



Alzheimer's Association and Alzheimer's Impact Movement Statement for the Record

United States House Committee on Education and Workforce, Full Committee Hearing on "Examining Policies and Priorities of the United States Department of Health & Human Services"

June 13, 2023

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit this statement for the record for the United States House Committee on Education and Workforce hearing on "Examining Policies and Priorities of the United States Department of Health and Human Services." The Association and AIM thank the Committee for its continued leadership on issues important to the millions of people living with Alzheimer's and other dementia and their caregivers.

This statement highlights the urgent need for full Medicare coverage for Food and Drug Administration (FDA)-approved Alzheimer's treatments in light of the Centers for Medicare and Medicaid Services' (CMS) harmful National Coverage Determination (NCD) on "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease" (mAbs). This NCD is imposing severe restrictions on access to the first class of treatments to change the course of Alzheimer's disease. We appreciate the growing bipartisan support in Congress for CMS to immediately open a reconsideration of this unprecedented decision and provide access to these breakthrough treatments if patients with their clinicians decide such treatment is right for them.

Founded in 1980, the Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support, and research. Our mission is to eliminate Alzheimer's and other dementia through the advancement of research; to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. AIM is the Association's advocacy affiliate, working in a strategic partnership to make Alzheimer's a national priority. Together, the Alzheimer's Association and AIM advocate for policies to fight Alzheimer's disease, including increased investment in research, improved care and support, and the development of approaches to reduce the risk of developing dementia.

Innovation and Breakthrough Treatments

Alzheimer's is one of the most significant health issues facing Medicare beneficiaries and their families, and now, for the first time, treatments have been approved by the FDA that change the course of the disease. Aducanumab (marketed as Aduhelm) received FDA accelerated approval on June 7, 2021 and lecanemab (marketed as Leqembi) received FDA accelerated approval on January 6, 2023. As with the first drugs in any class, additional therapies build upon initial breakthroughs to deliver more efficacious treatments. Lecanemab is proven to slow cognitive and functional decline over 18 months and significantly positively affect 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. This will mean patients have more months of recognizing their spouse, children and grandchildren. This will also mean more time for people to drive safely, accurately and promptly take care of family finances, and participate fully in hobbies and interests.

Adding to the strength of evidence around mAbs, on May 3, 2023, positive top-line results of the Phase 3 trial of donanemab were released and marked the strongest such results reported to date. The results showed donanemab met all of its primary and secondary endpoints, and slowed clinical decline by 35 percent compared to placebo on the primary outcome measure. According to the company, we anticipate the FDA issuing a traditional approval decision on donanemab perhaps as soon as the end of the year. Additional clinical trials are underway and offer the hope of additional treatments.

On June 9, 2023, an Advisory Committee to the FDA unanimously endorsed the efficacy and clinical benefit of lecanemab as part of the traditional approval process for this treatment. This committee vote is a vital step in the process to gain traditional FDA approval

This is just the beginning of meaningful treatment advances. History has shown that approvals of the first drugs in a new category invigorates the field, increases investments in new treatments, and encourages greater innovation. The progress we've seen in this class of treatments and in the diversification of treatment types and targets over the past few years provides hope to those impacted by this devastating disease.

CMS Continues to Restrict Patient Access

While these breakthroughs are exciting and offer hope to those with Alzheimer's disease and their families, without Medicare coverage of this class of treatments, access for those who could benefit from these newly-approved treatments will only be available to those who can afford to pay out-of-pocket and find a health system willing to administer such treatments. Without coverage, people simply are not able to access treatments.

Unfortunately, in 2022, CMS implemented an unprecedented and restrictive NCD that not only applies to the two currently approved FDA-approved Alzheimer's therapies but also applies to all future treatments in the same class. Using coverage with evidence development (CED) requirements, CMS will only cover mAbs treating Alzheimer's 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 an immediate barrier to care for older Americans; especially individuals living in rural and underserved areas. Unless CMS immediately reconsiders the NCD, access to these treatments for Alzheimer's will continue to be extremely limited, and for some nonexistent, by the agency's CED requirements even after traditional approval by the FDA.

Americans living with Alzheimer's disease are entitled to FDA-approved therapies, just as are people with conditions like cancer, heart disease and HIV/AIDS. And, they deserve the opportunity to assess if an FDA-approved treatment is right for them.

The Veterans Health Administration (VHA) now offers lecanemab for U.S. veterans. Medicare beneficiaries with early Alzheimer's deserve this same access, not delays. Treatments taken in the early stages of Alzheimer's would allow people more time to participate in daily life, remain independent and make health care decisions for their future.

Despite unequivocal evidence confirmed by the scientific community, CMS continues to state it is not "reasonable and necessary" for people living with Alzheimer's to access FDA-approved treatments without barriers. CMS has stated that it is not covering FDA-approved anti-amyloid treatments for Alzheimer's because it has a different standard than FDA. The CMS standard is defined in statute as "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Using that statutory definition, CMS has decided these treatments are unreasonable and unnecessary for the Medicare population, even though the treatments have been definitively shown to slow the progression of the disease and improve the quality of life for patients and their caregivers. This is unprecedented. CMS has never before determined an FDA-approved therapeutic drug to not be reasonable and necessary.

