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Medicare Coverage of Aducanumab — Implications for State Budgets

Rachel E. Sachs, J.D., M.P.H., and Nicholas Bagley, J.D.

Aducanumab (Aduhelm), the controversial \$56,000-per-year Alzheimer's disease drug approved by the Food and Drug Administration (FDA) in June 2021, has the potential to cost the federal government many billions of dollars — more, by one estimate, than it spends on agencies such as the Environmental Protection Agency or the National Aeronautics and Space Administration. The drug's extraordinary price tag helps explain why, soon after its approval, the Centers for Medicare and Medicaid Services (CMS) opened a national coverage determination to decide whether

and under what circumstances Medicare would pay for it.¹

A restrictive coverage determination could save the federal government a lot of money — but, as a recent letter from the National Association of Medicaid Directors (NAMD) noted, it would also shift substantial costs to the states.² The emerging debate over who will pay for aducanumab has important implications for Medicare spending, state fiscal health, and existing laws requiring Medicare and Medicaid to cover nearly all approved drugs, no matter their prices and no matter how poorly they work.

Usually, Medicare coverage of FDA-approved drugs is a foregone conclusion: the clinical evidence to support FDA approval is deemed sufficient to show that a product is “reasonable and necessary” for the treatment of an illness or injury, as the Medicare statute requires. But aducanumab is a special case. In granting accelerated approval to aducanumab, the FDA concluded that the drug's ability to reduce amyloid plaques was reasonably likely to translate into clinical benefits. But this claim is hotly contested and was not presented to the FDA's advisory committee, which voted against

recommending approval of the drug because of the lack of a demonstrated clinical benefit. Although the FDA instructed the drug's manufacturer, Biogen, to conduct additional trials over the next 9 years, and although the FDA may withdraw approval if the confirmatory trials fail to demonstrate a clinical benefit, the withdrawal process is typically long and highly contentious.

In making its coverage determination, CMS could point to the thin evidence base supporting the drug as a reason to limit Medicare coverage. Some other payers have restricted coverage of aducanumab, as have several influential health systems. A restrictive coverage determination, however, would in many cases make the states responsible for paying for aducanumab. More than 12 million people (mostly low-income older or disabled Americans) are dually eligible for Medicare and Medicaid. The federally run Medicare program covers most medical expenses for these beneficiaries, and Medicaid, the joint state–federal program, picks up the remaining costs. As a result, Medicaid is usually responsible only for taking care of Medicare's 20% cost-sharing requirement, at the most.

As a legal matter, however, state Medicaid programs are required to cover nearly all FDA-approved drugs — even drugs that Medicare chooses not to cover. Medicare's refusal to cover aducanumab would therefore leave states fully responsible for the drug's costs and associated expenses for dual-eligible beneficiaries. As the NAMD noted in its comments on the national coverage determination, the budgetary effects of CMS's decision

could be immense.² The Medicaid directors encouraged CMS to cover aducanumab, not because of its clinical value for patients, but because they are concerned about “shifting costs for such therapies to state Medicaid programs.”

The fiscal implications for states are serious. Unlike the federal government, states can't run budget deficits, which means they would have to raise taxes or reduce spending in other areas to pay for aducanumab. Similar budgetary pressures led states to restrict the availability of sofosbuvir (Sovaldi) for the treatment of hepatitis C in the years after its release, even though the drug was curative. These restrictive policies were successfully challenged in court as unlawful, but a delay in full coverage allowed states to spread the costs of sofosbuvir — a treatment that requires a single course, rather than long-term use — over several years. Aducanumab may put states in a similarly difficult fiscal position, notwithstanding the thin evidence that it will help patients with Alzheimer's disease.

State Medicaid programs have previously expressed concern regarding the budgetary effects of coverage requirements for prescription drugs — especially those that, like aducanumab, have been granted accelerated approval. Under this expedited-approval pathway, the FDA can approve drugs on the basis of a surrogate end point (such as a reduction in amyloid plaques, in the case of aducanumab), rather than a true clinical end point. In 2017, Massachusetts requested a waiver from CMS that would have allowed its Medicaid program not to cover prescription drugs for which there

is limited evidence of clinical efficacy.

Although CMS denied Massachusetts' request, it later permitted Tennessee's Medicaid program to restrict access to some drugs under certain conditions. More recently, the Medicaid and CHIP Payment and Access Commission (MACPAC) recommended changing the ways in which state Medicaid programs pay for drugs that are granted accelerated approval.³ For now, however, states remain responsible for covering all FDA-approved drugs, including those that have no demonstrated clinical benefits.

A proposed reimbursement decision is expected in January 2022, with the agency's final decision expected in April. At the same time, CMS's coverage-determination process is structured to consider only whether aducanumab is “reasonable and necessary” for treating Alzheimer's disease. CMS will assess the clinical evidence supporting the drug's use, but it probably cannot consider the implications of any potential ruling for state budgets.

The state Medicaid directors did present an alternative for CMS to consider. States are currently permitted to exclude from coverage only narrow classes of FDA-approved drugs, such as cosmetic products and fertility drugs. But CMS is empowered to “update the list of drugs or classes of drugs . . . or their medical uses” when it determines that drugs are subject to “inappropriate use.”⁴ The directors suggested that the agency could make such a determination and allow state Medicaid programs to exclude aducanumab from coverage.² But CMS has previously suggested that using a drug for its medically ac-

cepted indication does not constitute inappropriate use. (This issue arose in the context of a 1998 memo explaining why Medicaid programs must pay for erectile-dysfunction medication.⁵) If the agency adheres to this position, CMS would not be able to use this legal pathway to relieve states of their responsibility to cover aducanumab for the treatment of Alzheimer's disease.

The federal government could explore other options. CMS might, for example, revisit its decision to reject Medicaid waivers similar to the one sought by Massachusetts in 2017. Such waivers could lift the prevailing rules governing drug coverage and allow states to exclude products, like aducanumab, for which clinical evidence to support approval is lacking. If the traditional waiver process is too slow or cumbersome, CMS could explore similar waiver-based solutions through the CMS Innovation Center.

The cleanest solutions are likely to come from Congress, though the politics surrounding the first drug approved for treating Alzheimer's disease in decades will

be tricky to navigate. The legislature, for example, could pass a law automatically extending any Medicare national coverage determination to Medicaid or allowing states to make their own coverage determinations in cases in which CMS has made a national coverage determination. Alternatively, Congress could adopt new legislation specifying that state Medicaid programs need not cover aducanumab, much as it did in 2005 when it allowed Medicaid programs to exclude erectile-dysfunction drugs. More broadly, Congress could grant states coverage flexibility when it comes to the entire set of drugs that have been granted accelerated approval.

We believe that both the federal government and the states deserve better policy options in the face of a historic drug approval. Protecting state budgets shouldn't require Medicare to cover an expensive drug with unproven clinical benefits, and Congress should take steps to fix this problem. Perhaps aducanumab's high price will finally provide the impetus for revisiting Medicare's and Medicaid's exist-

ing commitments to covering all FDA-approved drugs.

Disclosure forms provided by the authors are available at [NEJM.org](https://www.nejm.org).

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