

# Aducanumab Frequently Asked Questions

The news regarding FDA approval of Aducanumab is a positive step towards offering more options for treating **early** stage Alzheimer's disease (AD). We understand that many of our patients and families have questions regarding this exciting news. Please see below FAQ's, for better understanding of what to expect with the FDA approval of Aducanumab.

## What is Aducanumab/Aduhelm?

- Aducanumab or Aduhelm is a new medication given by intravenous (IV) infusion once a month. It does not come in pill or injection forms.
- It is an antibody that binds and removes amyloid plaques from the brain. Plaques are increased in the brains of those suffering from Alzheimer's disease.
- Aducanumab is the first treatment the FDA has approved that targets these plaques.
- It is approved for use with persons who have been diagnosed with **mild cognitive impairment (MCI)** or **early stage dementia who have evidence of amyloid plaques in their brains.**
- It has not been shown effective for individuals in the moderate to severe stages of Alzheimer's disease.
- Aducanumab is not a cure for Alzheimer's Disease but **may** help slow the progression of the disease.
- In the research studies conducted, results indicate a 1-2 point reduction in Alzheimer's Disease symptoms compared to placebo.

## Has Aducanumab been approved by the Food and Drug Administration (FDA)?

- Yes, the FDA announced on June 7, 2021 that they have approved the drug on a provisional basis.
- Provisional basis means that the FDA has directed Biogen to continue research studies to make sure this medication shows clinical benefit for patients, and that it is safe when given to a large number of individuals.
- These requirements by the FDA are in place because there are still questions about the effectiveness of this medication. We will learn more as these studies are completed.

## How will I receive Aducanumab treatments if I am a candidate?

- Aducanumab is administered as an intravenous (using a small catheter in the arm) infusion at a specialized infusion center once a month.
- The infusion is administered over 1-2 hours each month.

## How safe is aducanumab?

- People receiving these medications may develop minor or severe allergic reactions and need to be monitored closely during the first few infusions.
- Aducanumab studies show that around 4 in 10 subjects developed small bleeds or swelling in the brain. For most subjects, these side effects did not cause significant symptoms, however, some had headache, confusion/delirium, dizziness, and nausea.
- More serious symptoms were noted in 0.3% of patients. Symptoms resolved in 88% of the subjects. Therefore, **multiple brain scans (MRI) are done while receiving this medication to monitor for bleeding and swelling in the brain.**

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### **How do I know if I am a candidate to receive Aducanumab?**

- We don't yet know all of the criteria that will be required for patients to be eligible to receive Aducanumab.
- The medication was tested in individuals in the **early** stage of Alzheimer's disease (mild cognitive impairment or early dementia), and will likely be restricted to such patients.
- There must be proof of the presence of amyloid plaques in the brain (confirmed either by a specialized scan called Amyloid PET scan or by evaluation of cerebrospinal fluid (through a spinal tap).
- Patients will be required to undergo multiple MRI scans to monitor for any changes while receiving this medication.

### **When and where will Aducanumab be available at Emory Healthcare?**

- There are multiple additional steps needed before it becomes available to patients, and many of them are outside of Emory Healthcare's control.
- Emory Healthcare and our clinic are currently developing our workflow and determining locations where it will be administered.
- We anticipate the processes to **take several months** before it is readily available to be administered.

### **How much will Aducanumab cost?**

- The cost of the medication for a year of monthly infusions is estimated to be \$56,000 per year.
- Additional costs include the infusion center time and supplies, multiple brain scans, clinical evaluations, and laboratory evaluations.
- Medicare and other health insurance carriers have not yet announced decisions about coverage, so currently, there is no coverage. We are actively seeking information about potential insurance/Medicare coverage.

### **Is there a waitlist to receive Aducanumab infusions at Emory?**

- Currently we do not have a waitlist. We are actively working through processes to ensure we can offer Aducanumab in the future, in the most cost-effective, safe and efficient manner to our patients. Eligible candidates will be contacted in the future.

We hope to have more detailed information to provide our patients in the coming weeks. As always, we appreciate your commitment to being an Emory Healthcare patient, and we thank you for working with us to find a cure for Alzheimer's disease. We look forward to an even brighter future for our patients and families.

### **Additional Resources**

**Goizueta Alzheimer's Disease Research Center – BrainTalk Live Aging Alzheimer's & Aducanumab Virtual Town Hall:** Learn more about the specific info about the pros and cons of Aducanumab, the target population, our center's participation as a site, drug delivery, and how Emory is addressing the rollout of Aducanumab.

View Townhall here: [Aging, Alzheimer's and Aducanumab](#)

**View the Alzheimer's Association "Dialogue: Current Perspectives on Aducanumab"** webinar to understand more about the science behind Aducanumab, clinical trial results, biomarkers and the perspectives of individuals with Alzheimer's and their care partners.

Link to webinar: [https://www.alz.org/research/for\\_researchers/grants/research-webinar](https://www.alz.org/research/for_researchers/grants/research-webinar)

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