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Eisai Co., Ltd.

# Eisai's Statement on the Draft National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

As always, our thoughts are with the people living with Alzheimer's disease and their families, and we understand how devastating the proposed National Coverage Determination (NCD) from the Centers for Medicare and Medicaid Services (CMS) is to our Alzheimer's community.

Eisai strongly opposes CMS' proposal to apply Coverage with Evidence Development (CED) to monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD).
Eisai cannot support a proposal that would severely restrict Medicare beneficiary access for the foreseeable future to all drugs in this class, exacerbate health inequities, and not account for important ongoing research. We are further concerned that this action directly calls into question the U.S. Food and Drug Administration's (FDA) role in determining safety and efficacy, as well as the agency's regulatory autonomy and scientific independence.

**CED Will Limit and Delay Patient Access**
Institution of CED requirements for anti-amyloid Monoclonal Antibodies (mAbs) would pose a high burden for investigators and severely restrict access for Medicare beneficiaries for whom treatment is appropriate, only a small proportion of whom will be able to receive treatment. We are troubled that this CED will drive significant inequalities in drug access to FDA approved therapies. Restricting coverage to a CED construct and limiting treatment to hospital-based outpatient settings will result in concentration of available treatment centers in limited geographic areas and compound inequities for patients lacking resources or support to travel for treatment.

**Use of CED Duplicates FDA Processes**
We separately have grave concerns about the potential use of CED in a way that undermines the Accelerated Approval pathway or duplicates the role of the FDA in assessing innovation. We encourage consideration of risks that CMS' action here could be precedent-setting in other disease states. It is unclear to stakeholders in the AD community why AD treatments are the only accelerated drug treatments that are receiving such potentially restrictive coverage that undermines this devastating disease and its impact on people with AD, their caregivers, and the broader healthcare system.

**CED Should Not Apply to Investigational Therapies**
Application of CED through a NCD for investigational therapies that are not approved by the FDA is both arbitrary and without precedent, as it prejudges clinical trial data and labeling. Eisai believes this proposal to apply CED to these therapies, based on the assumption that drugs in the class are identical, is wrong; it is also unscientific to apply findings from failed clinical trials for the first generation of anti-amyloid mAbs. Eisai does not believe that it is appropriate to institute a CED requirement now that will apply for the foreseeable future to therapies in development.

We strongly encourage CMS to reconsider its proposed decision on the national coverage for Monoclonal Antibodies for the Treatment of AD.

Eisai's investigational agent lecanemab demonstrated consistent reduction of clinical decline across several clinical endpoints and showed well tolerated safety profile in both our phase 2b randomized, controlled clinical trial and the open-label extension study. In September 2021, Eisai initiated a rolling submission to the FDA of a Biologics License Application (BLA) for lecanemab under the Accelerated Approval pathway for the treatment of early AD with confirmed amyloid pathology. We expect to complete this rolling submission in the 1st half of calendar year 2022. Additionally, Eisai completed enrollment of 1,795 patients in the lecanemab confirmatory Phase 3 CLARITY AD clinical trial, which is expected to report out in the Fall of 2022.

During the 30-day open comment period, Eisai will make a formal response. CMS' final decision is expected to be issued in April 2022. A link to the proposed decision memo is here

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