Medicare covers new Alzheimer's drug, but there is a catch

The federal health plan for older Americans will pay for the controversial new drug aducanumab only for patients participating in clinical trials. Susan Jaffe reports.

The Biden administration's long-awaited decision to pay for a controversial new Alzheimer's disease treatment, aducanumab, will not make it easier for many older Americans with Medicare health insurance to get it.

The federal Centers for Medicare & Medicaid Services (CMS), which administers the Medicare programme, will cover aducanumab (also known as Aduhelm) only for Medicare patients in the early stages of disease who participate in a randomised trial and meet other criteria. The unusual conditions follow intense criticism of the US Food and Drug Administration (FDA), which granted aducanumab an accelerated approval in 2021 over the objections of its advisory committee.

Last year, Biogen, the drug's manufacturer, slashed the price of an annual course of treatment by 50% (down from $56 000). But even this step has not helped patients access the drug, which is administered intravenously. About 6 million Americans have Alzheimer's disease and, without treatment, this number is expected to reach 14 million by 2060.

"While the cost of Aduhelm has been dramatically reduced, we continue to observe only small amounts of Aduhelm being purchased by our members", said Steven Lucio, Senior Principal for Pharmacy Solutions at Vizient, which negotiates contracts for medical supplies for more than half of hospitals in the USA. "We believe that most hospitals and providers are continuing a 'wait and see' approach for more efficacy evidence before fully adopting the medication as well as waiting for additional development of other drugs in this space," he said.

The CMS announcement has failed to persuade some top academic health systems to offer aducanumab to their Medicare patients, including the Cleveland Clinic, University of Michigan medical centre, and Johns Hopkins Health System. Keck Medicine, at the University of Southern California, based their refusal "on the relative lack of evidence supporting a clinically meaningful benefit and the known potentially serious safety concerns", said Chief Pharmacy Officer Krist Azizian. The Department of Veterans Affairs, which provides health care for 9 million military veterans, is also not offering the drug.

> "'....you should prove that there is meaningful benefit before you approve a drug...'"

However, the Mount Sinai Health System in New York, which was hesitant to provide the drug following FDA approval, supports the CMS decision "and looks forward to offering safe, meaningful therapeutic options to Medicare patients with Alzheimer's disease and related disorders", including aducanumab, said a spokesperson.

For CMS to pay for the drug, it must be provided to Medicare patients in randomised, placebo-controlled clinical trials to determine whether it slows cognitive decline and provides an overall clinical benefit. Investigators must include study participants who are representative of the Medicare population, including geographical, racial, and ethnic diversity. Participants must also have a diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia and have evidence of amyloid pathology, among other requirements. CMS will then pay most of the cost, with patients paying the rest.

Aducanumab received fast-track approval by the FDA under a 2012 federal law to increase access to drugs for diseases that had little or no treatment options. Instead of evidence of clinical improvement, the FDA relied on aducanumab's effect on a surrogate biomarker: its ability to reduce amyloid β plaque in the brain. However, there is no clear consensus on whether amyloid is a factor in cognitive decline. "CMS is creating a reliable pathway to Medicare coverage for any monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease that meets the coverage criteria," said a CMS spokesperson.

Those criteria reinforce the principle "that you should prove that there is meaningful benefit before you approve a drug and that you don't necessarily rely on a biomarker that is known not to be reliable" said Samuel Gandy, Director of the Mount Sinai Center for Cognitive Health.

But Harry Johns, Chief Executive Officer of the Alzheimer's Association, argues that CMS lacks legal authority to add restrictions to FDA-approved Alzheimer's treatments. "People living with mild cognitive impairment, Alzheimer's disease, or other dementia deserve the same access to therapies given to those living with other conditions like cancer, heart disease, and HIV/AIDS," he said. "They deserve the opportunity to assess if an FDA-approved treatment is right for them."

Medicare's 63 million beneficiaries are already paying for aducanumab in the form of record high monthly premiums, which cover their share of anticipated medical and drug expenses. AARP, which advocates on behalf of older Americans, wants CMS to roll back the premium increase because Biogen cut its price and fewer Medicare patients might receive it due to coverage restrictions.

Susan Jaffe

For more on the **CMS coverage decision** see https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx

For more on **aducanumab's approval by the FDA** see **Article** *Lancet* 2021; **398:** 3–9