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.**

(OVER)

How do I know if I am a possible candidate 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 MRI brain scans and cognitive testing prior to initiating infusions and to monitor for any changes while receiving this medication.

How much will Aducanumab cost?

- The cost of the medication for a year of monthly infusions was recently (December, 2021) dropped from $56,000 per year to $28,200 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 final decisions about coverage, so currently, there is no insurance coverage. In early January 2022, Medicare announced a preliminary coverage determination. The proposal is to cover aducanumab in the context of new clinical trials that seek to understand how helpful it may be for Medicare beneficiaries. This is a preliminary announcement and the final coverage determination is expected in April 2022. Until this occurs, exact out of pocket costs remain unknown. Similarly, it is not clear how these new clinical trials would be organized, who would organize them, or whether Emory would be a participating site.

When and where will Aducanumab be available at Emory Healthcare?

- Emory Healthcare recently (December, 2021) decided not to add aducanumab to its pharmacy formulary. This means that aducanumab will not be available for infusion within the Emory Healthcare system. This decision was based on review of all available data on aducanumab including the amount of benefit to patients, safety and risk of side effects, and value/cost to patients. This decision may be revisited in the future if additional data becomes available. Several other hospital systems also decided not to place aducanumab on the formulary including Cleveland Clinic, Massachusetts General Brigham, Mount Sinai, and Veterans Affairs Hospitals.

Is there a waitlist to receive Aducanumab infusions at Emory?

- Currently we do not have a waitlist. Since Emory Healthcare will not have aducanumab on formulary, we will not have a process for administering aducanumab infusions to our patients within the Emory Healthcare system. Once there is more information about insurance coverage, our team will determine if there are options for referring eligible patients to external facilities for aducanumab infusions.

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

<u>Additional Resources</u>

(OVER)

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

(OVER)