

Lecanemab Frequently Asked Questions

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On July 6, 2023, the Food and Drug Administration (FDA) provided approval for lecanemab (Leqembi) to treat early stage Alzheimer's disease. Lecanemab is a medication developed by Eisai and Biogen that may help slow the progression of early stage Alzheimer's disease. Many people living with dementia, families, and care professionals have questions regarding this news. Please see below frequently asked questions and some answers for a better understanding of what to expect with the FDA approval of lecanemab.

What is lecanemab (Leqembi)?

- Lecanemab or Leqembi (pronounced leh-KEM-bee) is a new medication given by intravenous (IV) infusion every two weeks.
- It is a monoclonal antibody that binds and removes amyloid plaques from the brain. Plaques are increased in the brains of those living with Alzheimer's disease.
- Lecanemab should be used for people with mild cognitive impairment or mild dementia, as these were the individuals who participated in the clinical trials testing the drug.
- There is no evidence of benefit for individuals in the moderate to severe stages of Alzheimer's disease or other types of dementia.
- Lecanemab is not a cure for Alzheimer's disease, but it may help to slow the progression of the disease.
- Eisai and Biogen, the drug developers, found lecanemab slowed cognitive decline associated with Alzheimer's disease by 27%.
- Participants taking lecanemab demonstrated a statistically significant and clinically meaningful reduction in decline over 18 months on the Clinical Dementia Rating Scale compared to participants taking a placebo in an experimental trial.
- Participants taking lecanemab also performed statistically significantly better on the Alzheimer's Disease Assessment Scale Cognitive Subscale 14 and the Alzheimer's Disease Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment. However, it is unclear if those differences were clinically meaningful.
- Of 1734 participants who completed a study evaluating lecanemab/Leqembi (859 in the lecanemab group and 875 in the placebo group), most were white, 2.5% were Black, 12.4% were Hispanic, and 17% were Asian.

How will I receive lecanemab treatments if I am a candidate?

- Lecanemab is administered as an intravenous infusion every two weeks and may be administered indefinitely.
- The infusion lasts about an hour.
- Infusions typically occur at a hospital or infusion therapy center.
- MRI scans occur prior to the 5th, 7th, and 14th infusions.

How safe is lecanemab?

- The most common side effects for people receiving this medication include infusion-related reactions, headache, and amyloid-related imaging abnormalities (ARIA). Some experts indicate that the occurrence of brain edema (i.e., swelling) and new brain micro/macro hemorrhages are potential safety concerns.

- Infusion-related reactions are the most common side effect of the treatment, occurring in 26.4% of participants (compared to 7.4% in the placebo group). Infusion-related reactions may include temporary symptoms, like flushing, chills, fever, rash, and body aches. The majority (96%) of these reactions were mild to moderate and 75% happened after the initial infusion.
- However, a severe reaction while having an infusion or shortly after an infusion may occur. You will be monitored by a doctor or nurse while you are receiving the infusion. If you experience any of the following symptoms, tell your doctor or nurse immediately: Fever, chills, body aches, joint pain, nausea, vomiting, dizziness or lightheadedness, feeling of racing heart rate or chest pounding, or difficulty breathing or shortness of breath.
- Your doctor may give you other medicines like Tylenol or Benadryl before receiving this medicine to help prevent infusion-related reactions, this may include allergy medicines, anti-inflammatory medicines, or steroids.
- People who carry a genetic risk for Alzheimer's in the ApoE gene are more vulnerable to the brain inflammation (ARIA), which can be detected with regular brain scans and controlled with careful monitoring.
- Inflammation of the brain occurred in about 12.6% of people taking lecanemab in the Eisai study
- Small brain bleeds occurred in 17% of participants in the Eisai study.

How do you know if you are a candidate to receive lecanemab?

- The medication was tested for individuals in the **early** stage of Alzheimer's disease (mild cognitive impairment or early dementia).
- Your physician will need to confirm the presence of beta-amyloid plaques before you can receive lecanemab. Diagnostic tools that could be used to determine elevated beta-amyloid include an amyloid PET scan or a lumbar puncture.
- Patients will also be required to undergo a MRI before they are prescribed lecanemab.
- Since some people have a genetic risk factor (ApoE ε4 gene carriers) that may cause an increased risk for the side effect of amyloid-related imaging abnormalities (ARIA), the FDA encourages testing for ApoE ε4 status prior to initiation of this medication.

When and where will lecanemab be available through healthcare providers?

- Although lecanemab (Leqembi) is approved, it is not available yet.
- Multiple additional steps, including manufacturing, distribution, and implementation, need to occur before the medication becomes available to patients.
- Contact your doctor to check on availability.

How much will lecanemab cost?

- The cost of a year's supply of the twice monthly infusions estimated to be \$26,500.
- Possible additional costs include the infusion center time and supplies, multiple brain scans, clinical evaluations, and laboratory evaluations.
- Medicare will cover a portion of the cost of lecanemab for individuals who: 1) have been diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, 2) have documented evidence of beta-amyloid plaque on the brain, 3) whose doctor participates in a qualifying registry, and 4) who has an appropriate clinical team and follow-up care.
- Medicare will not cover the entire cost of the medication.

- Enrollees in original Medicare will have to pay a co-payment of 20% of the cost of the drug, after meeting their deductible.
- Enrollees in Medicare Advantage also typically pay 20% of drugs' costs, up to their plan's out-of-pocket maximum.
- The Inflation Reduction Act (IRA) has a provision to cap out-of-pocket drug costs for Medicare recipients at \$2,000 starting in 2025, but it does not apply to Leqembi. The IRA targets drug costs prescribed through Medicare's Part D, which generally covers prescription drugs. However, Leqembi was approved under Medicare's Part B, which generally covers drugs administered in doctor's services.

Per a scientific and clinical expert: Lecanemab should be prescribed only by physicians who are experienced in caring for patients with Alzheimer's disease and who have a multi disciplinary team to manage the neuropsychological, neuro radiological, genetic and logistical challenges.

Information gathered from the following resources on 7/17/23:

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