HEALTH CARE NEWS

# Medicare Limits Payment for New Alzheimer's Drug

By Kevin Stone

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The Centers for Medicare and Medicaid Services (CMS) will only cover Aduhelm, a drug to treat Alzheimer's disease, for patients enrolled in clinical trials.

The CMS announced its decision on April 7, nearly a year after the U.S. Food and Drug Administration (FDA) approved Aduhelm under its "accelerated approval pathway." The FDA gave the drug the green light despite objections from 10 of the 11 members on its advisory panel, who said Aduhelm had failed to demonstrate efficacy.
One of the trials showed patients receiving high doses of the drug fared better than those receiving placebo, the drug's developer, Biogen Inc., announced in October. The other trial found no meaningful benefit.

The CMS approval was controversial because it could open the door for Medicare to cover a drug with questionable efficacy that has a significant price tag. An estimate of the minimum cost to Medicare if the drug were approved for widespread use is $29 billion annually or about $56,000 a year per Alzheimer's patient.

**Decision Applies Broadly**
The CMS's requirement for enrollment in an approved randomized controlled trial applies to all beta amyloid-directed monoclonal antibody treatments, not just Biogen's, indicating concern over this approach as an effective treatment of Alzheimer's.

The decision is a precedent against general Medicare coverage of therapies given accelerated approval by the FDA, Michelle McMurry-Heath, president and CEO of the Biotechnology Innovation Organization, said in a statement.

"With this decision, CMS is not just saying it has no confidence in Alzheimer's drugs approved under the FDA's accelerated approval pathway," said McMurry-Heath. "It also is undermining confidence in FDA's traditional drug approval process more broadly."

**FDA Process Delays Access**
The Medicare decision was correct, but the FDA approval is flawed, says Jeffrey A. Singer, M.D., a senior fellow at Cato Institute.

"I think CMS made the right decision, but this is probably an isolated decision, not a policy shift," said Singer. "The controversy … is another example of why the FDA should not base the approval process on its determination of a drug's efficacy. That falls under the realm of real-world clinical research. Efficacy requirements add years to the approval process."

CMS showed unusual common sense, says Michael F. Cannon, director of health policy studies at the Cato Institute.

"Refusing to purchase medical care that doesn't even work seems like a reasonable limit," said Cannon. "Unfortunately, this has not been Medicare's historical practice. Medicare pays for tons of medical care that does not work, which serves only to injure Peter and enrich Paul's health care providers, without benefiting Paul at all."

**Only Treatment Available**

Opening the gate to new treatments could yield unknown benefits, says Edward Hudgins, founder of the Human Achievement Alliance and author of a policy paper titled "A Modern System for Approving the Cures of the Future," published by The Heartland Institute, which co-publishes *Health Care News*, in 2019.

"No doubt the costs of the treatment played a part in the CMS decision to only cover patients in clinical trials," said Hudgins. "Policymakers have an incentive to keep costs down in the short term and ignore the long-term implications of this policy."

Making the treatment widely available could reveal more patients who benefit, says Hudgins.

"While it has shown results only in limited circumstances so far, Aduhelm is the first treatment in almost two decades to treat Alzheimer's," said Hudgins. "It would be better for this treatment to be tested as widely as possible because if it does in fact prove effective for a wider category of sufferers, it would reduce one of the worst scourges afflicting the elderly and reduce health care costs as well."

**Let Patients Choose, Pay**

One way to get around the cost concerns of testing innovative drugs is a reform proposal known as "Free to Choose Medicine," says Hudgins.

"The sponsor could offer Aduhelm on such a track to all who desired it," said Hudgins. "Results would be logged in a database which would supplement clinical trials and allow researchers to more quickly evaluate the treatment's efficacy. Further, if the treatment proves successful, over time, it would be refined and the market for the treatment would expand, bringing down costs."

The decision to participate in efficacy trials should be left to patients, not regulators, says Singer.

"I think patients should be allowed to purchase and try drugs that may have not been approved by the FDA but are approved by other credible third-party certifiers," said Singer. "With such a serious and fatal disease as Alzheimer's, many patients don't have the time to wait for the FDA to give them permission to save themselves from this terrible fate."

There are benefits to allowing patients to use unproven drugs they pay for themselves, says Singer.

"While rational people value the FDA's opinion on these matters, the decision is a personal one and an autonomous adult should not require permission from the government when they want to try to save their life," said Singer. "If the patients themselves are paying for the drug, they and their doctors will perform much better due diligence before committing their own money to what might be a dry hole."