Penn Medicine

LEQEMBI® (LECANEMAB)

Frequently Asked Questions

Leqembi (lecanemab) is FDA approved for the treatment of Alzheimer's disease in the mild cognitive impairment and mild dementia stages. Below are Penn Medicine's answers to your common questions:

What is Leqembi?

Leqembi (lecanemab) is a drug developed by BioArctic AB, Biogen, and Eisai Co., Ltd. Leqembi has been found to slow cognitive and functional decline in people living with early-stage Alzheimer's disease. Lecanemab is the scientific name of the drug. It is marketed as Leqembi.

How does Leqembi work?

Patients with Alzheimer's disease have a buildup of a protein called beta-amyloid in their brains. This buildup is commonly called "amyloid plaques." Leqembi is a human monoclonal antibody synthesized in a laboratory that selectively targets beta-amyloid.

Studies show that Leqembi reduces the buildup of beta-amyloid. It also slows the decline in a person's ability to carry out day-to-day activities.

How is Leqembi administered?

The drug is given as an hour-long intravenous (IV) infusion **every two weeks.**

How much does Leqembi cost?

Eisai has set Leqembi's annual price at $26,500. Penn Medicine is waiting for more guidance from the Centers for Medicare and Medicaid Services (CMS) and the insurance companies on costs.

Who is eligible for Leqembi?

People with mild cognitive impairment or mild-stage dementia due to Alzheimer's disease may be eligible to receive Leqembi.

How is it determined if I am eligible for Leqembi?

Several assessments inform the determination:

- **This drug is not safe for people who are on blood thinners.**
- **A history and assessment of cognition and day-to-day function:** This assessment, completed by your primary care provider or Alzheimer's disease specialist, determines if you have mild cognitive impairment or mild-stage dementia.
- **Magnetic Resonance Imaging (MRI) scan of the brain:** This scan determines if you have evidence of small areas of blood in the brain. These are called micro-hemorrhages. They are common in people with Alzheimer's disease. They may increase the risks of Leqembi.
- **Blood work:** Blood work helps to determine if there are causes of cognitive impairments other than Alzheimer's disease.
- **Genetic testing:** Your provider will recommend genetic testing for a gene called *APOE*. This test is completed using a sample of blood or saliva. Every person has two copies of the *APOE* gene. The copies come in three types, called e2, e3, and e4. The genetic test determines if you have the "e4" version of the gene. Having one or two copies of the e4 version of the gene increases the chances of side effects.
- **A test for the presence of beta-amyloid in the brain:** this test can be a Positron Emission Tomography (PET) scan or a spinal fluid sample obtained using a lumbar puncture.

LEQEMBI® (LECANEMAB) FAQs

What are the potential side effects of Leqembi?

The main side effects of Leqembi are microscopic hemorrhages (small bleeds) and edema in the brain. These are called Amyloid-Related Imaging Abnormalities or ARIA. These are abnormalities caused by inflammation around the small blood vessels in the brain.

The FDA has labeled Leqembi with a "warning" about this risk. This warning emphasizes that the risk of ARIA is associated with an e4 gene (see below).

In a study of 1,800 participants, those receiving Leqembi were twice as likely to experience brain bleeding and swelling than those receiving the placebo.

In most patients, ARIA is asymptomatic. It is detected using an MRI scan. About 25% of people with ARIA have mild symptoms (about 3% of all treated) and a small number have more serious and permanent neurological outcomes (about 1%).

Other side effects include hypersensitivity reactions, headaches, diarrhea, and falls.

What is the *APOE* gene?

APOE is a gene. Everyone has two copies of *APOE* because they inherit one from their mother and one from their father. There are three different types of *APOE*. We refer to them as the e2, e3, and e4 types of *APOE*. Knowing what types of the *APOE* gene someone has provides important risk information. *APOE* can impact the risk for developing Alzheimer's disease, and also the risk for ARIA (see above).

There are many people who develop Alzheimer's disease without having one or two copies of *APOE* e4, and there are people who have one or two copies of *APOE* e4 who never develop dementia.

The *APOE* gene is not the only gene associated with dementia. If you have a family history of dementia, especially with onset at a young age (less than 65 years old), it is important to share this information with your doctor. Your doctor might recommend that you have genetic counseling.

Why does *APOE* status matter for Leqembi prescription?

People taking Leqembi can develop small spots of bleeding or temporary swelling of the brain. This is also called ARIA (Amyloid-Related Imaging Abnormalities). These types of changes can be seen on a brain scan called an MRI.

Individuals with MRIs that show temporary brain swelling or small spots of bleeding often do not experience symptoms. But, symptoms such as headache, vision changes, confusion, and problems with walking are possible.

Individuals with one or two copies of the e4 type of *APOE* have an increased risk for ARIA.

If I have one or two copies of e4, can I still be prescribed Leqembi (Lecanemab)?

There are increased risks of side effects for individuals with one or two copies of *APOE* e4. The risks are higher in individuals with two copies of *APOE* e4. You and your physician should discuss all possible risks and benefits of Leqembi before making your decision about taking Leqembi.

In addition to the infusion appointments every other week, what other requirements are there to receive Leqembi?

Patients must receive a MRI scan of the brain before the 5th, 7th, and 14th infusions to ensure there is no brain bleeding and swelling (ARIA).

Patients with Medicare coverage will need to consent to data collection as part of Medicare's Coverage with Evidence Development (CED) policy.

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