Medicare proposes to only cover Alzheimer's drug aduhelm for use in clinical trials

January 12 2022, by Ernie Mundell and Dennis Thompson

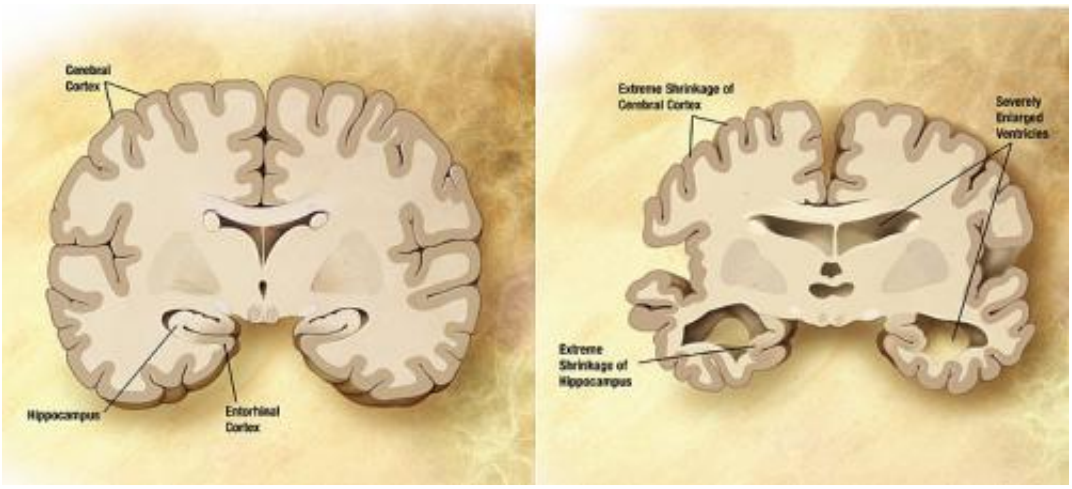

Diagram of the brain of a person with Alzheimer's Disease. Credit: Wikipedia/public domain.

(HealthDay)—It's a move that could severely limit the number of people taking the controversial new Alzheimer's drug Aduhelm: Medicare on Tuesday proposed to only cover the cost of the pricey medication for people enrolled in approved clinical trials.

A final decision on coverage is expected later this year.

The drug costs $28,200 per year, but that cost will only be covered for participants in randomized, controlled trials approved by the Centers for Medicare & Medicaid Services (CMS), the agency said in a statement, or

"in trials supported by the National Institutes of Health [NIH]. All trials must be conducted in a hospital-based outpatient setting."

The announcement comes after a months-long and unprecedented review. The benefits of Aduhelm (aducanumab) have been in question since it was approved by the U.S. Food and Drug Administration in June, when its maker, Biogen, had set a price tag for the drug at $56,000 per year.

CMS tends to cover with little fanfare most drugs approved by its sister agency, the FDA.

However, the FDA's approval of Aduhelm sparked a firestorm of criticism because clinical trials showed no clear improvement in patients' brain function, plus a host of safety concerns.

Proponents such as the Alzheimer's Association argue that Aduhelm's success could pave the way for even better treatments for the degenerative brain disease. It's the first drug ever approved to treat Alzheimer's.

"It's always been a progression from first treatments that weren't by any means all that we hoped for, but were an important first step leading to progressive advances treatment by treatment as we learned more and we had further research and development," said Robert Egge, chief policy officer for the Alzheimer's Association. "That's the path we see before us for Alzheimer's disease."

Critics counter that CMS has been put in the awkward position of rectifying a grave error made by the FDA when it approved Aduhelm based on shaky evidence.

"The drug, given the available evidence, provides false hope to

Alzheimer's disease patients and their families," said Dr. Michael Carome, director of Public Citizen's Health Research Group. "The right decision for CMS is to not cover the drug until there's sufficient evidence that the drug works."

Cost and equity issues

Medicare coverage would have thrown a lifeline to Aduhelm, which has been struggling to find its place in the pharmaceutical market.

A number of major health systems—the U.S. Department of Veterans Affairs, Cleveland Clinic, Mount Sinai and Mass General—have already said they will not offer Aduhelm to patients. Following weak sales, Biogen slashed the drug's annual cost in half last month.

