

Medicare mulls coverage for controversial Alzheimer's drug

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(Healthday)—Medicare launched a formal process on Monday that will

determine whether the agency will cover Aduhelm, the newly approved Alzheimer's drug whose high price tag and unproven benefits have prompted widespread controversy.

Medicare's announcement came the same day that leaders of two House committees that are investigating Aduhelm's approval asked drugmaker Biogen to turn over all documents on how it developed and priced the [drug](#). Biogen was also asked to turn over records on any of its dealings with U.S. Food and Drug Administration officials, the *Associated Press* reported.

A final decision on coverage isn't likely until next spring, the U.S. Centers for Medicare and Medicaid Services said. At the moment, Medicare is making case-by-case calls on whether to cover Aduhelm, which is given intravenously in a doctor's office and costs \$56,000 a year per patient.

The recent FDA approval of Aduhelm prompted an unusually intense backlash after the agency went against the recommendation of its independent advisers. Since then, the agency has limited the recommended use of the drug and requested an investigation by an independent watchdog into its dealings with Biogen.

"We want to consider Medicare coverage of new treatments very carefully in light of the evidence available," CMS Administrator Chiquita Brooks-LaSure said in a statement that acknowledged the toll of Alzheimer's disease, the *AP* reported. "Our process will include opportunities to hear from many stakeholders, including patient advocacy groups, [medical experts](#), states, issuers, industry professionals, and family members and caregivers of those living with this disease."

A 30-day public comment period began Monday, and there will be two public hearings on the drug, the *AP* said.

Before Aduhelm's approval, Biogen and the FDA reanalyzed Aduhelm's data together after the company's studies suggested the drug did not slow mental decline, the *AP* reported. The collaboration ultimately led to the FDA granting conditional approval for the drug.

Last week, the FDA asked the government's independent watchdog to investigate unusual interactions between some FDA staffers and Biogen. That included reports of at least one "off the books" discussion between a Biogen executive and the FDA's top Alzheimer's drug reviewer.

Meanwhile, a large part of the lawmakers' request for documents includes details how Biogen arrived at the drug's price. The drug requires monthly IVs and the dosage is based on a patient's weight. The House committee chairs noted that a nonprofit think tank focused on drug pricing pegged the drug's actual value at between \$3,000 and \$8,400 per year, based on its unproven benefits.

"While the company has claimed this [\$56,000 a year] price is 'fair' and 'substantiated by the value it is expected to bring,' an independent analysis determined that a fair price for Aduhelm would be a small fraction of Biogen's price," said committee chairs Rep. Carolyn Maloney and Rep. Frank Pallone.

More information: Visit the U.S. National Institute on Aging for more on [Alzheimer's disease](#).

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