



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

United States Senate Committee on Finance, Health Subcommittee Hearing on Improving Health Care Access in Rural Communities: Obstacles and Opportunities

May 17, 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 Senate Committee on Finance, Health Subcommittee hearing on "Improving Health Care Access in Rural Communities: Obstacles and Opportunities." 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.

We encourage the Committee to consider the below recommendations to improve care for the growing number of families affected by Alzheimer's, particularly those in rural areas given the unique challenges faced in these communities. This statement highlights the urgency of addressing a harmful decision made by the Centers for Medicare and Medicaid Services (CMS) that continues to block access to Food and Drug Administration (FDA)-approved Alzheimer's therapies, particularly for individuals living in rural areas. Specifically, the CMS National Coverage Determination (NCD) on "Monoclonal Antibodies Directed Against Amyloid (mAbs) for the Treatment of Alzheimer's Disease" is imposing severe restrictions on access to the first class of treatments to change the course of Alzheimer's disease. We also encourage the Subcommittee to expand rural access to a quality trained workforce through the expansion of Project ECHO models.

Alzheimer's Nationwide Impact

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.

An estimated 6.7 million Americans age 65 and older are currently living with Alzheimer's dementia. In 2023, Alzheimer's and other dementia will cost the nation \$345 billion — not including the value of unpaid caregiving. Medicare and Medicaid are expected to cover \$222 billion — or 64 percent — of those costs while out-of-pocket spending is expected to be \$87 billion. Total payments for health care, long-term care, and hospice care for people living with dementia are projected to increase to nearly \$1 trillion in 2050. These mounting costs threaten

to bankrupt families, businesses, and our health care system. Unfortunately, our work is only growing more urgent.

Access to 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 affects 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 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 pharmaceutical company, we anticipate the FDA issuing a traditional approval decision on donanemab as soon as 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 advances. 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 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 them. Without coverage, people, particularly those living in rural areas, 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 those living in rural and underserved areas as these unprecedented required studies will not exist in these areas. Unless CMS immediately reconsiders the NCD, access to these treatments for Alzheimer's will continue to be extremely limited, and for some in rural and underserved areas 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.

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 drug to not be reasonable and necessary.

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 will not just be people living with 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. The dangerous precedent will widen the already existing care gaps in rural and underserved communities across all diseases.

These new FDA-approved treatments taken in the early stages of Alzheimer's could mean a better quality of life. They allow people more time to participate in daily life, remain independent and make future health care decisions. These benefits will only be realized if patients have access to the treatments. Any barrier — whether cost, coverage, logistics, or knowledge — to accessing FDA-approved treatments is unacceptable and is not patient-focused.

Expanding Capacity for Health Outcomes (Project ECHO)

Communities across America are facing severe health care workforce shortages. While the shortage of geriatricians and other specialists extends nationwide, it appears to be most acute in rural settings. It is crucial that legitimate steps are taken to equip providers in these areas with the tools and resources needed to provide quality care to individuals living with Alzheimer's.

We ask that you support an expansion of the use of technology-enabled collaborative learning and capacity-building models, often referred to as Project ECHO. These education models can improve the capacity of providers, especially those in rural and underserved areas, on how to best meet the needs of all patients, including people living with Alzheimer's. In 2018, the Alzheimer's Association launched an Alzheimer's and Dementia Care Project ECHO Network – a highly successful telementoring program that has trained more than 330 health care professionals from 116 primary care practices and more than 250 professional care providers from 91 long-term care communities in a free continuing education series of interactive, case-based video conferencing sessions across the United States.

Project ECHO dementia models are helping primary care physicians in real-time, throughout the country, understand how to use validated assessment tools appropriate for early and accurate diagnoses, educate families about the diagnosis and home management strategies, and help caregivers understand the behavioral changes associated with Alzheimer's. Participants express high levels of satisfaction with the program and the majority (95%) of primary care clinicians who join the Alzheimer's and Dementia Care ECHO program said the quality of care they provide improved as a result of their experience. Long-term and community-based care providers also benefit from Project ECHO dementia programs. Recent evaluations demonstrate statistically meaningful increases in confidence in working with people living with dementia and overall disease knowledge post-ECHO completion and 92 percent of long-term care participants felt that the information gained through participation was valuable in their work.

In 2020, the Alzheimer's Association launched the Alzheimer's and Dementia Care ECHO Global Collaborative. One partner in this collaborative is the Dementia ECHO Indian Country Program, designed to support clinicians at the Indian Health Service and caregivers that provide care to dementia tribal patients. These teleECHO programs are interactive online learning environments where clinicians and staff serving American Indian and Alaska Native patients connect with peers, engage in didactic presentations, collaborate on case consultations, and receive mentorship from clinical experts from across Indian Country. As a result, these ECHO programs enable primary care providers to better understand Alzheimer's and other forms of dementia and emphasize high-quality, person-centered care in community-based settings and aim to improve health outcomes while reducing geographic barriers and the cost of care through a team-based approach.

Conclusion

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. As the Subcommittee looks to remove obstacles for people living in rural areas, we stress the urgency of CMS immediately opening an NCD reconsideration to remove the CED requirements for FDA-approved mAbs. We also look forward to working with the Subcommittee in a bipartisan way on opportunities to expand access to quality care for those living in rural areas through increased use of Project ECHO models.