Medical Policy Bulletin
Title:
Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer Disease
Policy #:
MA08.151e

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

This policy uses coverage criteria developed solely based on applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals and other applicable Medicare coverage documents.

In accordance with Medicare, monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease is considered experimental/investigational and, therefore, not covered, with the exception of Coverage with Evidence Development.

COVERAGE WITH EVIDENCE DEVELOPMENT (CED)

Monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease is eligible for coverage consideration for individuals who (1) meet all the requirements of Original Medicare's Coverage with Evidence Development (CED) provisions for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease, and (2) are enrolled in a Medicare-approved clinical study. These monoclonal antibodies include aducanumab (Aduhelm), lecanemab-irmb (Leqembi), and donanemab-azbt (Kisunla).

Claims for monoclonal antibodies directed against amyloid for the treatment of Alzheimer’s disease for individuals enrolled in a CED clinical trial should be submitted to the Medicare Advantage plan.

Guidelines

This policy is consistent with Medicare’s coverage determination for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD). The Company’s payment methodology may differ from Medicare.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

In June 2021, aducanumab-avwa (Aduhelm; Biogen) was approved by the FDA for treatment of AD. This indication was approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with aducanumab-avwa (Aduhelm). Continued approval for this indication may be contingent on verification of clinical benefit in confirmatory trial(s).

The FDA, under the accelerated approval regulations (21 CFR 601.41), requires that Biogen conduct a randomized controlled trial to evaluate the efficacy of aducanumab-avwa (Aduhelm) compared to an appropriate control for the treatment of AD. The trial should be of sufficient duration to observe changes on an acceptable endpoint in the patient population enrolled in the trial. The expected date of trial completion is August 2029 and final report submission to the FDA is expected by February 2030.

In January 2023, the FDA approved lecanemab-irmb (Leqembi) as the second humanized IgG1 monoclonal antibody directed against amyloid beta for the treatment of AD. Like aducanumab-avwa (Aduhelm), lecanemab-irmb (Leqembi) was approved via the accelerated approval pathway based on amyloid plaque reduction in a Phase 2 clinical trial, and continued approval will be contingent upon verification of a clinical benefit in a confirmatory trial. Lecanemab-irmb (Leqembi) is limited to treating patients with mild cognitive impairment (MCI) due to Alzheimer's or mild Alzheimer's dementia as this was the population evaluated in clinical trials, and no safety or effectiveness data are available on initiating treatment earlier or later in the disease course.

In July 2023, the FDA converted lecanemab-irmb (Leqembi), indicated to treat adult patients with AD, to traditional approval. Lecanemab-irmb (Leqembi) is the first amyloid beta-directed antibody to be converted from an accelerated approval to a traditional approval for the treatment of AD.

In July 2024, the FDA approved donanemab-azbt (Kisunla), which is an amyloid beta–directed antibody, as indicated for the treatment of Alzheimer's disease. Per the FDA: "Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials."

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, monoclonal antibodies directed against amyloid for the treatment of AD is covered under the applicable medical benefits of the Company's Medicare Advantage products when the requirements for Coverage with Evidence Development listed in this medical policy are met.

Services that are experimental/investigational are excluded for the Company's Medicare Advantage products. Therefore, they are not eligible for reimbursement consideration.

Description

The Centers for Medicare & Medicaid Services (CMS) covers US Food and Drug Administration (FDA)–approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease (AD), including but not limited to Original Medicare's Coverage with Evidence Development (CED), when furnished in accordance with Coverage Criteria under the CED for individuals who have a 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. More information and details, including coverage criteria, for the Decision Memo by CMS and related requirements on this topic are located at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305.

References

Centers for Medicare & Medicaid Services (CMS). Decision Memo for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N). [CMS Web site]. 04/07/2022. Available at: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=305. Accessed June 16, 2022.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)

G30.0 Alzheimer's disease with early onset
G30.1 Alzheimer's disease with late onset
G30.8 Other Alzheimer's disease
G30.9 Alzheimer's disease, unspecified
G31.84 Mild cognitive impairment of uncertain or unknown etiology

HCPCS Level II Code Number(s)
J0172 Injection, aducanumab-avwa, 2 mg
J0174 Injection, lecanemab-irmb, 1 mg
J0175 Injection, donanemab-azbt, 2 mg

Revenue Code Number(s)
N/A

Coding and Billing Requirements
BILLING REQUIREMENTS

For drugs that have more than one method of administration, the appropriate modifier must be appended to indicate the route of administration.

To report the intravenous route of administration, append the following modifier: JA Administered Intravenously

To report the subcutaneous route of administration, append the following modifier: JB Administered Subcutaneously

Inclusion of a code in this policy does not imply reimbursement. Eligibility, benefits, limitations, exclusions, utilization management/referral requirements, provider contracts, and Company policies apply.

Policy History

Revisions From MA08.151e:

03/20/2026	This version of the policy will become effective 03/20/2026. It continues to communicate the Company's policy position for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease for Medicare Advantage Members according to CMS' NCD on this topic.

Revisions From MA08.151d:

12/15/2025	This policy has been reissued in accordance with the Company's annual review process.
09/16/2024	This version of the policy is effective as of 09/16/2024 due to a code update. Procedure code J0175 has been added to the policy. Company's previous coverage position for Medicare Advantage Members, which is based on CMS' NCD regarding CED directions, for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease remains in place

Revisions From MA08.151c:

01/26/2024	This version of the policy update is effective as of 07/06/2023. The policy update communicates the Company's continued policy position for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease for Medicare Advantage members per CMS' National Coverage Determination regarding Coverage with Evidence Development for this topic. FDA's updated approval on this topic from July 2023 is documented as well.

Revisions From MA08.151b:

07/06/2023	This version of the policy is effective as of 07/06/2023 due to a code update. Procedure code J0174 has been added to the policy. Company's previous coverage position for Medicare Advantage Members, which is based on CMS' NCD regarding CED directions, for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease remains in place.

Revisions From MA08.151a:

06/05/2023	This version of the policy update is effective 06/05/2023. This policy update communicates the Company's policy position for lecanemab-irmb (Leqembi) for Medicare Advantage Members.

Revisions from MA08.151:

04/07/2022	New policy #MA08.151, issued on 07/01/2022, is retro-actively effective to 04/07/2022, to communicate the Company's policy position on monoclonal antibodies directed against amyloid (inclduing Aduhelm™ (aducanumab-avwa)) for the treatment of Alzheimer’s disease.

Version Effective Date:
03/20/2026
Version Issued Date:
03/20/2026
Version Reissued Date:
N/A