Critics remained concerned that, even at $28,000 per year, Aduhelm could still bankrupt Medicare and place a huge financial burden on families desperate for anything to help aging relatives struggling with Alzheimer's.

Medicare patients are already feeling the financial strain from Aduhelm, Carome noted.

Medicare premiums for 2022 rose by about 15%, and CMS cited its potential coverage of Aduhelm as one reason for the hike. However, those projections may be rendered obsolete if Medicare limits coverage of Aduhelm.

Aduhelm's cost isn't limited to its sticker price, Carome added.

Patients receive Aduhelm through an IV infusion, which requires staffing and space at either a hospital or clinic. They also need regular MRI scans to make sure the drug hasn't caused any harmful side effects.

The costs that would "fall on Medicare and patients go far beyond the drug itself," Carome said.

Narrowed access

To such concerns, the Alzheimer's Association's Egge responded that steps have already been taken to limit Aduhelm's financial impact on Medicare and families.

Shortly after issuing its approval, the FDA narrowed Aduhelm's label so that only patients with early and mild Alzheimer's should be treated with the drug. That, on top of Biogen's price cut, would have an impact on the cost to Medicare, Egge argued.

Further, he believes treatments like Aduhelm are needed to head off the fiscal crisis Medicare already faces from an aging population falling prey to cognitive decline.

"Alzheimer's and other dementias already put a tremendous strain on the Medicare system, as well as Medicaid. That impact has been profound for years," Egge said. "If you look at it from a fiscal impact, on not just families and family balance sheets but the federal government and state government and their balance sheets, there's been a tremendous strain."

The threat of Medicare bankruptcy is already here, Egge said, and the only path to changing that is through treatments.

More access, more risks?

But Medicare coverage of Aduhelm might also expose more patients to health dangers, opponents countered.

The biggest concern is that there will be more health issues and deaths "if aducanumab is released into the wild of normal clinical practice," said Dr. Michael Greicius, medical director of the Stanford Center for Memory Disorders.

He cited the risk of potentially deadly brain bleeding and swelling found in clinical trials.

It's likely that patients treated outside the rigors of a clinical trial won't receive the regular MRIs needed to spot these dangerous side effects, Greicius said.

"A lot of these imaging complications that we saw in the trial like brain swelling I think in a lot of cases won't get picked up pre-symptomatically on a screening MRI," Greicius said. "They'll get picked up late, when people are already symptomatic."

The FDA's approval of Aduhelm was based on data from two nearly identical trials that were shut down early in 2019 because independent monitors concluded the drug wasn't helping patients.

Aduhelm *does* clear brain-clogging amyloid beta proteins from patients' blood. Amyloid is a protein that clumps together in the brain, and amyloid plaques are considered a hallmark of Alzheimer's.

However, the two trials split when it came to any benefit to patients in terms of reduced symptoms. Clearing amyloid from the bloodstream didn't seem to make any difference in patients' brain function in one trial, but on further analysis, researchers found a slight slowing of mental decline in patients receiving the highest dose of Aduhelm.

More clinical trials

Both Carome and Greicius agreed that by offering a limited approval—one that would only cover Alzheimer's patients who enroll in clinical trials for the drug—CMS might help resolve the controversy surrounding the drug.

As part of its approval, the FDA required Biogen to conduct a post-market clinical trial, but the company has nine years to complete it, Carome said. Using Medicare coverage to spur a third clinical trial could settle the matter more quickly, he believes.

"It would be great if they said we're going to cover it for a randomized placebo-controlled trial," Greicius said. "It would give everybody the information that we need."

But Egge said the Alzheimer's Association wouldn't favor such a move, because it would severely limit access to Aduhelm.

Only the well-heeled or health-system-savvy would be able to get into a third trial, which would "almost certainly increase health inequities," he said.

"In general, the more restrictive we are on access, it's those with financial resources who can still find a way to get treatment," Egge said.

For its part, Biogen issued a statement Tuesday that said the new proposal from CMS "denies the daily burden of people living with Alzheimer's disease," adding that the clinical trial requirement "will exclude almost all patients who may benefit," *The New York Times* reported.

The CMS proposal on coverage now enters a 30-day period of public comment. A final decision is expected sometime in April.

More information: The U.S. Centers for Medicare and Medicaid Services has more on its review of Aduhelm.