



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

United States House Committee on Energy and Commerce, Health Subcommittee Legislative Hearing on "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices and Technology"

September 19, 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 legislative hearing on "Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices and Technology." The Association and AIM thank the Subcommittee for holding this hearing to consider a number of key pieces of legislation important to the millions of people living with Alzheimer's and other dementia and their caregivers.

As the Subcommittee is well aware, there has been much controversy around the Centers for Medicare & Medicaid Services' (CMS) coverage of new and innovative Alzheimer's treatments. Last year, CMS unnecessarily limited access to FDA-approved Alzheimer's therapies. 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 through the coverage with evidence development registry requirement. We appreciate the strong bipartisan support in Congress and the Subcommittee calling on CMS to open a reconsideration of this decision and provide access without barriers to these breakthrough treatments if patients, along with their clinicians, decide such treatment is right for them.

Many of the Alzheimer's scientific breakthroughs over the last decade can be attributed to the great work of the bipartisan National Alzheimer's Project Act (P.L. 111-375) and the Alzheimer's Accountability Act (P.L. 113-235). There is no doubt that, since the passage of these two laws, history has been made in the Alzheimer's space. Together, these laws ensure Alzheimer's is a national priority and that there are sufficient resources available to continue the strong momentum of innovative research in dementia treatment and care. Both of these laws, which the Subcommittee originally supported, need to be reauthorized so this essential work and progress can continue. As such, we strongly urge the Subcommittee to consider and pass the bipartisan NAPA Reauthorization Act (H.R. 619/S.133) and Alzheimer's Accountability and Investment Act (H.R.620/S.134), which play an essential role in continuing the innovation of Alzheimer's treatments and diagnostic services.

Innovation and Breakthrough: Treatments

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 the disease had an even greater benefit, with a 60 percent slowing of decline compared to placebo. According to the company, the FDA is expected to issue a traditional approval decision on donanemab before the end of 2023. 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 invigorate the field, increase investments in new treatments, and encourage 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 researchers 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.

Innovation and Breakthrough: Diagnostics

Alzheimer's is one of the most significant health issues facing Medicare beneficiaries and their families. As such, an early and accurate diagnosis of the disease is vital, as it has a positive impact on health outcomes, access to treatments, eligibility for clinical trials, and access to much-needed support and services. An essential tool required for the diagnosis of Alzheimer's disease is brain amyloid positron emission tomography (PET) imaging. On July 17, 2023, CMS

announced a draft decision to expand coverage of PET scans for the diagnosis of Alzheimer's beyond clinical trials. The proposed new policy will retire the NCD which includes the CED data collection requirements and lifetime one scan limit, which create unnecessary barriers to this important diagnostic and patient safety tool. Based on the extensive published evidence over the past decade, [we recommended](#) that CMS establish national coverage of beta-amyloid PET through an NCD, so as not to leave the decision up to local contractors, but without the CED requirement of one scan per lifetime.

Increased access to diagnostic PET scans for the treatment of Alzheimer's disease allows patients to receive treatment while they are still in the early stages of the disease and eligible for innovative disease-modifying treatments. In addition to PET scans and cerebral spinal fluid (CSF) tests, in the next few months to years, it is anticipated that there will be blood tests available equivalent to the specificity and sensitivity of CSF tests, which are currently some of the most accurate diagnostics. These blood tests have the ability to transform the detection, diagnosis, and treatment of Alzheimer's disease with access and ease of testing. These diagnostic blood tests must be covered by Medicare and other payers, without delay from the beginning to ensure timely access to new and innovative FDA-approved treatments.

Bipartisan Support for Access to Treatments and Diagnostics

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 mAb and PET NCDs. Representatives LaHood (R-IL) and Tonko (D-NY) led 72 bipartisan members in February in sending a [letter](#) to the 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 mAb NCD.

Despite this growing momentum and ample evidence, CMS did not accept the Alzheimer's Association's [request for mAb NCD 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 strongly support bipartisan legislation considered before the Subcommittee 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 bipartisan 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.

Finally, we support legislation to further improve access to diagnostic imaging tools, through the Facilitating Innovative Nuclear Diagnostics (FIND) Act of 2023. This bipartisan legislation closes a loophole and allows HHS to pay providers separately for all diagnostic radiopharmaceuticals. In the new era of treatment, multiple amyloid PET scans may be needed to test for eligibility, establish a baseline, track changes in a person's amyloid levels over time, and even determine that treatment should be terminated because lower amyloid levels have been achieved. Revising the currently bundled reimbursement policy will further support physicians who provide diagnostic imaging services, such as PET scans, and have the ability to accurately tailor the course of treatment.

Conclusion

Any barrier to accessing FDA-approved treatments and diagnostics — whether cost, coverage, logistics, or knowledge — is unacceptable and is not patient-focused. Restrictions on access can stifle innovation across the scientific spectrum. In the last decade alone and with substantial investment from Congress through appropriations, the scientific community has made great strides to combat Alzheimer's disease. The next few years are likely to be ripe with breakthroughs and innovation so long as there is coverage and access to diagnostics and treatments.

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 disease and other dementia. We look forward to working with you in a bipartisan way to ensure Medicare beneficiaries living with mild cognitive impairment and early-stage Alzheimer's have access to FDA-approved treatments and diagnostics, including PET scans and blood tests.