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

MLN Matters Number: MM12950 Related Request (CR) Number: 12950

Related CR Release Date: November 9, 2022 Effective Date: April 7, 2022

Related CR Transmittal Number: R11692NCD Implementation Date: December 12, 2022

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

Provider Types Affected

This MLN Matters Article is for physicians and other providers billing Medicare Administrative Contractors (MACs) for treatment of AD in Medicare patients.

Provider Action Needed

Make sure your billing staff knows about coverage for:

- FDA-approved monoclonal antibodies
- CMS-approved studies

Background

AD is currently an irreversible brain disorder that progressively degrades memory, cognitive function, and ability to carry out tasks of daily living. AD is the leading cause of dementia in older Americans.

Antiamyloid-beta monoclonal antibodies (antiamyloid mAbs) are laboratory-made proteins designed to bind to a specific substance in the body, with the goal of marking it for destruction by the body's immune system. Scientists design various mAbs as treatments with the goal of targeting and neutralizing or clearing infections (like the COVID-19 virus), cancer cells, and in the case of AD, amyloid accumulation in the brain.

Coverage Criteria

Effective April 7, 2022, CMS covers FDA-approved monoclonal antibodies directed against

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amyloid for the treatment of AD under coverage with evidence development (CED) for patients 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 below.

The coverage criteria are:

- We may cover FDA-approved monoclonal antibodies directed against amyloid to treat AD based upon evidence of efficacy from a change in a surrogate endpoint (for example, amyloid reduction), considered as reasonably likely to predict clinical benefit in a randomized controlled trial conducted under an investigational new drug application.
- We may cover FDA-approved monoclonal antibodies directed against amyloid for the treatment of AD based upon evidence of efficacy from a direct measure of clinical benefit in CMS-approved prospective comparative studies. Study data for CMS-approved prospective comparative studies may be collected in a registry.
- For CMS-approved studies, the protocol, including the analysis plan, must include specific criteria in the NCD.
- CMS-approved studies of a monoclonal antibody directed against amyloid (antiamyloid mAb) and FDA-approved to treat AD based upon evidence of efficacy from a direct measure of clinical benefit must address specific NCD questions.
- CMS-approved studies must adhere to the standards of scientific integrity specified in the NCD as identified by the Agency for Healthcare Research and Quality.

We cover monoclonal antibodies directed against amyloid indicated to treat AD when given according to the FDA-approved indication in National Institutes of Health (NIH)-supported trials.

For any CMS-approved study, or NIH-supported trial, that includes a beta amyloid positron emission tomography (PET) scan as part of the protocol, these trials or studies meet the CED requirements included in the Beta Amyloid PET in Dementia and Neurodegenerative Disease NCD (220.6.20)

Monoclonal antibodies directed against amyloid for the treatment of AD provided outside an FDA-approved randomized controlled trial, CMS-approved studies, or NIH-supported studies are non-covered.

NOTE: Individually approved clinical trials require a new HCPCS code specific to the therapy being studied. Use existing HCPCS codes J3490 or J3590 to identify therapies with FDA approval that don't have an assigned and dedicated HCPCS code.

More Information

We issued CR 12950 to your MAC as the official instruction for this change. See Section 200.3 of the NCD Manual, which is part of CR 12950 for more details.

For more information, find your MAC's website.

Document History

Date of Change	Description
December 8, 2022	Initial article released.