

Congress of the United States

Washington, DC 20515

June 16, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 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:

We thank you for your leadership on issues important to Americans living with Alzheimer's and other dementia, as well as their caregivers. On behalf of the more than 6 million Americans living with Alzheimer's disease (AD) and their families, we are concerned about our constituents' continued inability to access Food and Drug Administration (FDA)-approved treatments to slow cognitive decline for those with mild cognitive impairment (MCI) and early AD.

Earlier this year, nearly 100 bipartisan members of Congress sent letters to you raising concerns that the Coverage with Evidence Development (CED) requirements for FDA-approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of AD that have effectively prevented Medicare beneficiaries from getting access to these therapies. While there are currently two FDA-approved anti-amyloid treatments, neither therapy is available to the Medicare population due to the restrictive nature of Medicare's national coverage determination (NCD).

As we noted in our January 2023 letter, positive results from the Phase 3 trial of Leqembi (lecanemab), a mAb for the treatment of mild cognitive impairment due to AD and early-stage AD, were reported in November 2022. The results show that lecanemab will provide patients with more time to participate in daily life, live independently, and have many more months of patients recognizing their spouse, children, and grandchildren.

On June 1, 2023, CMS announced the conceptual approach to a registry for access to mAbs approved by the FDA under the traditional approval pathway. This is the first time CMS is requiring registry participation as a condition of coverage for an FDA-approved therapeutic drug. Registries should not be a requirement for coverage of a FDA-approved treatment as they can create an additional barrier to access. CMS said a nationwide CMS-facilitated portal will be available when FDA grants traditional approval. However, although this very complicated roll

out is only weeks away, CMS has declined to share additional information about the data submission, registry requirements and details about how patients and physicians can enroll.

You've heard from many of our colleagues, from both sides of the aisle, and both the House and Senate over the past few months. We remain deeply concerned about our constituents' lack of access to these FDA-approved therapies. Processes that may delay coverage decisions by months or years can impose significant access delays, resulting in irreversible disease progression for beneficiaries living with Alzheimer's, and added burdens for their caregivers and loved ones. Given the progressive nature of this terminal disease and the absence of treatment alternatives, delays would deny these Medicare beneficiaries the opportunity to benefit from this treatment.¹

Please provide us with timely answers to the below questions.

1. Administrator Brooks-LaSure, you stated in testimony to the House Energy & Commerce Health Subcommittee that CMS plans to cover these treatments once they are approved under traditional approval at FDA. You also stated your intent to continue in CED which requires the traditional approval treatment to have patients enrolled in a prospective comparative study. In recent comments, CMS has confirmed the fact that it has never before used a registry for a drug treatment, further raising concerns about the state of CMS's preparations to date. Can you please explain in detail the steps CMS is taking to:
 - a. Set up a registry that will be operational the day FDA grants traditional approval
 - b. Ensure equitable access, particularly for those living in rural and underserved communities, to the treatment via the registry;
 - c. Collect the scientific data CMS does not believe has yet been collected; and
 - d. Anything else pertinent to access for our constituents?
2. Secretary Becerra and Administrator Brooks-LaSure, you have both stated that CMS is not covering FDA-approved anti-amyloid treatments for AD because CMS has a different standard than FDA. As you have stated, the CMS standard is "reasonable and necessary" which 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." Based on that statutory definition, why has CMS decided these treatments are unreasonable and unnecessary for the Medicare population? Why has CMS held Alzheimer's treatments to a different standard than other diseases?
3. During testimony in both the House and the Senate earlier this year, you both referenced "full approval" when discussing traditional approval. Congress and the FDA have been very clear that accelerated approval and traditional approval are both considered "full approval." Why does CMS not consider accelerated approval as full approval for

¹To determine this number, the Alzheimer's Association started with prevalence estimates of individuals age 65 and older with Alzheimer's dementia (Rajan 2021) and mild cognitive impairment (Petersen 2018). They adjusted the Alzheimer's dementia estimate using Graham 1997 to estimate the number of those in the mild stage and used Petersen 2013 to estimate the number of those with MCI who are amyloid positive, resulting in the number of those who would be eligible for an Alzheimer's treatment. They then applied annual transition rates of amyloid positive individuals reported by Potashman 2021 and annual transition rates of people with all-cause MCI from Mitchell 2009 to determine the number of people with mild Alzheimer's dementia and the number of people with MCI due to Alzheimer's disease who progress to the more severe stages of dementia for which the treatments are not indicated.

Alzheimer's treatments when it does for other diseases?

We still strongly believe CMS should open a reconsideration of the NCD to remove the CED requirements for FDA-approved monoclonal antibodies targeting amyloid for the treatment of AD based on substantial new evidence published since the finalization of the NCD. 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, that was subsequently denied by CMS. This overdue CMS action will ensure Medicare beneficiaries, including many of our constituents, living with MCI due to Alzheimer's disease and early-stage Alzheimer's disease have immediate access to FDA-approved treatments if the patient and clinician decide it is right for them.

Sincerely,



Darin LaHood
Member of Congress



Paul Tonko
Member of Congress



Christopher H. Smith
Member of Congress



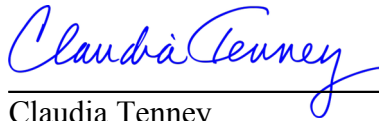
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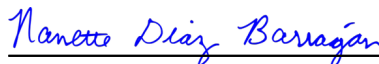
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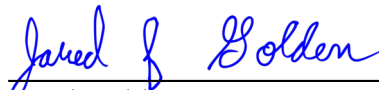
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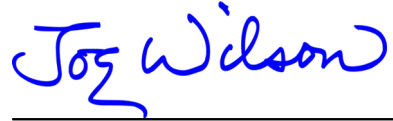
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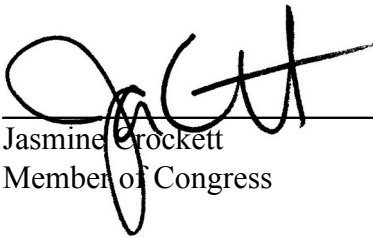
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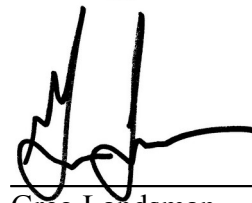
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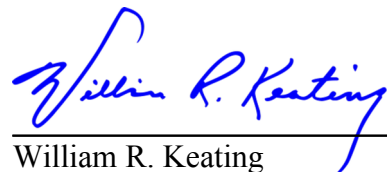
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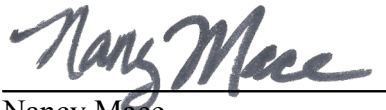
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