

FACTSHEET

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Alzheimer's Treatment Coverage

What is the new class of treatments for Alzheimer's?

- Monoclonal antibodies directed against amyloid ("anti-amyloid mAbs") are a new class of disease-modifying treatments, some of which have already been approved by the U.S. Food & Drug Administration (FDA), for those with early Alzheimer's.
- In June 2021, the FDA granted accelerated approval to Aduhelm (aducanumab), making it the first anti-amyloid mAb treatment on the market.
- In January 2023, the FDA granted accelerated approval to a second anti-amyloid mAb treatment, Leqembi (lecanemab). The Phase 3 trial results confirmed this treatment can meaningfully change the course of the disease for people with early Alzheimer's.

How does the Centers for Medicare & Medicaid Services (CMS) affect access?

- CMS is the agency responsible for administering Medicare. Through National Coverage Determinations (NCDs), CMS can determine if and under what circumstances Medicare will pay for treatments or services on the market.
- In April 2022, CMS issued an NCD severely limiting Medicare coverage of FDA-approved anti-amyloid Alzheimer's treatments, current and future, to only those in specific clinical trials and comparative studies.

What is the impact of the CMS decision to restrict access to approved treatments?

- Because of the anti-amyloid NCD CMS has put in place, patients cannot receive Medicare coverage for these FDA-approved treatments.
- These are the only FDA-approved drugs that Medicare does not cover.
- Every day more than 2,000 individuals with Alzheimer's transition to a more advanced stage of the disease where they are no longer eligible for the existing anti-amyloid treatments.
- The NCD disproportionately affects access for rural and traditionally underserved populations who tend to live further from, feel less welcome at, and be underrepresented at research institutions and in medical research.

How can equitable access to care and treatment for early Alzheimer's improve?

- Leading Alzheimer's researchers and clinicians overwhelmingly agree that patients should have Medicare coverage for these treatments.
- CMS must provide full and unrestricted coverage for FDA-approved Alzheimer's treatments the same way it does for FDA-approved treatments for every other disease. In February 2023 CMS denied a formal request filed by the Alzheimer's Association to reconsider the anti-amyloid NCD.
- While decisions on Medicare coverage are made by CMS, Congress must make its voice heard.

For more information visit: alz.org/coverage.