August 10, 2021

WHAT YOU NEED TO KNOW ABOUT

Alzheimer's Treatments

PRO POINTS

- **In early June 2021, the Food and Drug Administration** approved Aduhelm, a drug intended to treat Alzheimer's disease.
- **The approval was met with controversy because** critics say the drug's benefits are unproven, and the FDA is requiring drugmaker Biogen to conduct additional trials after approval.
- **Aduhelm's potential $56,000 annual price tag also** raised fears it would quickly become one of Medicare's most expensive treatments overall.
- **The federal health agency's internal watchdog** announced an investigation into the accelerated approval process that led to the drug's controversial green light.

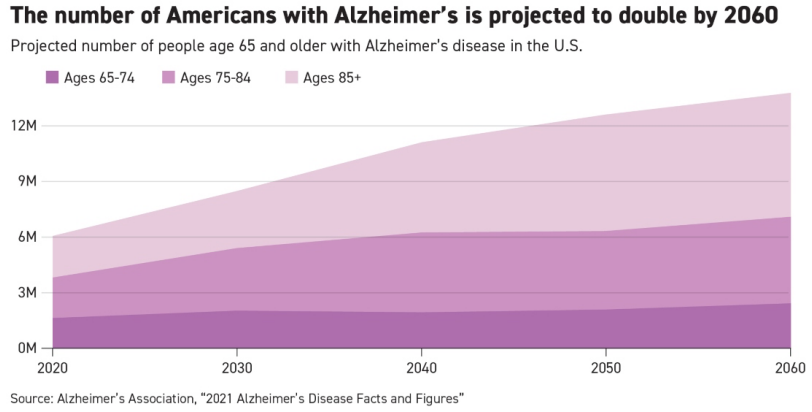
HOW WE GOT HERE

The FDA announced on June 7, 2021 that it would approve Aduhelm, also known by its generic name aducanumab, a treatment that aims to slow the progression of Alzheimer's disease by reducing the buildup of deformed proteins in the brain.

The approval was met with fanfare by patient advocates such as the Alzheimer's Association, but it was also criticized by outside experts who argued that there is little evidence that removing the plaque buildup in the brain actually slows or stops a person's cognitive decline. An FDA panel found in November 2020 that the agency lacked strong evidence for the drug's efficacy, and three advisors to the FDA resigned after the drug's approval.

The initial $56,000 annual price tag per person proposed by the drugmaker Biogen raised fears that the drug could quickly become one of Medicare's most expensive line items, with cost estimates ranging from $6 billion to $29 billion in a single year.

Approximately 6 million Americans have Alzheimer's, including more than 2 million on Medicare who use available treatments covered under Part D. Because Aduhelm is administered as an IV infusion by a physician, it would instead be covered by Medicare Part B.



WHAT'S NEXT

Following criticism, the FDA narrowed the label for Aduhelm, saying the drug should only be used on patients with mild cognitive impairment or early dementia, a significantly smaller pool of potential patients.

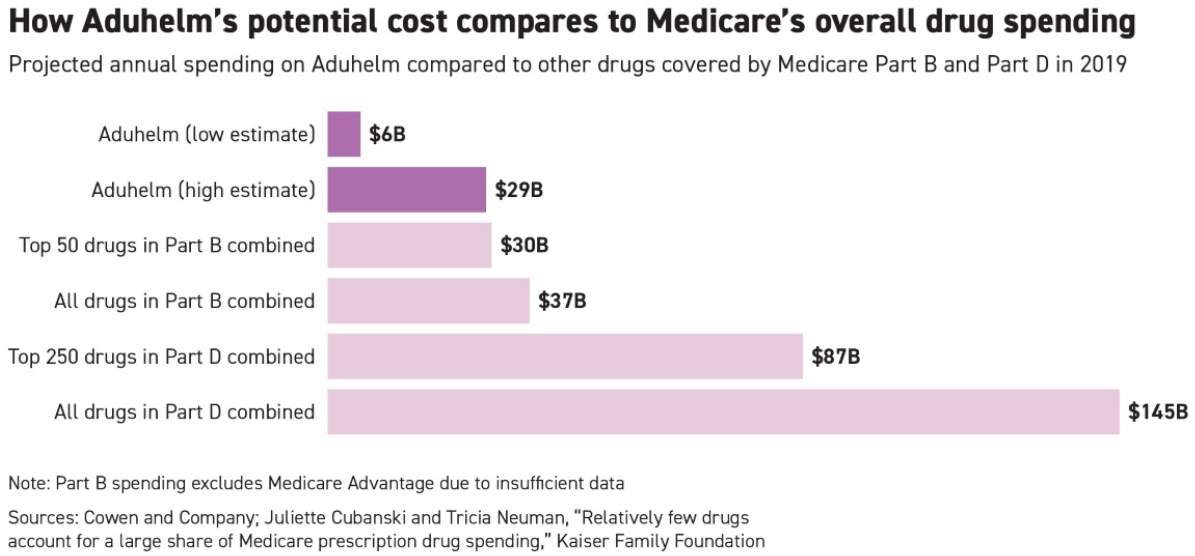
The FDA approval is contingent on the outcome of a post-marketing clinical trial it has asked Biogen to conduct, with

results not expected until 2029. But the drug's approval could mean ethical and practical problems for the trial, however, in part because recruited patients might simply choose to get a normal prescription rather than risk receiving a placebo in the trial.

Biogen is also voluntarily conducting an observational study on those who receive the drug with no placebo group, and it's continuing some of its Phase III trials on the drug to see the long-term effects.

In an unusual step, the Centers for Medicare and Medicaid Services began a National Coverage Determination to decide whether the drug is "reasonable and necessary," calling into question whether Medicare will be required to pay for it. Major providers and insurers in the private sector have also declined to administer or cover the drug pending further reviews.

After reports surfaced accusing the FDA of having a close relationship with the drugmaker and patient advocates, the Department of Health and Human Services' internal watchdog announced that it would investigate the accelerated process that led to the drug's approval.



POWER PLAYERS

- **Janet Woodcock:** A longtime agency official who became President Joe Biden's acting FDA commissioner. She has remained in the position for months while Biden struggles to nominate a successor who will pass muster in a closely divided Senate.

- **Biogen:** The biopharmaceutical company behind the new treatment is already an industry giant, with more than $13 billion in annual revenue.

- **The Alzheimer's Association:** As one of the leading advocates for patients with the disease nationwide, the association celebrated the drug's approval but also criticized the price point. It is one of the largest, single-disease advocacy groups in the country, and has received some of its funding from some pharmaceutical companies, including Biogen.

- **Centers for Medicare and Medicaid Services:** This agency within HHS sets policy for the nation's largest health safety-net programs, and its post-approval review could limit the use of Aduhelm and set precedent for private payers.