CMS has said it views therapies approved under FDA's accelerated approval pathway differently than those approved under traditional approval. However, there is no scientific or medical justification for CMS to restrict access to a product that has demonstrated a clinical benefit in peer-reviewed randomized controlled clinical trials solely because it received approval from FDA under a pathway other than traditional approval. The accelerated approval pathway at the FDA is full approval. This fact continues to be reaffirmed by bipartisan members of Congress who established the accelerated approval pathway and by the FDA itself. Prior to these Alzheimer's therapies, CMS has provided Medicare coverage for every FDA-approved drug under the accelerated approval pathway.

This decision sets a dangerous precedent that could stifle innovation for Americans who have no other options. If CMS continues to treat the accelerated approval pathway differently, it won't just be people living with Mild Cognitive Impairment (MCI) and early-stage Alzheimer's who are unable to access treatments that change the course of the disease, it will ripple down to rare diseases, cancer, and others. If Medicare will not cover new treatments under accelerated approval, it discourages the research industry from pursuing crucial treatments for populations with unmet needs. This delay could mean fewer therapies on a slower timeline when days, weeks, and months matter.

On June 1, 2023, CMS stated in a conceptual announcement that it will cover these treatments the day they are approved under traditional approval at FDA. However, patients will be required to be enrolled in a registry as a condition to receive traditionally approved treatments. CMS has confirmed that it has never before used a registry for a drug treatment, further raising concerns about the state of CMS' preparations to date. It is unclear how CMS plans to ensure equitable

access, particularly for those living in rural and underserved communities, to the treatment via the registry. It is also not clear how CMS plans to collect the scientific data the agency states has not already yet been collected, or what that data is. **Even with CMS' unpreparedness, one thing remains evidently clear: registry as a condition of coverage is an unnecessary and potentially harmful barrier to care.**

Alzheimer's Community Losing Meaningful Time

Because of these unprecedented and unnecessary CMS coverage obstacles, people are losing the opportunity to discuss with their health care providers and their families if these treatments are right for them. They are losing days, weeks, months — memories, skills, and independence. They are losing time. And it is unacceptable.

Underscoring this urgency, based on Alzheimer's Association projections, **more than 2,000 individuals aged 65 or older transition per day from mild dementia due to Alzheimer's to moderate dementia due to Alzheimer's, and therefore outside the anticipated indicated population of these treatments.** Given the progressive nature of this terminal disease and the absence of treatment alternatives, delays are denying these Medicare beneficiaries the opportunity to benefit from this treatment. **As of June 12, that number is approximately 316,000 people who have progressed past the point of eligibility for lecanemab since it was first approved on January 6, 2023.**

All individuals, families, and caregivers facing a devastating, fatal disease deserve the opportunity to access FDA-approved treatments. We need to listen to people living with the disease. They deserve the right to access these FDA-approved therapies now, while they still can, if they and their clinician decide it is right for them.

Growing Bipartisan Calls for Access to Treatments

The consequences of CMS' decisions are devastating for those with early Alzheimer's disease — a progressive, terminal disease — who are currently denied access to FDA-approved treatments within their limited window of clinical eligibility. This is causing real harm to Medicare beneficiaries, leading to growing confusion and anger throughout the Alzheimer's and other dementia community.

Because of this impact on constituents across the country, there is growing momentum and political pressure on CMS to change its policy and stop blocking access to FDA-approved Alzheimer's treatments. In February 2023, Representatives Darin LaHood (R-IL) and Paul Tonko (D-NY) led 72 bipartisan members in sending a [letter](#) to HHS and CMS emphasizing the importance of access to FDA-approved Alzheimer's treatments. Senators Susan Collins (R-ME) and Shelley Moore Capito (R-WV) led a similar [letter](#) in the Senate, signed by 20 bipartisan leaders. During the numerous budget and legislative hearings in March and April, over 50 bipartisan members in the House and Senate questioned HHS Secretary Becerra and

Administrator Brooks-LaSure on why CMS continues to hold Alzheimer's treatments to a different standard than other diseases.

Adding to the nationwide support, in April, a [bipartisan group of attorneys general](#) from 26 states and territories sent letters urging HHS and CMS to reverse the unprecedented decision to block access to FDA-approved Alzheimer's therapies.

Despite this growing momentum and the urgency of the issue, CMS rejected the Alzheimer's Association's [request for reconsideration](#) even though it is obligated to do so when provided with, "additional scientific evidence that was not considered during the most recent review along with a sound premise by the requester that new evidence may change the NCD decision." That reconsideration request, submitted to CMS on December 19, 2022, included a [letter signed by more than 200 Alzheimer's researchers and experts](#) expressing their confidence in the lecanemab data, saying there should be "no barriers" to accessing the drug if it is approved.

Conclusion

With the recent endorsement by the FDA Advisory Committee and the likelihood of FDA traditional approval, in addition to the growing bipartisan support in Congress and the new donanemab data, CMS must immediately initiate a reconsideration of the harmful NCD. The initiation of the process itself is crucial. Declining to reopen the NCD upon traditional approval would further escalate the stark and expanding divide between CMS on one hand and the FDA and VHA on the other, as well as between CMS and the Alzheimer's community.

The Alzheimer's Association and AIM appreciate the steadfast support of the Committee and its continued commitment to issues important to the millions of families affected by Alzheimer's and other dementia. We ask that the Committee continue to stress the urgency to HHS and CMS of immediately opening a reconsideration of the NCD to remove the CED requirements for FDA-approved mAbs for the treatment of Alzheimer's, based on substantial new evidence published since the finalization of the NCD. We look forward to working with the Committee and other members of Congress in a bipartisan way to ensure Medicare beneficiaries living with MCI and early Alzheimer's have immediate access to FDA-approved treatments if the patient and clinician decide it is right for them.