies. This decision creates a barrier to care for older Americans, especially individuals living in rural and underserved areas. Alzheimer's does not discriminate and patients across the country are losing access to this treatment based on CED requirements. Patients, families, and caregivers living in rural and underserved areas should have the same opportunity for access to treatment. It is an enormous physical and financial burden for Medicare beneficiaries to spend countless hours traveling to limited 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, nearly nonexistent, by the agency's CED requirements.

Processes that may delay coverage decisions by several months can impose significant access delays, resulting in irreversible disease progression for beneficiaries living with Alzheimer's, and added burdens for their caregivers and loved ones. Underscoring this urgency, 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 Leqembi (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.[1]

We ask that CMS reconsider the CED requirements for FDA-approved monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease. This overdue CMS action will ensure Medicare beneficiaries living with MCI 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,

1To 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.

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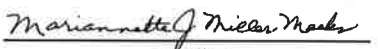

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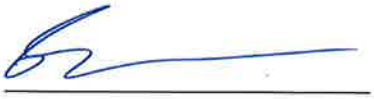

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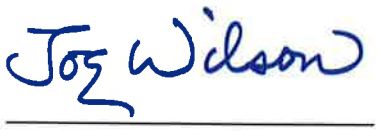

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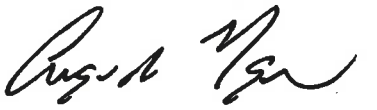

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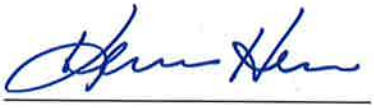

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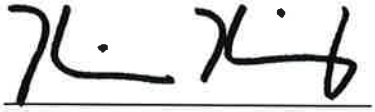

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