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# Lecanemab *(Leqembi)*

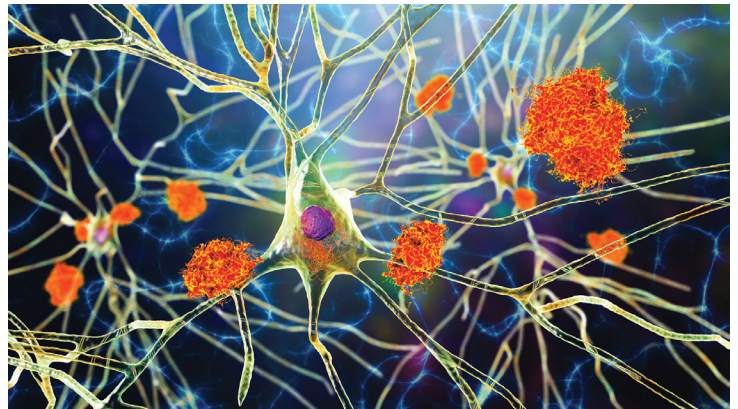
## Information for patients and families about a new drug for Alzheimer's disease

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Lecanemab is an intravenous medication designed to remove a protein called amyloid from the brain. Many scientists think that a buildup of amyloid causes Alzheimer's disease. However, not everybody with Alzheimer's disease has a great deal of amyloid buildup, and not everybody with amyloid buildup has major problems with mental functioning.

### **Lecanemab does not improve mental function.**

**It just slows the loss of mental functioning somewhat.** In the main study of the drug in people with mild cognitive impairment (MCI) or early Alzheimer's disease, during a year and a half of treatment the rate of decline in patients given the drug was somewhat slower than the rate of decline in those who weren't given the drug. In additional results, 67% (about two-thirds) of patients who were not given the drug had stable mental functioning, compared to 76% (about three-quarters) of patients who were given the drug. Experts differ in their opinions of how meaningful these differences will be for individual patients. The effects of the drug in women were smaller than those seen in men.



Some patients and families might see these benefits as worthwhile. Others might see them as too small to justify the treatment, especially when compared to its risks, burdens, and costs (see below).



Lecanemab has not been studied in people with worse mental functioning, such as moderate or severe Alzheimer's disease. It is approved for use only in patients with elevated amyloid levels.

### **Lecanemab is not a pill.**

It is a liquid that must be given every two weeks through an intravenous (IV) drip directly into a patient's vein. Treatment takes over an hour and must be completed at an infusion center over a period of at least 18 months.

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## Measuring amyloid levels

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Before treatment is begun, a patient should have one of two tests to measure amyloid:

**Test 1 - PET (Positron Emission Tomography) scan**, available at specialized centers; or



**Test 2 - Lumbar puncture (spinal tap)**, in which a needle is inserted into the fluid around the spinal cord to measure amyloid levels.

In addition, before starting lecanemab, patients must have a brain MRI scan. This test may make patients with claustrophobia uncomfortable, but most are able to tolerate it. The patient's head is put in a plastic cage and their body is passed into a small tunnel where powerful magnets spin around to create an image of the brain. During the 20-minute test, the patient must lie motionless. Sometimes sedation is required to finish the test if the patient cannot lie flat or cannot remain motionless.

After lecanemab has been started, additional brain MRI scans are required periodically to monitor for signs of brain bleeding or brain swelling, about every three months for the first year. More scans are needed if brain bleeding or swelling occur. The intravenous treatments are held or may have to be completely stopped if one of those abnormalities occurs.

## Genetic testing

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Some patients' genes may make them less likely to benefit from lecanemab and more likely to have serious side effects from it like brain bleeding or swelling. The "APOE  $\epsilon$ 4" gene variant is the most well-known of these. Patients with two copies of this gene have a higher risk of developing Alzheimer's disease, and of developing brain swelling or bleeding when given lecanemab. Furthermore, people with two copies of the APOE  $\epsilon$ 4 gene are far less likely to get any benefit from the drug. As a result, the FDA suggests that patients be tested for APOE  $\epsilon$ 4 before being given lecanemab.

