May 4, 2023

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Becerra and Administrator Brooks-LaSure,

President Biden recently referred to Medicare as, "the rock-solid guarantee that Americans have counted on to be there for them when they retire."[1] This guarantee is not being honored for Medicare beneficiaries with Alzheimer's disease.

One of the most significant health issues facing Medicare beneficiaries and their families is Alzheimer's disease, and now, for the first time, treatments have been approved by the Food and Drug Administration (FDA) that change the course of the disease.

However, the Centers for Medicare & Medicaid Services (CMS) is denying Medicare beneficiaries access to FDA-approved Alzheimer's treatments. This unprecedented Medicare policy, solely focused on those living with Alzheimer's, interferes with these beneficiaries' fundamental patient right to decide with their families and health care providers the course of care that is most appropriate for them.

We understand the only path to change this policy is through formal reconsideration of the National Coverage Determination (NCD) on "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease" that is imposing these severe restrictions on access to the first and only disease-modifying Alzheimer's drugs.

On February 22, 2023, CMS's Coverage and Analysis Group (CAG) rejected the Alzheimer's Association's request for reconsideration despite its obligation to do so when provided with, "additional scientific evidence that was not considered during the most recent review along with a sound premise by the requester that new evidence may change the NCD decision."[2] We renew our call for CMS to initiate this reconsideration based on the facts below that demonstrate CMS has been inconsistent in its methodology, and is sustaining a policy that cannot be justified on scientific or clinical grounds.

Following are the relevant events:

- In its April 22, 2022, final NCD decision memo, CMS stated its methodology was to evaluate all Phase 3 trials for drugs in this class and, determining that none showed "a

[1] Joseph R. Biden, Jr. "Joe Biden: My Plan to Extend Medicare for Another Generation," *The New York Times*, March 7, 2023. https://www.nytimes.com/2023/03/07/opinion/joe-biden-medicare.html
[2] CMS correspondence. https://www.alz.org/media/Documents/NCD-letter.pdf

clear (non-conflicting) improved health outcome," concluded all current *and future* FDA-approved treatments in the class to not be "reasonable and necessary."[3]

- On November 29, 2022, the *New England Journal of Medicine* published a review of Leqembi's (lecanemab's) Phase 3 Clarity AD trial. This trial fully met CAG's own NCD criteria for inclusion as relevant evidence, and convincingly met all of its prespecified primary and secondary outcome measures.[4]

- On December 19, 2022, the Alzheimer's Association formally requested a reconsideration of the NCD[5] with optimism based on prior CMS comments such as the statement by then-CAG Director, Tamara Syrek Jensen, that, "if there is any new evidence, we can reopen this NCD at any time to reconsider our coverage determination as a class, or on a specific drug."[6]

- On February 22, 2023, CAG rejected the Alzheimer's Association's request stating "there is not yet evidence meeting the criteria for reconsideration" despite the fact that the Clarity AD trial *fully met CMS's own defined criteria in the NCD*. Notably, CAG's rejection letter did not address its inconsistency. CAG was certainly aware that *had this new evidence been considered, it would have undercut the foundational justification of the NCD itself*.

The evidence in favor of Leqembi, approved by the FDA via accelerated approval on January 6, 2023, indisputably exceeds CMS's standards that have led to Medicare coverage of all other FDA-approved drugs (regardless of approval pathway) for all other diseases.

Adding to the strength of evidence running counter to CMS's NCD policy, just this week the topline results of a Phase 3 trial for another drug in this class, donanemab, were released, marking the strongest such results reported to date.[7]

The consequences of CMS's decisions are devastating for those with early symptomatic Alzheimer's disease — a progressive, terminal disease — who are currently denied access to FDA-approved treatments within their limited window of clinical eligibility. This is causing real harm, right now, to Medicare beneficiaries, leading to growing confusion and anger throughout our community.

Fortunately, not all federal agencies have declined to evaluate Leqembi's evidence. We are encouraged that the U.S. Veterans Health Administration reviewed this evidence and determined that coverage of Leqembi is, in fact, appropriate for U.S. veterans.

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[3] CMS Decision Memo - National Coverage Determination on Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (April 22, 2022), page 23, https://alzimpact.org/sites/default/files/2023-05/CAG-00460N_decision_memo_20230502_1.pdf

[4] Christopher H. van Dyck et al., Lecanemab in Early Alzheimer's Disease, NEW ENGLAND J. MED. (Nov. 29, 2022); Lecanemab Confirmatory Phase 3 Clarity AD Study Met Primary Endpoint, Eisai (Sept. 28, 2022), https://www.eisai.com/news/2022/news202271.html

[5] https://www.alz.org/media/Documents/final-NCD-reconsideration-request.pdf

[6] Tamara Syrek Jensen, Stakeholder Call on the Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (May 11, 2022).

[7] Alzheimer's Association Statement on Donanemab Phase 3 Topline Data Release. https://www.alz.org/news/2023/association-statement-donanemab

On or before July 6, 2023, it is widely anticipated that the FDA will again approve Leqembi; this time through the traditional approval pathway based on a confirmation of clinical benefit.

This moment, in addition to the new data announced this week regarding donanemab, will provide CMS with a new opportunity to initiate a reconsideration. We are not asking for any commitments to the outcome of such a reconsideration process. It is the initiation of the process itself that is crucial. Declining to reopen the NCD upon traditional approval would further escalate the stark and expanding divide between CMS on one hand and the FDA and VA on the other, as well as between CMS and the Alzheimer's community.

As we, at long last, enter an exciting era of treatments for those with Alzheimer's, decisions must be science- and patient-driven. CMS's current policy is neither. Regardless of any steps CMS may take to expand Medicare coverage in the coming months, we will continue to make the initiation of an NCD reconsideration the Alzheimer's Association's top organizational priority. Please do not hesitate to contact Robert Egge (regge@alz.org), Chief Public Policy Officer, if you have any questions.

Sincerely,

Joanne Pike, DrPH
President and Chief Executive Officer
Alzheimer's Association
Alzheimer's Impact Movement

CC: Susan Rice, Director, Domestic Policy Council
Christen Linke Young, Deputy Director, Domestic Policy Council for Health and Veterans
Senate Finance Committee Chair Ron Wyden
Senate Finance Committee Ranking Member Mike Crapo
Senate HELP Committee Chair Bernie Sanders
Senate HELP Committee Ranking Member Bill Cassidy, MD
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