



February 10, 2022

Tamara Syrek Jensen, JD  
Director, Coverage and Analysis Group  
Center for Clinical Standards and Quality  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Ms. Syrek Jensen,

The Lewy Body Dementia Association (LBDA) is writing to submit public comment in response to the Centers for Medicare and Medicaid Services (CMS) proposed National Coverage Determination (NCD) for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

Lewy body dementia (LBD) is the second-most common progressive dementia after Alzheimer's disease, affecting approximately 1.4 million Americans and their families. Approximately one-third of those with dementia with Lewy bodies, one form of LBD, have sufficient co-existing pathology for an Alzheimer's disease diagnosis. There are no disease-modifying therapies for Lewy body diseases currently available. As such, regulatory decisions in Alzheimer's disease are highly relevant for LBD; the decisions may even be precedent-setting for future regulatory decisions that will impact people with Lewy body dementias. As such it is imperative for LBDA to comment on behalf of those we serve.

We appreciate the complexity of considerations CMS must balance on behalf of society, regarding the potential clinical benefit versus potential harms of any new treatment and thank CMS for the efforts required to make the proposed NCD. The access CMS has made to their personnel through various events, for the purpose of learning more about the NCD and how it could be modified when more compelling evidence emerges has been very helpful to informing our public comment.

Alzheimer's disease (AD) is a fatal disease with an average duration of 8 years, which unlike most other fatal conditions, robs individuals of their ability to think and reason, and steals from entire families the persona and presence of the person diagnosed. This loss of self, intensely and indescribably painful to entire families, not just the person diagnosed, ruins many families financially due to the cost of care in late-stage disease, and places undue burden and poor health outcomes on family caregivers without the resources to supplement the care they provide. For communities already affected by health disparities, a diagnosis of Alzheimer's may make the burden truly immeasurable.

We would like to highlight several points we feel warrant reconsideration of the recently proposed CMS NCD.

- A public comment opportunity truly does not reach the public. It largely only reaches the professional stakeholders for any disease and tiny proportion of people directly affected. Decisions on a new class of drugs for Alzheimer's disease, the first that may halt progression, should be done in greater consultation with the patient community, not just the scientific, clinical care and advocacy community, which is not representative of the diversity of the

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Alzheimer's community. Focus groups with members of the public who are diagnosed with, or caring for a person diagnosed with, Alzheimer's disease and that are representative of the diversity of the Alzheimer's community, should be immediately convened to gain real world insights on perspectives on the potential risk/benefit ratio of anti-amyloid interventions, and delve further into what the Alzheimer's community considers to be clinically meaningful benefit. The insights gleaned from the focus groups should be made publicly available as part of any final NCD.

- The draft NCD establishes two distinctly separate tiers of access. Wealthy individuals who qualify for the drug can pay out of pocket. The rest of those who may benefit from such a treatment can only access the drug through clinical trial participation. This widens the considerable economic disadvantages born by people living with Alzheimer's disease who do not have the logistical and financial resources required to participate in a clinical trial. Further, communities disproportionately affected by AD, such as African Americans and Hispanic/Latino communities, are underrepresented in clinical trials. Limiting coverage to clinical trial participants may worsen health disparities.
- In the case of fatal diseases lacking disease-modifying treatments, an NCD that impacts coverage for an entire class of drugs is overly restrictive and counter to the purpose of the FDA's accelerated approval of aducanumab. We strongly recommend amending the NCD to be limited only to aducanumab.
- The concept of CMS analyzing published data of failed trials of anti-amyloid interventions as a means to determine cumulative evidence of clinical benefit from the only FDA-approved treatment in that class is concerning. Through its memorandum of understanding with the FDA or under confidentiality agreement with the sponsor, CMS should evaluate the same data on aducanumab evaluated by the FDA, before finalizing the NCD.

#### Clinical Trial Requirements

- The proposed NCD includes a requirement that delivery of these therapies be restricted to "hospital-based outpatient settings." LBDA urges CMS to reconsider this limitation, as this was not a requirement for the clinical trials of aducanumab. Other appropriate settings should be considered, such as infusion centers and clinical research centers that are not designated as "hospital-based outpatient settings."
- The concept that "the diversity of patients included in each trial must be representative of the national population" is a critical step towards equity and inclusion. However, if clinical trials are the only pathway to obtaining treatment with anti-amyloid interventions, CMS should be more specific on its expectations. The final version of the NCD should be either a) be more explicit about the required diversity of the cohort or b) require the trial protocol provide details on how it will achieve its diversity goals.

Lastly, the United States has a national strategy to address Alzheimer's disease and related dementias. The first goal of the plan is to prevent and effectively treat Alzheimer's disease and related dementias by 2025, such as by slowing down progression or delaying the onset of dementia. The CMS NCD as it is currently written is at odds of achieving this national goal.

In closing, because anti-amyloid therapies are directly relevant in LBD which commonly co-occurs with Alzheimer's disease, the Lewy Body Dementia Association recommends further revisions to the NCD.

We thank CMS for its diligence and hope these public comments will be given serious consideration as part of finalizing the NCD.

Sincerely,

A handwritten signature in cursive script that reads "Angela Taylor". The signature is written in black ink on a white background.

Angela Taylor  
Senior Director, Research and Advocacy