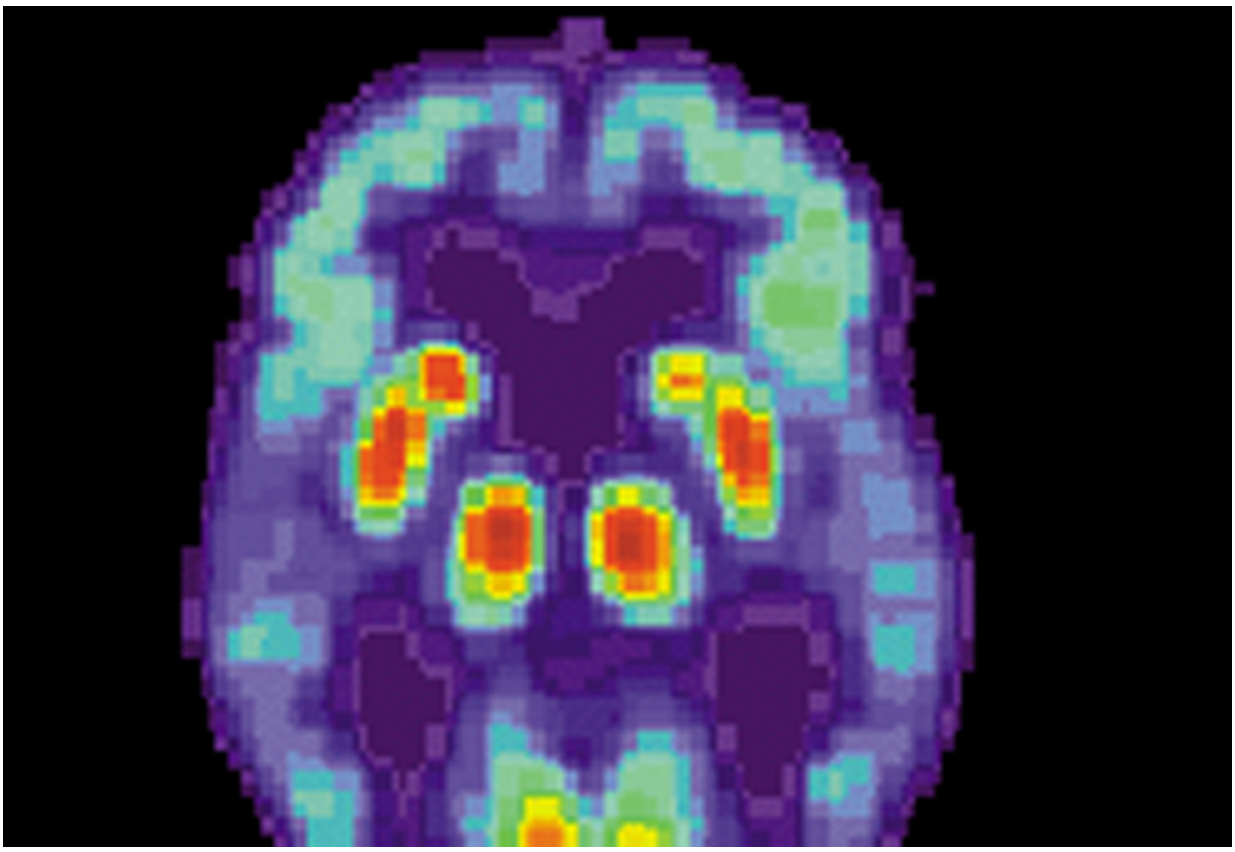
Medical Xpress

Patients' groups, progressives square off over Medicare Alzheimer's decision

February 16 2022, by Lauren Clason



PET scan of a human brain with Alzheimer's disease. Credit: public domain

Advocates on both sides of a debate over dramatically restricting Medicare's coverage of an expensive and controversial Alzheimer's treatment are waging competing campaigns to influence a final decision

in April.

The dispute also raises larger questions about whether lawmakers and regulators will revisit the fast-track pathway the drug was approved under, with the issue even entangling Robert Califf's embattled nomination to lead the Food and Drug Administration.

In January, the Centers for Medicare and Medicaid Services proposed restricting coverage of Aduhelm—a new monoclonal antibody treatment from Biogen and Eisai that targets brain plaques—to patients participating in approved clinical trials only. If finalized, the decision would also extend to future amyloid products for Alzheimer's disease.

The comment period that closed last week pitted patient access groups and drug manufacturers against progressive advocates in a race to generate the most responses to CMS. The proposal garnered more than 8,300 comments total.

