

Frequently asked questions about the newly approved Alzheimer's drug, Aduhelm™ (aducanumab)

Is this drug a cure for Alzheimer's disease?

No. This medication, marketed under the name Aduhelm™, is not a cure. It does not reverse damage already caused by Alzheimer's disease, nor does it completely stop the disease. Aducanumab works to slow the progression of Alzheimer's and is called a disease-modifying drug.

How does aducanumab work?

Persons with Alzheimer's disease develop deposits (called plaques) of a protein in the brain called beta-amyloid. The buildup of beta-amyloid plaques is thought to be related to the cognitive impairment seen in Alzheimer's disease. Aducanumab is a monoclonal antibody which is a class of medications that are used to treat other neurological disorders. It works to remove plaques from the brain.

How well does aducanumab work?

Aducanumab was evaluated in two large studies. In one of the studies, high doses of Aducanumab slowed the rate of cognitive decline in patients with Alzheimer's disease. It did not make a difference in the second study. In both studies though, aducanumab reduced the number of beta-amyloid plaques.

These studies were done in a highly selected group of mildly impaired patients.

It is not clear how much benefit the drug will have in routine use. Researchers believe that reducing the amount of beta-amyloid plaques should reduce the rate of cognitive decline, but this has not been proven.

What patients and their families are interested in is the 'real world' benefit of treatment, namely, allowing a person with cognitive deficits to remain relatively stable for as long as possible. Evidence suggesting a benefit was required for the FDA to approve this drug. However, the extent of this benefit remains to be determined especially in patients with advanced disease.

As a result, the FDA has approved aducanumab for patients with mild cognitive impairment and early stage Alzheimer's dementia. The FDA is also requiring the pharmaceutical company to conduct another study, after the drug is released, to better clarify the benefits of this drug.

How is this medication given?

It is given once a month through a needle in your arm (IV or Intravenous needle) in an outpatient setting. A specially trained treatment team will give the medicine and watch for possible side effects.

Are there side effects of aducanumab?

Yes. Some potential serious side effects are brain swelling and small micro-hemorrhages or bleeds. These complications are more likely to occur at higher doses of the medication. Other common adverse reactions are headache, and falls. Patients receiving aducanumab need to have a baseline MRI scan and periodic follow up scans. Patients are also

monitored for any allergic reactions that can occur as part of the infusion.

Who can try this medication as a treatment option?

Aducanumab was most helpful in patients with mild impairment due to Alzheimer's disease. There are many causes of cognitive impairment and patients with cognitive impairment due to other causes, like vascular dementia for example, will not benefit from this treatment.

A diagnosis of Alzheimer's disease requires a careful clinical examination that can include taking an extensive history of the patient, reviewing their medical conditions, conducting a neurological examination, cognitive testing, and brain imaging. Brain imaging helps to rule out other conditions such as stroke which may cause cognitive impairment. An MRI is one type of brain scan that is required before starting the medication and periodically during therapy.

Specialized brain scans, such as an amyloid PET scan, can identify the presence of amyloid plaques in the brain. These specialized scans may be required in some cases to help confirm the diagnosis of Alzheimer's disease.

When will this medication be available?

While the drug has been approved by the FDA, it is not yet available to patients. The timeline for the drug to be made available by the drug company is not yet clear. It could be several months.

Will patients be able to get aducanumab at the Alzheimer's Disease Research Center (ADRC)?

No. Eventually the drug will be available at various specialty treatment centers but the ADRC, as a research center, will not be a provider of aducanumab treatment.

In the meanwhile, our partners at UPMC are setting up a process so that interested patients can be evaluated and, if appropriate, start treatment. The ADRC website will be updated as more information becomes available.

Is this an expensive treatment for patients?

Right now, information regarding the cost of the therapy is still uncertain. So far, the proposed cost of the medication by Biogen is \$56,000 per year. However, there will be additional costs associated with ancillary studies (such as the cost of the MRI scans, blood tests, the cost of the infusion). It is not known at this time how insurance companies will handle authorization for this medication.

Can patients on current symptomatic therapies (e.g., Aricept®, Namenda®) continue using them during the administration of Aducanumab?

Yes, patients may continue their current medications, there is no interaction between these treatments and aducanumab