

Medicare Plans to Restrict Coverage of New Alzheimer's Drug

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newly approved drug aducanumab (Aduhelm), would be covered for people with Medicare only if they are enrolled in qualifying clinical trials, according to CMS plans announced Tuesday.

The proposed CMS [National Coverage Determination](#) (NCD) would cover approved monoclonal antibodies targeting amyloid through coverage with evidence development (CED). To date, the only such [approved treatment](#) is aducanumab, and the move from CMS would sharply limit the number of beneficiaries eligible for the pricey therapy.

"CMS has proposed an evidence-based coverage policy after experts reviewed all relevant publicly available evidence and feedback received from stakeholders," CMS Administrator Chiquita Brooks-LaSure said in a [statement](#).

If the proposed NCD is finalized, CMS will review each submitted clinical trial to determine whether it meets specific criteria. Trials must address whether using anti-amyloid antibodies in Alzheimer's results in a statistically significant and clinically meaningful difference in decline in cognition and function, in addition to studying adverse events associated with treatment.

Of note, the diversity of patients included in each trial must be representative of the national population diagnosed with Alzheimer's disease, the agency said. All trials must be conducted in a hospital-based outpatient setting.

"Given the disappointing lack of inclusion of underserved populations in past trials, we are requiring a representative ... patient population," Tamara Jensen, JD, of the Center for

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In addition to CMS-approved trials, NINDS-sponsored clinical trials also would be covered under the proposed determination. Medicare patients in the trials would be eligible to receive coverage of the drug, related services, and other routine costs, including PET scans.

"This proposed National Coverage Determination is the result of robust evidence analysis conducted through a thorough review process that found while there may be the potential for promise with this treatment, there is also the potential for harm to patients. This harm may range from headaches, dizziness, and falls, to other potentially serious complications such as brain bleeds," said CMS Chief Medical Officer Lee Fleisher, MD, in a statement.

[Brain edema or bleeding](#), effects of anti-amyloid treatment that have the potential to be serious and occurred in about 40% of participants in the aducanumab trials, was a particular concern for FDA's [advisory committee](#), which voted overwhelmingly against the data presented about the drug prior to the approval.

"We believe that any appropriate assessment of patient health outcomes must weigh both harm and benefit before arriving at a final decision," added Fleisher, who is also the director of the Center for Clinical Standards and Quality at CMS. "Therefore, based on the public comments submitted previously and evidence CMS reviewed, the potential for harm, and important questions that remain, we have determined that coverage with evidence development through clinical trials is the right decision for Medicare patients, clinicians, and caregivers, and we look forward to receiving feedback on the proposal."

FDA approved aducanumab under the [accelerated approval pathway](#) based on its ability to reduce amyloid plaques and the likelihood that this would correspond to clinical benefit. In past trials, many anti-amyloid monoclonal antibodies demonstrated they could reduce brain amyloid, but showed no clinical benefit on cognition.

"Coverage with evidence development under a randomized clinical trial will exclude almost all patients who may benefit," a spokesperson for aducanumab's drugmaker Biogen said in an email to *MedPage Today*. "This will significantly limit patient access to an FDA-approved treatment, especially for underserved patients as evidenced in other CED determinations."

"We will continue to urge CMS to align Medicare coverage for the class of amyloid-directed therapies with the populations studied in the respective clinical trials and guided by expert recommendations for appropriate use," the spokesperson continued. "We believe Alzheimer's patients should have access consistent with other therapies with FDA accelerated approval."

Uncertainty over the extent of Medicare coverage of aducanumab, which was initially listed at an annual cost of \$56,000, was in part to blame for a recent hike in Medicare Part B premiums. On Monday, HHS Secretary Xavier Becerra announced that he had instructed CMS to reassess these premiums after Biogen halved the drug's price to \$28,200 per year.

During Tuesday's press briefing, Beth Lynk, director of the CMS Office of Communications, stressed that the Part B premium determination and the NCD for this treatment are separate processes.

"The evidence-based National Coverage Determination does not take cost into account when making decisions concerning whether a treatment is reasonable and necessary to treat a particular medical condition," said Lynk.

The proposed determination is open to public comment for 30 days. CMS plans to announce its final decision by April 11, 2022.

Washington correspondent Shannon Firth contributed to this story.

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