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# Side effects of lecanemab

## Infusion reactions

During the I.V. treatments, about a quarter of people will develop symptoms such as fever, chills, aches, or joint pain. This is usually brief and can be treated effectively with medication. Severe allergic reactions can also occur, but are not common.

## Brain swelling or bleeding

One in five people given lecanemab will develop signs on brain scan of swelling or bleeding caused by the drug. Most of the time this does not cause symptoms. But if it is more severe, patients can develop headache, confusion, dizziness, vision changes, nausea, difficulty speaking, weakness, or in rare instances seizures. When these symptoms appear, it is important for the patient or family to contact their clinician. An additional brain MRI scan should be performed if these symptoms develop.



Patients taking anticoagulants (blood thinners) other than low-dose aspirin, or those who have had bleeding in their brain before beginning treatment, and those who have two copies of the APOE  $\epsilon$ 4 gene are more likely to develop brain bleeding if given lecanemab.

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## How much will lecanemab cost?

The expense of lecanemab (Leqembi) may be an important factor for some patients and families. Its manufacturer has set a list price for the drug of \$26,500 per patient for each year of treatment. That does not include the additional costs of doctor visits, tests, and infusion charges required, which have been estimated at about \$7,300 more per year, or a total of approximately \$33,800 per year. Medicare will pay for 80% of these costs for people with “Part B coverage,” with the rest of the bill potentially payable by the patient. Many Medicare patients have supplemental (“Medigap”) coverage that can help cover that amount, or they may be enrolled in a “Medicare Advantage” or retiree health insurance plan that may do so, but not all people have such supplementary coverage. One estimate found that for some Medicare patients, their share of the total bill could be as high as \$6,600 per year.



# Choosing the right healthcare team

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Treatment with lecanemab requires a team of several healthcare professionals. **Dementia care specialists** are more likely to have the necessary experience to properly diagnose MCI or mild dementia due to Alzheimer's disease and to determine if the severity of symptoms fits into the optimal range for treatment with lecanemab. **Radiologists** experienced in reading amyloid PET scans and brain MRI scans are also critical. The treatment team also needs to have a good working relationship with the infusion center where lecanemab is administered as well as the **primary care clinician** who will continue to follow up with patients for their overall health. Families or other caregivers will also have to be available to help the patient get to the every-other-week intravenous infusion sessions, and to monitor for side effects.

## Summary

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*To begin with, patients with cognitive impairment must have a thorough evaluation to make the right diagnosis or to see if there is a cause other than Alzheimer's disease. Other conditions can cause similar thought problems, including medication side effects, depression, or thyroid disease; these other problems must be considered and treated if needed before resorting to an amyloid-lowering drug like lecanemab. In addition, patients and families need a thorough understanding of the likely future for mild cognitive impairment (MCI) or dementia due to Alzheimer's disease: Although these conditions generally worsen, the course can vary a great deal from person to person, and the timeframe can stretch out for many years.*

*Lecanemab and other amyloid-lowering medications hold some hope for certain patients with mild cognitive impairment and Alzheimer's disease. However, the benefits seen to date are not large and potential burdens of treatment are not small. Each individual patient and family will have to weigh the potential benefits, the potential side effects, the burden in administering the treatment, and the costs to make the decision that is best for them.*

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Alosa Health is a non-profit educational organization that accepts no funding from any pharmaceutical company.

More information on Alzheimer's disease and caring for older patients with cognitive impairment is at: [AlosaHealth.org/dementia/](https://AlosaHealth.org/dementia/)

These materials for families and patients are being disseminated with support from the PACE program of the Department of Aging of the Commonwealth of Pennsylvania, The John A. Hartford Foundation, and Aetna. They will be updated as new information becomes available.



**These are general recommendations only; specific clinical decisions should be made by the treating clinician based on an individual patient's clinical condition.**