Penn Medicine

# LEQEMBI® (LECANEMAB)

## Understanding Leqembi's Side Effects: A Guide for Patients

**Leqembi (Leqembi) is FDA approved for the treatment of Alzheimer's disease in the mild cognitive impairment and mild dementia stages.**

Leqembi is a significant advancement in the treatment of Alzheimer's disease. However, like many medications, it has risks. Understanding these risks, how they are detected, and their management is key to making an informed decision about your care.
This document explains one risk known as Amyloid-Related Imaging Abnormalities (ARIA).

### What is ARIA?

Amyloid Related Imaging Abnormalities (ARIA) refers to changes seen on brain scans, typically manifesting as swelling (or edema) called ARIA-E, or small bleeding spots (or hemorrhage), called ARIA-H.

### The Symptoms of ARIA

ARIA typically occurs early in the treatment process – within the first six months. Most people who develop ARIA do not have symptoms, but some can. Patients may experience:

- Headaches
- Confusion
- Dizziness
- Vision disturbances
- Nausea
- Gait difficulties
- Seizures

### Who is at Risk of ARIA?

Approximately 15% of people with Alzheimer's disease have two copies of a gene called ApoE ε4, which increases their risk of developing ARIA compared to those who have one or no copies of the gene. Penn Medicine patients who are being considered for treatment with Leqembi will be tested for ApoE ε4 and learn their risk of developing ARIA. For a breakdown of how ApoE ε4 impacts risk of ARIA-H and ARIA-E, please refer to the information on the back. These numbers are based on an 18-month clinical trial, called Clarity AD, involving 1,795 participants, where 898 received Leqembi and 897 received a placebo.

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### ARIA-H

ARIA-H refers to changes seen on MRI scans that show bleeds in the brain. These bleeds are usually small. They are often referred to as microbleeds or microhemorrhages. Some people can have larger areas of bleeding. In the Clarity AD trial, ARIA-H occurred in 17.3% of those given Leqembi and in 9% of those given a placebo. The finding that 9% of individuals on placebo had bleeding re-confirms the well-known finding that Alzheimer's disease can cause microbleeds in the brain. Only 0.7% of patients given Leqembi had symptoms from ARIA-H.

### ApoE ε4 and Risk of ARIA-H with Leqembi

- **Two copies of ApoE ε4:** 39% (0% with symptoms)
- **One copy of ApoE ε4:** 14% (1% with symptoms)
- **No copies of ApoE ε4:** 11.9% (0.4% with symptoms)

### ARIA-E

ARIA-E refers to swelling in the brain caused by fluid leakage from blood vessels. In the Clarity AD trial, 12.6% of participants treated with Leqembi developed ARIA-E, compared to 1.7% of participants given placebo. Only 2.8% of individuals who developed ARIA-E had symptoms from it.

### ApoE ε4 and Risk of ARIA-E with Leqembi:

- **Two copies of ApoE ε4:** 32.6% (9.2% with symptoms)
- **One copy of ApoE ε4:** 10.9% (1.7% with symptoms)
- **No copies of ApoE ε4:** 5.4% (1.4% with symptoms)

### Monitoring and Management

- **Genetic Testing:** Testing for the ApoE ε4 gene is required before starting treatment. This allows you and your healthcare provider to assess your risk of ARIA.
- **MRI Scans:** Patients will have brain MRI scans done before the 5th, 7th, and 14th infusions to check for any signs of ARIA-H or ARIA -E.
- **Follow-up:** Regular monitoring and adjustments in treatment will be managed by your healthcare provider based on your health and response to treatment.
- **Emergency:** Immediate medical attention should be sought if any of the symptoms listed above develop.

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