Mercer

Mercer Pharmacy Flash

# FDA Approves New Alzheimer's Drug

**Mercer Government**
Ready for next. Together.

A Business of Marsh McLennan

**January 2023**

## FDA approves Leqembi® for the treatment of Alzheimer's disease

The U.S. Food and Drug Administration (FDA) granted accelerated approval to Leqembi, pronounced leh-KEM-bee (lecanemab), an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease (AD). This treatment is administered intravenously (IV) every two weeks to slow cognitive decline in patients with early stage disease. Leqembi has an initial annual cost of $26,500. Severe potential adverse effects include brain swelling and bleeding which will require additional monitoring.

## Approval Pathway

Leqembi was approved under the accelerated approval pathway which provides a quicker path to market. This is the same controversial pathway under which Aduhelm® (aducanumab) was approved.

In clinical trials, Leqembi slowed cognitive decline, somewhat, in patients with mild impairment due to AD. Under the National Coverage Determination (NCD) issued in April 2022, Medicare coverage for anti-amyloid therapies approved under the accelerated pathway requires patients to be enrolled in approved clinical trials, none of which are planned or ongoing for Leqembi. If Leqembi is considered to meet the "reasonable and necessary criteria", the Centers for Medicare & Medicaid (CMS) could remove some of the barriers it implemented as part of the NCD. However, the manufacturer of Leqembi has submitted additional efficacy data to the FDA for full approval. If granted full approval, Medicare coverage is expected to be less restrictive.

## Background

### Medicare Coverage Decision

On April 7, 2022, CMS released a NCD decision regarding the Medicare coverage of approved monoclonal antibodies that target amyloid for the treatment of AD.

- Under the decision, drugs approved under the accelerated pathway, based on amyloid reduction, are covered ***only*** in CMS approved clinical trials. Both Aduhelm and Leqembi would be included in the requirement.

- Amyloid targeting therapies that receive full approval may be covered as part of a less rigorous prospective study. ***If Leqembi is able to receive full approval*** from the FDA based on the additional data they submitted regarding the slowing of cognitive decline, the drug would receive broader Medicare coverage consistent with a prospective study.

CMS has indicated ***they would review emerging data*** for consideration of altering the barriers it implemented for beta-amyloid monoclonal antibodies in the NCD issued in April 2022.

**Aduhelm**

Uptake of Aduhelm remained minimal, with prescribers citing safety and efficacy concerns in addition to cost as limiting factors. In late December 2021, Biogen announced the company was reducing the price of Aduhelm by 50% (to $28,200 wholesale acquisition cost) at the yearly maintenance dose to encourage uptake and patient access. Despite the price decline, sales remained minimal prompting the company to abandon marketing efforts for Aduhelm.

## Leqembi

Leqembi targets beta-amyloid, a protein in the brain thought to increase cognitive decline in patients with AD. It is administered via an IV infusion every two weeks. FDA approval of Leqembi is limited to patients with mild cognitive impairment or early stage AD that also have imaging confirmed evidence of amyloid buildup in the brain.

In clinical trials of approximately 1,800 patients with early-stage AD, Leqembi ***slowed clinical decline*** by 27% compared with placebo after 18 months. Leqembi reduced beta-amyloid plaques in the brain and slowed the decline of three other validated measures of memory and function.

Patients are required to undergo three additional brain scans, in addition to the confirmatory pretreatment scan, during the first 14 weeks of treatment to monitor for brain swelling or bleeding episodes. Approximately 13% of patients in Eisai's study had swelling of the brain and 17% had small brain bleeds. In most cases, the swelling and bleeding were minor with minimal associated symptoms. Risks for brain bleeding and swelling are increased in patients receiving blood-thinning medications. At least two deaths have occurred in individuals receiving both Leqembi and blood thinners, prompting the FDA to warn prescribers to exercise caution in patients using blood thinners.

The estimated potential U.S. patient population, limited to those with mild cognitive impairment, is approximately one million people. Eisai, the manufacturer of Leqembi, estimates that 100,000 individuals over three years might be prescribed Leqembi, with potential longer term growth as the company pursues a formulation that can be injected under the skin. Unless Medicare changes the way it covers monoclonal antibodies that target amyloid for the treatment of AD, such as like Leqembi, Eisai has indicated it expects a relatively slow rollout.

Although patients may be good candidates for treatment, they may not rush to be early adopters of Leqembi due to the potential side effects and limited efficacy data. Following the FDA's approval of Aduhelm against the advice of the agency's expert panel due to questionable efficacy, uptake was minimal. The FDA did not consult the same expert panel before approving Leqembi.

## Cost and Availability

**Eisai Pricing for Leqembi**

**Wholesale Acquisition Cost**

$26,500 per year for a person of average weight

**Institute for Clinical and Economic Review (ICER)**

**Leqembi Cost Evaluation**

Determined cost-effective if priced between $8,500 and $20,600 per year

At a 23.1% minimum discount (based on Average Manufacturer Price), the drug's price is likely near ICER's top price point.

Eisai will provide information related to product availability and additional access resources the week of January 23, 2023.

## Next Steps for State Medicaid Programs

CMS has previously instructed state Medicaid programs to not cover Aduhelm or similar monoclonal antibodies that target amyloid for the treatment of AD for individuals eligible for Medicare Part D. For Medicaid-only individuals, CMS reiterated that states are required to cover these therapies when the drug is used for a medically-accepted indication.

State Medicaid programs could subject the products to utilization management techniques, such as prior authorization and medical necessity criteria. CMS also reiterated that as covered outpatient drugs, manufacturers ***are required to pay rebates***, as appropriate, when dispensed and paid for under the state plan, including when Medicaid pays the coinsurance amount for dual enrollees.

As CMS coverage decisions for monoclonal antibodies that target amyloid evolve, state Medicaid programs ***should be prepared to evaluate how each drug*** can best be managed in the fee-for-service and managed care environments.

In particular, states should consider:

- Current Medicare coverage policies related to these therapies.
- Site of service and claims payment: IV administered drugs can be billed through the medical or pharmacy claim systems. States should establish policy to ensure consistency and efficiency in payment and administration.
- Prior authorization and medical necessity criteria, as appropriate.
- Potential impact to managed care capitation rates in select populations as utilization accelerates.

Please contact Bethany Holderread, Sara Drake, or your Mercer pharmacy consultant to talk through the potential impact of Leqembi, and other similar therapies, to your specific state program.

View more information at www.mercer-government.mercer.com

## References


FDA approves Alzheimer's drug shown to moderately slow cognitive decline in early stages of the disease | STAT

The FDA has approved a new Alzheimer's drug, but wide access may depend on CMS easing restrictions | STAT

Alzheimer's Drug Lecanemab's Positive Phase 3 Data Could Lead to Loosening of Medicare Coverage Restrictions | Forbes

The first drug to have even a limited impact on Alzheimer's just got FDA approval. 'This drug is not a cure.' | Fortune

Biogen Scraps Infrastructure for Aduhelm Sales in US | Alzheimer's News Today

F.D.A. Approves New Treatment for Early Alzheimer's | New York Times

Legembi Prescribing Information | Eisai

Legembi Patient Support | Eisai

CMS Finalizes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's disease | CMS

Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease | CMS

Biogen Announces Reduced Price for ADUHELM® to Improve Access for Patients with Early Alzheimer's Disease | Biogen