Drug FAQs for Members
FREQUENTLY ASKED QUESTIONS

Aducanumab (Aduhelm) and Alzheimer's Disease

In June 2021, aducanumab (also known as Aduhelm) was approved by the U.S. Food and Drug Administration (FDA) for the treatment of Alzheimer's disease. This disease is a progressive brain disorder that slowly destroys a person's memory and thinking skills. Over time, the effects of the disease may become severe enough that a person cannot perform even simple tasks causing them to become dependent on caretakers.

The exact cause of Alzheimer's disease is not fully known. Changes in the brain occur that lead to a loss of nerve cells and their connections. These changes include the presence of beta-amyloid plaques (abnormal clusters of protein between nerve cells) and neurofibrillary tangles (dead or dying nerve cells twisted with another protein called p-tau). While there are no studies to prove this theory, scientists believe that preventing buildup of p-tau plaques may slow or delay the symptoms of Alzheimer's disease. It is important to note that the accumulation of beta-amyloid after onset of symptoms does not associate with a decline in a person's memory and thinking skills.

Aducanumab is not a cure for Alzheimer's disease and has not been shown to improve memory or function. The drug reduces beta-amyloid in the brain. The link between reduction of beta-amyloid and a clinical benefit has yet to be proven even though it has been widely studied. Aducanumab is not without significant safety risks; 30% to 40% of patients developed brain swelling and bleeding after only 12 to 18 months of treatment.

What are the current treatments for Alzheimer's disease?

- There is no cure for Alzheimer's disease.
- Treatments include drug and non-drug options that help treat symptoms.
  - Medicines used to help with memory and thinking symptoms include cholinesterase inhibitors (donepezil, rivastigmine, and galantamine) and N-methyl-D-aspartate antagonists (memantine).
  - To help with behavior changes, non-drug approaches are preferred.
  - Physical activity and behavior targeted therapy are some non-drug strategies used in the care of people with Alzheimer's disease.
- Lifestyle changes to reduce the risk of Alzheimer's disease include regular physical exercise, keeping mentally active, healthy eating, and controlling risks for cardiovascular disease (such as high blood pressure, diabetes, and high cholesterol).

How does aducanumab work?

- Aducanumab reduces the beta-amyloid plaques in the brain.
- The removal of beta-amyloid plaques has not been proven to slow or delay the symptoms of Alzheimer's disease, even though it has been widely studied.

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Is aducanumab effective for Alzheimer's disease?

- Aducanumab is not a cure and has not been shown to improve memory or function. The drug reduces beta-amyloid in the brain. The link between reduction of beta-amyloid and a clinical benefit has yet to be proven.
- Aducanumab has only been studied in patients with early or mild Alzheimer's disease with confirmed beta-amyloid plaque in the brain.
- There are no high quality studies showing that aducanumab is effective. There is also potential for significant harm with aducanumab.

What are the safety concerns associated with aducanumab?

- There is significant concern about the safety of aducanumab due to brain swelling and bleeding that were noted in 30% to 40% of the patients studied.
    - Patients treated with aducanumab will need brain magnetic resonance imaging (MRI) occasionally while on treatment to monitor for brain swelling and bleeding.
- The most common adverse events reported with aducanumab in clinical studies were brain swelling and bleeding, headache, falls, diarrhea, and confusion/altered mental status.
- Serious allergic reactions may occur during the infusion of aducanumab. Swelling of the face, lips, mouth, or tongue and hives have been reported.

How is aducanumab given?

- Aducanumab is given as an intravenous (through a vein) infusion over one hour every four weeks.
- The dose of aducanumab is increased over the first six infusions until the recommended dose is reached starting with the seventh infusion and beyond.
- Brain MRIs are needed to monitor for the brain swelling and bleeding than can occur.

Kaiser Permanente doctors are committed to prescribing medications that show evidence of safety and effectiveness. We continue to review new evidence from clinical studies to help us determine how to best use a medication.