



National Coverage Determination 200.3: Monoclonal Antibodies for the Treatment of Alzheimer's Disease

Related CR Release Date: May 23, 2024

MLN Matters Number: MM13598

Effective Date: April 7, 2022

Related Change Request (CR) Number: [CR 13598](#)

Implementation Date: June 24, 2024

Related CR Transmittal Number: R12649CP

Related CR Title: National Coverage Determination (NCD) 200.3 - Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD)

Affected Providers

- Physicians
- Hospitals
- Other providers billing Medicare Administrative Contractors (MACs) for treatment of AD in Medicare patients

Action Needed

Make sure your billing staff knows about:

- FDA-approved monoclonal antibodies
- Criteria for coverage
- Coding information
- Claims processing instructions

Background

CR 13598 implements revisions to NCD 200.3, by updating Section 412 of the Medicare Claims Processing Manual, [Chapter 32](#), to include associated claims processing instructions.

Effective April 7, 2022, CMS covers FDA-approved monoclonal antibodies directed against amyloid for the treatment of AD when you provide it in accordance with the coverage criteria below, under Coverage with Evidence Development (CED) for patients 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. See [CR 12950](#), Transmittal 11692, dated November 2, 2022, in addition to this CR.

Clinical trials, studies, or registries under NCD 200.3 are designed around a specific therapy being studied, for example, J0174 for Leqembi, and are assigned differing National Clinical Trial

(NCT) numbers. The NCT number could be 06058234, for example, default 99999999 NCT number, or another NCT number assigned to another trial, study, or registry under NCD 200.3. Future therapies with FDA approval that fall under NCD 200.3 that don't have a dedicated HCPCS code would be identified either by existing unspecified HCPCS codes J3490, J3590, or a dedicated HCPCS code once it's assigned.

Effective with claims with dates of service of April 7, 2022, your MAC will accept claims with:

- ICD-10 diagnosis code Z00.6, along with 1 of the following diagnosis codes: G30.0, G30.1, G30.8, G30.9, G31.84, the Q0 or Q1 modifier, and condition code 30 (for institutional claims only).
- HCPCS J0174, Injection, Iecanemab-irmb, 1 mg, (Leqembi®) or HCPCS J3490, J3590, or C9399 (for an FDA-approved therapy that's covered under NCD 200.3 that hasn't received a dedicated HCPCS code), or a dedicated HCPCS code, for any future FDA-approved therapies under NCD 200.3
- NCT 8-digit number or the default NCT number 99999999

Claims for monoclonal antibodies for the treatment of AD must be on types of bills 012X, 013X, or 085X.

MACs won't search for claims already processed, but they'll adjust claims you bring to their attention.

More Information

We issued CR 13598 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

Document History

Date of Change	Description
May 24, 2024	Initial article released.

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