GENTNER DRUMMOND
ATTORNEY GENERAL

April 26, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 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:

As Democratic and Republican Attorneys General representing nearly half of the states and territories of the United States, we ask the Centers for Medicare & Medicaid Services ("CMS") to reconsider the requirements for Coverage with Evidence Development ("CED") for Food and Drug Administration ("FDA")-approved monoclonal antibodies ("mAbs") directed against amyloid for the treatment of Alzheimer's disease. Specifically, we ask that CMS provide full and unrestricted Medicare coverage for FDA-approved Alzheimer's treatments, consistent with its decades-long practice of covering FDA-approved prescription drugs for Medicare beneficiaries. This coverage will ensure that all Americans benefit from treatments that the FDA has concluded are "important advancement[s] in the ongoing fight to effectively treat Alzheimer's disease."[1]

Today, more than six million Americans are living with Alzheimer's disease, adversely impacting their families, our medical communities, and our economy. Given the progressive nature of this terminal disease, we ask you to ensure all patients have appropriate access to FDA-approved treatments.

As you likely know, 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

[1] Press Release, Federal Drug Administration, *FDA Grants Accelerated Approval for Alzheimer's Disease Treatment* (Jan. 6, 2023), https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-disease-treatment.

313 N.E. 21ST STREET • OKLAHOMA CITY, OK 73105 • (405) 521-3921 • FAX: (405) 521-6246

recycled paper

functions.[2] By 2050, nearly 13 million Americans are projected to live with Alzheimer's disease. In 2022 alone, Alzheimer's and other dementia cost the nation $321 billion; 64 percent, or $206 billion, was covered by the taxpayer-funded Medicare and Medicaid programs.[3] 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).[4]

In November 2022, positive results from the Phase 3 trial of lecanemab, an mAb for the treatment of mild cognitive impairment due to early-stage Alzheimer's disease, were reported by the trial's sponsors Eisai and Biogen.[5] The data demonstrated that this mAb therapy slows cognitive and functional decline over 18 months and reduced amyloid, a biological marker of Alzheimer's disease. In a study of nearly 1,800 individuals in the early stages of Alzheimer's, patients who received lecanemab had a reduced rate of cognitive decline, which suggests that lecanemab will give people with Alzheimer's more time to participate in daily life and live independently. While lecanamab was also associated with certain adverse effects, patients and their providers can assess these risks against the potential benefit of many more months of being able to recognize and interact with loved ones. Lecanemab received accelerated approval by the FDA on January 6, 2023,[6] and other mAbs directed against amyloid for the treatment of Alzheimer's disease are currently under FDA review.

As you know, last year CMS evaluated a different mAb treatment and issued a national coverage determination ("NCD") for not just that product, but all future mAb therapies directed at amyloid for the treatment of Alzheimer's disease.[7] Under the current NCD, CMS will only cover mAbs when they are administered through clinical trials or other studies. This decision creates a barrier to care for older Americans, especially individuals living in rural and underserved areas that are unlikely to be served by institutions administering clinical trials. It is an enormous physical and financial burden for Medicare beneficiaries to travel to the few research institutions that host the trials. Patients, families, and caregivers living in rural and underserved areas should have the same opportunity for access to treatment. Unless CMS reconsiders the April 2022 NCD, access to this important therapy for Alzheimer's disease will be extremely limited or nearly nonexistent. Given how quickly Alzheimer's can progress, ensuring that patients across the United States have fair access to potential life-changing treatment is extremely important. Otherwise, only patients wealthy enough to pay for the treatment entirely out-of-pocket, or those who happen to live someplace with an ongoing clinical trial, will have access to these new therapies.

We encourage CMS to reconsider the CED requirements for FDA-approved monoclonal antibodies targeting amyloid for the treatment of Alzheimer's disease. This would provide

---

[2] *Id.*

[3] ALZHEIMER'S ASSOCIATION FACTS AND FIGURES, https://www.alz.org/alzheimers-dementia/facts-figures (last visited March 3, 2023).

[4] *Id.*

[5] Van Dyck, Christopher H. et al., *Lecanemab in Early Alzheimer's Disease*, NEW ENGLAND J. MED (Jan. 5, 2023), https://www.nejm.org/doi/10.1056/NEJMoa2212948.

[6] *See* Press Release, Federal Drug Administration, *supra* note 1.

