



Evidence in Focus:

# Aducanumab Use in Symptomatic Alzheimer Disease

# **Q&A** for Patients and Families

Aducanumab is the first drug approved by the Food and Drug Administration to treat some of the underlying brain changes associated with Alzheimer disease. Studies have shown that this drug helps remove amyloid-B plaques from the brain, one substance thought to play a role in the development of Alzheimer disease. However, we still do not know what effect aducanumab has on symptoms related to Alzheimer disease. One study showed that patients receiving this medication had slightly slower rates of memory decline (than patients receiving a placebo), while another study failed to show such an effect.

Aducanumab is intended for patients with relatively mild memory problems—not patients with moderate-to-severe problems. Side effects are common with aducanumab use, and patients taking this drug will need to be monitored often for side effects. Aducanumab is a new drug, so what to expect with long-term treatment is unknown.

If your clinician suggests that you consider using aducanumab, the following questions and answers may help quide your discussions.

#### How does aducanumab work?

 Aducanumab removes amyloid-β plaques from the brain. Accumulation of amyloid-β is thought to play a role in the development of Alzheimer disease and memory problems (mild cognitive impairment or dementia) due to Alzheimer disease.

#### Who should use aducanumab?

- The Food and Drug Administration approved aducanumab only for people with brain changes due to Alzheimer disease who are at the mild cognitive impairment or initial stages of dementia. Mild cognitive impairment is when a person's memory is worse, but they can still do day-to-day activities on their own. Dementia is when a person's memory and thinking are more severely affected, and the person needs help with day-to-day activities. Dementia is often thought of as occurring in older adults; however, it can occur in younger adults as well (young-onset dementia).
- The Food and Drug Administration did not specify who should not receive aducanumab. However, studies of aducanumab did not include:
  - People with dementia that is not related to Alzheimer disease
  - People who take blood thinners or have a history of bleeding disorders, brain bleeding, or stroke

Also, traditionally underrepresented minority groups were not well represented in the studies.

## Aducanumab Use in Symptomatic Alzheimer Disease —continued

## How is aducanumab given?

- Aducanumab is given through a process called intravenous infusion during which the medicine is slowly given through a needle that is inserted into one of your veins. Aducanumab infusion usually takes one to three hours.
- Infusions are given every month. To reduce the chance of side effects, the dose of this medication is gradually increased over the first seven to eight treatments to reach the target dose of 10 mg of medication per kilogram of weight.

### What are the side effects of aducanumab?

- Up to 40 percent of patients receiving aducanumab may develop brain swelling or bleeding. In most patients, this brain swelling or bleeding was identified on routine brain imaging and did not cause symptoms. One fourth of patients with these brain changes had mild symptoms, most commonly headache. A smaller number of patients had more severe symptoms and signs (confusion or weakness), requiring the patients to be hospitalized.
- In most patients, symptoms of brain swelling or bleeding went away when the medication was stopped. A small number of patients had severe swelling and experienced persistent side effects (weakness, confusion) even after the medication was stopped. One patient died from brain swelling and bleeding thought to be caused by this medication.
- Your clinician may ask you to have routine brain MRIs, one before treatment and at least two during the first year after starting this medication, to look for brain changes that may suggest swelling or bleeding.

#### How much does aducanumab cost?

- In the United States, aducanumab is expected to cost about \$28,000 per year (for a person of average weight).
- These drug costs do not include the costs for the hospital visits when the procedure is done, the costs of physicians who give the medications, the clinic visits to monitor the treatment, or the cost of brain MRIs that need to be done while this drug is being given. When these costs are included, the yearly cost of treatment may be as much as \$75,000 or more.

## How long do you need to take aducanumab?

- In the studies of aducanumab, it was given for up to 1.5 years.
- We do not know how long aducanumab should be administered or how to decide when to stop it.
  Studies are being done to answer these questions.

## Do insurance companies pay for aducanumab?

- Each insurance company has different policies about paying for aducanumab.
- Because not all clinics offer aducanumab, you may have to pay extra costs (out-of-network costs, travel expenses, additional lost work time) if the treatment center you need to use is not in your insurance company's provider network or is far from where you live.

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