

Monoclonal antibody infusions for Alzheimer's Disease (aducanumab and lecanemab): Frequently Asked Questions

We understand that many of our patients and families have questions regarding new medicines for Alzheimer's disease (aducanumab, lecanemab). Please see below FAQ's for better understanding of the medications, FDA approval, Medicare coverage and availability at Emory Healthcare.

What are aducanumab and lecanemab?

- The medicines are monoclonal antibodies that target and remove amyloid plaques from the brain. Amyloid plaques are increased in the brains of those with Alzheimer's disease.
- The medicines were tested in patients diagnosed with **mild cognitive impairment (MCI)** or **early-stage dementia who have evidence of amyloid plaques in their brains**. Patients with moderate to severe stages of Alzheimer's disease were not included in the clinical trials and will not be eligible.
- Clinical studies were mixed on whether aducanumab could slow the cognitive decline associated with Alzheimer's disease.
- An article published January 5, 2023, in the New England Journal of Medicine ('Lecanemab in Early Alzheimer's Disease') demonstrated less cognitive decline in subjects on lecanemab as compared to those on placebo.

How are aducanumab and lecanemab administered?

- Both medications are given by intravenous infusion at a specialized infusion center using a small temporary IV catheter in the arm (aducanumab: monthly; lecanemab: every two weeks.)
- The infusion is administered over 1-2 hours.
- People receiving these medications may develop minor or severe allergic reactions and need to be monitored closely during the first few infusions.
- The clinical trials showed that subjects developed small bleeds or swelling in the brain (~2 in 10 for lecanemab; ~4 in 10 for aducanumab). For most subjects, these side effects did not cause significant symptoms and required subjects to briefly stop the medication to allow the brain changes to go away. Some subjects had headaches, confusion, dizziness, and nausea.
- More serious symptoms were noted in a small number of patients, including death.
- **Brain scans (MRIs) are needed every few months to monitor for bleeding and swelling in the brain.** Patients not able to have MRIs will not be eligible for treatment.

Are aducanumab and lecanemab approved by the U.S. Food and Drug Administration (FDA)?

- Aducanumab (Aduhelm) received accelerated approval from the FDA on June 7, 2021. Accelerated approval means that aducanumab affects the underlying disease process that may predict a clinical benefit to patients. Two large randomized controlled trials were mixed in whether aducanumab had clinical benefit.
- Lecanemab (Leqembi) was approved by the FDA on January 6, 2023, also under accelerated approval. One large randomized controlled demonstrated that subjects on lecanemab had less cognitive decline.

What is the cost of these medications and are they covered by Medicare or other insurance companies?

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- The last reported cost of aducanumab was ~\$28,200 per year without insurance. As of January 6, 2023, the reported cost per year for lecanemab is \$26,500.
- Additional costs include the infusion center time and supplies, multiple brain scans, clinical evaluations, and laboratory evaluations.
- Medicare [announced](#) that aducanumab will only be covered by Medicare through Medicare-approved research studies that are aimed at understanding how helpful aducanumab is for patients. Details on how these research studies will work or the sites where the studies will occur are not yet available. Medicare will not cover the cost of aducanumab if prescribed in a clinical setting by a provider. Patients with insurance coverage other than Medicare should check with their insurance provider to see if similar restrictions apply.
- Medicare and other insurance companies have not announced whether they will cover lecanemab. Given the positive trial results, it is likely that Medicare will approve coverage based on its broad determination about this class of medications ([monoclonal antibodies that target amyloid](#)). A decision is not expected until well into 2023.

Are aducanumab and lecanemab available at Emory Healthcare?

- Aducanumab: Emory Healthcare, along with other institutions like Cleveland Clinic, Mount Sinai, Mass General Brigham, and the Veterans Affairs Hospital System, decided not to add aducanumab to its pharmacy formulary. The decision was based on review of all available data on aducanumab including the amount of benefit to patients, safety and risk of side effects, and value/cost to patients. This decision may be revisited in the future if additional data becomes available. In summary, aducanumab is not available for infusion within the Emory Healthcare system.
- Lecanemab is not yet available at Emory Healthcare. An Emory Healthcare decision on placing lecanemab in the pharmacy formulary has not yet been made but will be forthcoming later in 2023.

How do I know if I am eligible for lecanemab?

- There are still several items to resolve before the Emory Cognitive Clinic can recommend and/or administer lecanemab. This includes the decision to place lecanemab on the Emory Healthcare formulary, a coverage determination from Medicare and other insurers, and the logistics around lecanemab manufacturing/delivery. These items will likely take several months or more.
- If you have questions about your eligibility, please discuss this with your Cognitive Neurology Clinic provider at your next visit.
- The Emory Cognitive Neurology Clinic team will begin to review patients and reach out to those who may be eligible once the issues above are resolved.
- If you are not a patient in the Emory Cognitive Neurology clinic, please speak with your primary care provider to discuss any concerning cognitive symptoms and whether additional workup or referral to the Cognitive Clinic is right for you.