

https://www.statnews.com/2021/06/07/faqs-what-you-need-to-know-about-the-alzheimers-drug-aduhelm/?utm_campaign=rss

Alzheimer's drug controversy -aducanumab (Aduhelm)

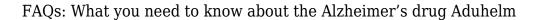
Decent summary can be found here -> <u>F.D.A. Approves Alzheimer's Drug Despite Fierce</u>

<u>Debate Over Whether It Works (msn.com)</u>

Patient information - It's a New Day | Aducanumab Approved for Treatment | alz.org

- FDA recently approved aducanumab for treatment of AD

- Trials specifically enrolled patients with <u>early</u>memory changes and abnormal beta amyloid seen on brain scans.
- MRI will likely be required before starting the drug and intermittently during therapy.
- The drug attempts to reduce beta amyloid accumulation in the brain. It is thought that beta amyloid may be a significant component to the development of AD and other dementias. That theory has come under fire in recent years because other drugs reducing beta amyloid production have not shown enough efficacy for FDA approval. There are other proteins that appeared to, potentially, be more important than beta amyloid
- No specific indication was given but it MAY have some efficacy in early disease.
- It MAY prevent the speed of progression.
- Controversy exists because the data are not very impressive.
- FDA is requiring a phase 4 trial along with the approval and reserves the right to resend





its approval depending on the data from this trial.

- Side effects (Aduhelm (aducanumab) dosing, indications, interactions, adverse effects,
 and more (medscape.com))
 - o ARIA-E (amyloid-imaging abnormalities- Edema) = Brain swelling or bleeding $\sim 40\%$. Most were asymptomatic. Requires monitoring.
 - o Headache 21%
 - o Microhemorrhages 19%
 - o Superficial siderosis 15%
 - o Falls 15%
 - o Confusion/delirium/altered mental status/disorientation 8%
 - o Diarrhea
- More to come.....