



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

United States House Committee on Energy and Commerce, Health Subcommittee Hearing on "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology"

July 18, 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 Energy and Commerce, Health Subcommittee hearing on "Innovation Saves Lives: Evaluating Medicare Coverage Pathways for Innovative Drugs, Medical Devices, and Technology." The Association and AIM thank the Subcommittee 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 continued urgency of addressing the Centers for Medicare & Medicaid Services (CMS) coverage decision that unnecessarily limits access to Food and Drug Administration (FDA)-approved Alzheimer's therapies, especially those living in rural and underserved areas. Specifically, the CMS National Coverage Determination (NCD) on "Monoclonal Antibodies Directed Against Amyloid (mAbs) for the Treatment of Alzheimer's Disease" continues to limit the abilities of people living with mild cognitive impairment (MCI) and early stage Alzheimer's disease to access the first class of treatments to change the course of Alzheimer's disease. We appreciate the strong bipartisan support in Congress for CMS to immediately open a reconsideration of this decision and provide access without barriers to these breakthrough treatments if patients, along with their clinicians, decide such a 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. As with the first drugs in any class, additional therapies build upon initial breakthroughs to deliver more efficacious treatments. Aducanumab (marketed as Aduhelm)

received FDA accelerated approval on June 7, 2021. Lecanemab (marketed as Leqembi) received accelerated approval on January 6, 2023 and traditional approval on July 6, 2023. Lecanemab is the first Alzheimer's treatment to receive traditional FDA-approval that changes the underlying biology of the disease, slowing cognitive and functional decline over 18 months and significantly improving 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. On well-established measures to assess the quality of life for dementia patients and caregivers, it slowed the decline by half. The peer-reviewed, published results show lecanemab will provide individuals with more time to participate in daily life and live independently. This will mean they have more months of recognizing their spouses, children, and grandchildren. This will also mean more time for people to drive safely, take care of family finances, and participate fully in hobbies and interests.

Adding to the strength of evidence around mAbs, on July 17, 2023, full results of the Phase 3 trial of donanemab were released at the Alzheimer's Association International Conference (AAIC) in Amsterdam, Netherlands, and simultaneously published in the *Journal of the American Medical Association*. These results clearly show that donanemab significantly slowed cognitive and functional decline in people with amyloid-positive early symptomatic Alzheimer's disease, confirming the May 2023 topline data release. Study participants at the earliest stage of disease had an even greater benefit, with 60 percent slowing of decline compared to placebo. According to the company, we anticipate the FDA issuing a traditional approval decision on donanemab before the end of the year. Additional clinical trials are underway and offer the hope of additional treatments.

This is just the beginning of meaningful treatment advancements. 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 have 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. While we continue efforts to discover new targets and test new treatments, people living with this fatal disease deserve the opportunity to discuss and make the choice with their doctors if an FDA-approved treatment is right for them.

Continued Barriers to Accessing FDA-Approved Treatments

In 2022, CMS implemented an unprecedented 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 only covers 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 a registry. This decision creates an unnecessary barrier to care for older Americans, especially those living in rural and underserved areas.

Following FDA's traditional approval of Leqembi, CMS announced additional details about its low-touch registry. It is clear that CMS leaders listened to experts, members of Congress, people living with Alzheimer's and their families, and advocates across the country in taking action to reduce physician burden in their registry approach. Registries are an important tool to gather much-needed real-world evidence to transform and improve patient care, but should not be a requirement for coverage of a FDA-approved treatment. The Alzheimer's Association and AIM will support implementation of this coverage plan so that doctors can easily navigate the registry process and provide access to their eligible patients. However, we are disappointed that CMS did not take this opportunity to initiate the formal process to reconsider their NCD in order to eliminate all barriers to access and to treat Medicare coverage of Alzheimer's drugs consistent with drugs for all other diseases. We urge CMS to do so immediately.