[7] Press Release, Centers for Medicare and Medicaid Services, *CMS Proposes Medicare Policy for Monoclonal Antibodies*.... (Jan. 11, 2023), https://www.cms.gov/newsroom/press-releases/cms-proposes-medicare-coverage-policy-monoclonal-antibodies-directed-against-amyloid-treatment.

Medicare beneficiaries living with mild cognitive impairment due to Alzheimer's disease and early-stage Alzheimer's disease with immediate access to an FDA-approved treatment if the patient and clinician weigh the benefits and risks and decide it is the right treatment plan. Our request reflects that of the patient community and is consistent with a request the Alzheimer's Association submitted to CMS on December 19, 2022,[8] and letters submitted by members of Congress on January 30, 2023,[9] and February 17, 2023.[10] The Alzheimer's Association's request included a letter signed by more than 200 Alzheimer's disease researchers and experts expressing their confidence in the lecanemab data, saying there should be "no barriers" to accessing the drug if it is approved.[11] Perhaps even more importantly, CMS's reconsideration would also ensure that the federal government is addressing this important class of drugs in a consistent and fair manner. Unlike CMS, the Veterans Health Administration is covering the cost of lecanemab when patients meet certain criteria.[12]

We thank you for your leadership on issues important to Americans living with Alzheimer's and other dementia, their caregivers and our Nation. Directing CMS to reconsider its requirements for CED for FDA-approved mAbs may be the most impactful decision of your careers—and certainly the lives of millions of Americans.

Sincerely,

Gentner Drummond
Oklahoma Attorney General

Keith Ellison
Minnesota Attorney General

---

[8] Letter from Joanne Pike, President, Alzheimer's Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services (Dec. 19, 2022), https://alz.org/media/Documents/final-NCD-reconsideration-request.pdf.

[9] Letter from Darin LaHood et. al, Members of United States Congress, to Xavier Becerra, Secretary of U.S. Department of Health and Human Services, and Chiquita Brooks-LaSure, Administrator of Centers for Medicare and Medicaid Services (Jan. 30, 2023), https://portal.alzimpact.org/media/serve/id/63f5385de2f42.

[10] Letter from Susan M. Collins et. al., Senators, United States Senate to Xavier Becerra, Secretary of U.S. Department of Health and Human Services, and Chiquita Brooks-LaSure, Administrator of Centers for Medicare and Medicaid Services (Feb.17, 2023), https://portal.alzimpact.org/media/serve/id/63e18cbda47a2.

[11] Letter from Paul Aisen, MD., et al., to Xavier Becerra, Secretary of U.S. Department of Health and Human Services, and Chiquita Brooks-LaSure, Administrator of Centers for Medicare and Medicaid Services (Dec. 20, 2022), https://www.alz.org/media/Documents/joint-letter-alzheimers-scientists-lecanemab.pdf.

[12] Department of Veterans Affairs, Lecanemab-irmb Criteria for Use, Feb. 2023, https://www.va.gov/formularyadvisor/DOC_PDF/CFU_Lecanemab-irmb_LEQEMBI_CFU.pdf & Spencer Kimball, *Veterans Health Administration Will Cover Alzheimer's Treatment Lequembi, Eisai Says,* CNBC, March 13, 2023, https://www.msn.com/en-us/health/medical/veterans-health-will-cover-alzheimers-treatment-leqembi-for-some-patients/ar-AA18A3Bq.

Kris Mayes
Arizona Attorney General

Dave Yost
Ohio Attorney General

Tim Griffin
Arkansas Attorney General

William Tong
Connecticut Attorney General

Brian Schwalb
District of Columbia Attorney General

Ashley Moody
Florida Attorney General

Raúl Labrador
Idaho Attorney General

Todd Rokita
Indiana Attorney General

Aaron M. Frey
Maine Attorney General

Dana Nessel
Michigan Attorney General

John M. Formella
New Hampshire Attorney General

Matthew J. Platkin
New Jersey Attorney General

Raúl Torrez
New Mexico Attorney General

Drew H. Wrigley
North Dakota Attorney General

Edward Manibusan
Northern Mariana Islands Attorney General

Ellen F. Rosenblum
Oregon Attorney General

Michelle Henry
Pennsylvania Attorney General

Domingo Emanuelli-Hernández
Puerto Rico Attorney General

Alan Wilson
South Carolina Attorney General

Ken Paxton
Texas Attorney General

Sean D. Reyes
Utah Attorney General

Charity Clark
Vermont Attorney General

Jason S. Miyares
Virginia Attorney General

Patrick Morrisey
West Virginia Attorney General