MVP Health Care Medical Policy

Medicare Part B: Monoclonal Antibodies for Alzheimer's Disease

Type of Policy: **Drug Therapy**

Prior Approval Date: **11/01/2023**

Approval Date: **11/01/2024**

Effective Date: **01/01/2025**

Related Policies: **N/A**

Drugs Requiring Prior Authorization (covered under the medical benefit)

J0172 Aduhelm (aducanumab-avwa)

J0174 Leqembi (lecanemab-irmb)

J0175 Kisunla (donanemab-azbt)

Overview

Aduhelm, Kisunla and Leqembi are amyloid beta-directed antibody therapies indicated for the treatment of Alzheimer's disease. This indication is approved under Accelerated Approval based on reduction in amyloid beta plaques observed in members. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trials.

Aduhelm, Kisunlaand Leqembi can cause amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema or sulcal effusions, and amyloid related imaging abnormalities hemosiderin deposition (ARIA-H), which includes microhemorrhage and superficial siderosis.

This policy may not list all available therapies for the treatment of Alzheimer's Disease (AD). If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in accordance with the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3).

Clinical Criteria

Effective April 7, 2022, CMS covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD) under coverage with evidence development (CED) for members with a clinical diagnosis of mild cognitive impairment due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD, according to the coverage criteria outlined in the National Coverage Determination (NCD) for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (NCD 200.3). Please refer to this NCD for coverage guidance.

Before initiating treatment for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease (AD), the following criteria must be met (consistent with NCD 200.3):

- Clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with confirmed presence of amyloid beta pathology consistent with AD
- The member must have a physician participating in a registry with an appropriate clinical team and follow-up care. Registries are listed at www.cms.gov. If the Food and Drug Administration (FDA) grants traditional approval for a drug used to slow the progression of Alzheimer's disease, Medicare will cover the drug in appropriate settings that also support the collection of real-world information to study the usefulness of these drugs for people with Medicare. Clinicians must participate in the Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease Registry available nationwide at www.cms.gov.

Approval Duration: (unless otherwise indicated in applicable NCD/LCD or CMS guidance if available)*

Initial authorization for 6 months

For continuation of therapy, providers must provide documentation necessary for approval based on current NCD/CMS guidance and will be for up to 6 months

Exclusions

- Indication, diagnosis, dosing, age, and/or frequency outside of the FDA approved package labeling
- Monoclonal antibodies directed against amyloid for the treatment of AD provided outside of an FDA-approved randomized controlled trial, CMS-approved studies, or studies supported by the NIH are nationally non-covered.

References

1. FDA News Release: https://www.fda.gov/news-events/press-announcements/fda-grantsaccelerated-approval-alzheimers-drug.
2. Biogen Press Release (FDA Approval): https://investors.biogen.com/news-releases/news-releasedetails/fda-grants-accelerated-approval-aduhelmtm-first-and-only.
3. ICER Press Release: https://icer.org/news-insights/press-releases/icer-issues-statement-on-thefdas-approval-of-aducanumab-for-alzheimers-disease/.
4. Aduhelm Label: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761178s000lbl.pdf.
5. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. April 7, 2022. Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease | CMS. Accessed April 21, 2022.
6. Medicare National Coverage Analysis Decision Memo for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N). Effective Date: 04/07/2022.
7. Updates to Medicaid Fee-For-Service Practitioner Administered Drug Policies and Billing Guidance: Aducanumab-avwa (Aduhelm). New York State Medicaid Update November 2022 Volume 38 Number 13 (ny.gov)
8. Medicare National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (NCD 200.3). Effective Date: 04/07/2022; Implementation Date: 12/12/2022. Available at: https://www.cms.gov.
9. Medicare Learning Network Article National Coverage Determination 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. MLN Matters: MM12950. Related Request (CR) Number: 12950. Initial article release date: 12/08/2022.CMS announces new details of plan to cover Alzheimer's drugs Fact Sheet. June 22, 2023. Available at: www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-alzheimers-drugs.
10. Clinical Dementia Rating - an overview | ScienceDirect Topics
11. Prescribing-Information.pdf (leqembi.com). Revised 07/2023. Kisunla package insert