Congress of the United States
House of Representatives
Washington, DC 20515

February 4, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, D.C. 20201

Dear Secretary Becerra:

We write today regarding your recent *Proposed National Coverage Determination (NCD) for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease*. This proposed decision most immediately affects five anti-amyloid treatments, one that is currently approved by the Food and Drug Administration (FDA) and four that are in late-stage trials. On behalf of our constituents living with Alzheimer's disease, their caregivers, and their families, we urge you to fully consider the limitations with the proposed NCD and to evaluate if there are ways to provide better access for all who could benefit from FDA-approved treatments.

Alzheimer's is a progressive brain disorder that damages and eventually destroys brain cells, leading to a loss of memory, thinking, and other brain functions. Ultimately, Alzheimer's is fatal. While an estimated 6.2 million Americans age 65 and older are currently living with Alzheimer's, nearly 13 million Americans will have Alzheimer's by 2050 and costs will exceed $1.1 trillion (in 2021 dollars). Alzheimer's is also creating an enormous strain on the health care system, families, and federal and state budgets. The annual cost for all individuals living with Alzheimer's and other dementia totaled $355 billion for health care, long-term care, and hospice care in 2021. This does not include the over $250 billion in unpaid caregiver costs. The U.S. taxpayer-funded federal health care programs Medicare and Medicaid are expected to cover about $239 billion, or 67 percent, of these costs.

Under the proposed NCD, the Centers for Medicare & Medicaid Services (CMS) would only cover this class of treatments for people enrolled in randomized controlled clinical trials. We are hearing many concerns voiced that this approach will severely limit access due to the scarcity of the settings in which these trials must occur, the delay that will occur as trials are designed and approved, and the fact that many trial participants may not receive the treatment at all. We are concerned that this will effectively restrict access to a privileged few — those who live near research institutions, or can afford to pay out-of-pocket and skip the steps imposed by this decision. This will have a particularly negative impact on those living in rural and underserved

communities. Furthermore, a delay in access could mean a person living with the disease progresses into the later stages and therefore would no longer be eligible to receive the treatment.

With these concerns in mind, we ask that you respond to the following:

1. What is the justification for preemptively assigning future Alzheimer's treatments in this class to a CED with this extraordinary clinical trial requirement, even before FDA has completed its evaluation and findings of those treatments?

2. Can you address the almost certain and lengthy delay that people living with Alzheimer's disease — which is degenerative and always fatal — are going to face in accessing treatment while these clinical trials are designed, approved, and established? What do you estimate to be the elapsed time before the first of these trials will present completed results for your evaluation?

3. Did CMS consider the role of a registry in its CED? If so, why did it not include this option in the proposed decision as it did in its NCD draft decision for CAR-T therapies?

4. While a stated objective of the NCD is to ensure appropriate representation of those communities affected by the disease, including Blacks, Hispanics, and Latinos, it seems that the proposal puts the onus of ensuring their participation on the investigators designing these trials. As participation of these communities has historically been a challenge for trials across all diseases, how do you intend to support investigators and trial sites in this pursuit?

Thank you for your consideration. This coverage decision will impact access for future therapies and is an historic opportunity to give individuals, families, and caregivers facing a devastating, fatal disease more life. We urge you to fully consider the concerns raised above regarding the proposed NCD in order to ensure full access for all who could benefit from FDA-approved treatments.

Sincerely,

Paul D. Tonko
Member of Congress

Darin LaHood
Member of Congress

Cc: The Honorable Chiquita Brooks-LaSure, CMS Administrator