DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality
Coverage and Analysis Group

July 28, 2023

Dr. Carlayne Jackson
201 Chicago Avenue
Minneapolis, MN, 55415

Dear Dr. Jackson:

I am writing to respond to your June 12, 2023, request on behalf of the American Academy of Neurology for reconsideration of the National Coverage Determination (NCD) for Monoclonal Antibodies (mAbs) Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (see https://www.cms.gov/medicare-coverage-database/view/nca.aspx?ncaid=305). Alzheimer's disease is a devastating illness that affects millions of Americans and their families. The Centers for Medicare & Medicaid Services (CMS) is committed to timely access to treatments, including drugs, that demonstrate clinically meaningful improvement in health outcomes.

At this time, CMS is not granting the request for reconsideration. We recognize that these medications are a unique, new class of drugs, and we are optimistic that patients can access these drugs now under the current coverage framework while we continue to gather evidence on how the treatments work in the Medicare population. Under the current NCD, when the Food and Drug Administration (FDA) approves a drug in this class based on a direct measure of clinical benefit, CMS provides broader coverage for people with Medicare in CMS-approved studies.

On July 6, 2023, with traditional approval from the FDA for lecanemab, CMS announced the opening of a CMS-facilitated registry that is available nationwide for clinicians to use. With respect to the CMS-facilitated registry, clinicians across the country may submit information through a free, online portal that is available for any drug in this class that gains FDA traditional approval. Clinicians participating in the registry will only need to complete a short, easy-to-use data submission that should be easily available from the patient's medical record, such as a clinical diagnosis or adverse event.

We appreciate your recognition of evidence gaps in the available body of literature and your input on CMS's CED questions that are designed to help CMS assess the drug's longer-term harm/benefit profile and the generalizability of use in the Medicare population outside of clinical trials. As you know, the CED questions are:

a. Does the antiamyloid mAb meaningfully improve health outcomes (i.e., slow the decline of cognition and function) for patients in broad community practice?
b. Do benefits, and harms such as brain hemorrhage and edema, associated with use of the antiamyloid mAb, depend on characteristics of patients, treating clinicians, and settings?
c. How do the benefits and harms change over time?

These are important questions that still need to be answered to support people with Medicare, caregivers, and their referring and treating physicians to make informed, appropriate decisions about use of any drug in this particular class. The NCD was structured to provide flexibility and assurance that CMS can respond quickly to providing coverage for any new drugs in this class when approved based on a direct measure of clinical benefit. CMS appreciates your concern regarding CED and we are committed to reviewing additional data when it is available in order to timely reconsider the NCD if appropriate.

Thank you for your detailed feedback on this NCD and for your concern for people with Alzheimer's disease. CMS looks forward to continuing a dialogue as your members prescribe this drug and more information becomes available. Please feel free to contact David Dolan at david.dolan@cms.hhs.gov or 410-786-3365 for further discussion.

Sincerely,

Lee A. Fleisher, MD
Chief Medical Officer & Director
Center for Clinical Standards & Quality