There continue to be outstanding questions on the scientific need for and implementation of registries as a condition of coverage. CMS has not effectively explained what size and scope of data is needed to end the CED and how long reconsideration may take. It is also unclear how CMS plans to ensure equitable access, particularly for those living in rural and underserved communities, to the treatment via the registry.

The barriers to accessing these mAb treatments led to thousands of Medicare beneficiaries with a progressive, terminal disease, for the first time in history, losing the opportunity to receive FDA-approved treatments. While we welcome the greater access now available to the first traditionally approved drug in this class, this delayed access implicitly concedes that this treatment should have been made available upon FDA's initial approval. It is increasingly evident that CMS' decision to treat this class of mAb treatments differently from all others is out of step with the scientific evidence and, for many who had counted on Medicare's support, it has been a deeply harmful policy.

All individuals, families, and caregivers facing a devastating, fatal disease deserve the opportunity to access FDA-approved treatments. As Alzheimer's Association advocate Sue Wronsky stated in her testimony to the Subcommittee, the benefits of these treatments will only be realized if patients have access. If there had been an FDA-approved treatment in 1991 when her mother was first diagnosed, she may have been able to spend more time with her family and remain independent. Access to treatment that could have slowed her mother's decline would have helped lessen the burdens of caregiving. When facing the diagnosis of a progressive brain disease, the last thing families affected by Alzheimer's need is more roadblocks: they need full access to these treatments.

Bipartisan Support for Access to Treatments

Given the impact on constituents across the country, particularly for rural and underserved populations, there has been strong and consistent bipartisan Congressional support for CMS to reconsider its CED policy. Representatives LaHood (R-IL) and Tonko (D-NY) led 72 bipartisan members in February in sending a [letter](#) to the US Department of Health and Human Services (HHS) and CMS and led 44 champions in a [follow-up letter](#) in June, emphasizing the urgency

and importance of access to FDA-approved Alzheimer's treatments. Senators Collins (R-ME) and Capito (R-WV) led a similar [letter](#) in the Senate, signed by 20 bipartisan leaders. During the numerous budget and legislative hearings in March, April, and May, over 50 bipartisan members in the House and Senate raised Alzheimer's and [questioned](#) HHS Secretary Becerra and Administrator Brooks-LaSure on why CMS holds 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 NCD.

Despite this growing momentum, CMS denied the Alzheimer's Association's [request for reconsideration](#) submitted in December 2022. That request 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 once approved. We continue to urge CMS to reconsider the NCD, especially as we continue to see strong data from FDA-approved treatments, those pending before the FDA and those in the pipeline.

The Alzheimer's Association and AIM support bipartisan legislation to ensure timely Medicare coverage of FDA-approved therapies. As no two treatments are the same, it is important that CMS evaluate each treatment individually and based on their own scientific evidence, rather than as one broad category. The Mandating Exclusive Review of Individual Treatments (MERIT) Act (H.R. 133) would require CMS to evaluate treatments and cures individually and based on their own merits, rather than as a broad class of drugs. We also support the bipartisan Access to Innovative Treatments Act (H.R. 2408) which would create a transparent process for ensuring that CMS responds and reconsiders drugs for Medicare coverage when sufficient data is collected on the drug's effectiveness.

Conclusion

Given the substantial new clinical evidence published since the NCD was developed and the FDA's confirmation of clinical benefit in granting traditional approval of a treatment in this class, CMS should reconsider the policy to provide full access for Medicare beneficiaries to these FDA-approved Alzheimer's treatments. Any barrier — whether cost, coverage, logistics, or knowledge — to accessing FDA-approved treatments is unacceptable and is not patient-focused.

The Alzheimer's Association and AIM appreciate the steadfast support of the Subcommittee and its continued commitment to issues important to the millions of families affected by Alzheimer's and other dementia. We ask that the Subcommittee 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 targeting amyloid 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 Subcommittee and other members of Congress in a bipartisan way to ensure Medicare beneficiaries living with mild cognitive impairment and early-stage Alzheimer's have access to FDA-approved treatments if the patient and clinician decide it is right for them.