Patient groups, many of which have close ties to drugmakers developing treatments, say the move will block most of the country's 6 million Alzheimer's patients from a potential opportunity to slow cognitive decline, while chilling future innovation in the drug class. Eli Lilly and Co. recently delayed the completion of its FDA application for a similar drug.

But progressive advocates view the $28,200 treatment as the poster child for a broken regulatory system that allows drugmakers to gouge consumers with ineffective products. Advocacy group More Perfect Union, largely run by former staffers for Sens. Bernie Sanders, I-Vt., and Elizabeth Warren, D-Mass., led likely the largest response urging CMS to hold firm on its plan.

The group does not accept donations from corporate- or union-related

organizations, a spokesperson said, but does receive money from philanthropies like the Open Society Foundations run by billionaire Democratic donor George Soros. More Perfect Union alerted its 150,000-person email list to the cause after Biogen encouraged counteradvocates to make their voices heard.

"Given the lack of scientific evidence that Aduhelm provides any clinically meaningful benefit in terms of cognitive function outcomes in Alzheimer's disease patients, the drug cannot possibly be deemed reasonable and necessary for treatment of such patients," the comments said.

That prompted GCI Health, a communications firm hired by Biogen, to proactively flag for reporters that CMS considers such campaigns to be a single comment because they are "not useful."

Biogen also accused the agency of exceeding its authority by refusing to cover an FDA-approved drug.

"The draft decision does not consider the burden and harm of its proposed policy – including the effective denial of treatment to all but a few thousand Alzheimer's disease patients for an unlimited period of time—and is therefore arbitrary and capricious," the company wrote.

Fierce fight

The backlash against Aduhelm, or aducanumab in its generic form, centers on the lack of evidence that it slows the progression of Alzheimer's. The drug reduces brain plaques and abnormal proteins associated with the disease, earning a green light from the FDA through an accelerated pathway meant for products that are reasonably likely to show a clinical benefit. Biogen is required to conduct a follow-up study confirming the drug's efficacy, which is expected to be completed in

four years.

The drug has a high risk of serious side effects like brain swelling and bleeding, and scientists are split over whether targeting brain plaques will reduce the severity of Alzheimer's.

The controversy is sparking scrutiny on Capitol Hill, where Senate Finance Chair Ron Wyden, D-Ore., secured commitments from Califf, the FDA nominee, to strengthen oversight of the accelerated program in exchange for Wyden's support.

Califf told Wyden that ensuring confirmatory trials were done in a timely manner would be a "high priority" for him if confirmed and he would work with Congress on additional authorities.

The issue has divided some Democrats and Republicans. Rep. Jan Schakowsky, D-Ill., called for a closer look at accelerated approval during a recent Energy and Commerce Health Subcommittee hearing, while top Republicans like Energy and Commerce ranking member Cathy McMorris Rodgers, R-Wash., and Ways and Means ranking member Kevin Brady, R-Texas, urged the agency to reverse the coverage proposal.

Some Democrats also question the coverage decision. Rep. Maxine Waters, D-Calif., tweeted against the proposal when it was unveiled last month. Rep. Nanette Barragán, D-Calif., is working to recruit lawmakers to send CMS a bipartisan protest letter. Barragán's 81-year-old mother has late-stage Alzheimer's, and does not qualify for Aduhelm.

"Every six months we have a follow-up with my mom's neurologist, and every six months I go to him and I say, is there anything we can take to slow this down? Is there anything you can give her? What do you mean there's no option? You're telling me I can't do anything at all?" she told

CQ Roll Call. "And that is something that I'm experiencing, but every other family member who has a loved one with Alzheimer's is experiencing."

Paul Aisen, the Alzheimer's Therapeutic Research Institute director at the University of Southern California and a co-chair of the steering committee for Biogen's phase 3 trial, said accelerated approval is critical for new therapeutics. Aisen disagreed with the CMS decision because he said it was partially based on a meta-analysis of other ineffective monoclonal antibodies, and because it ignores Aduhelm's clinical potential for early-stage patients.

Researchers are also now studying experimental therapies in earliest-stage patients with the potential to develop Alzheimer's through build-up of brain plaques, but who have not yet shown signs of memory impairment. Demonstrating long-term clinical benefit to these types of patients requires a different way of thinking, he argued.

"We need the accelerated approval pathway," he said. "Should there be additional discussion and education about this pathway? Definitely. But do we need it? I think we absolutely need it."

Equity and discrimination concerns also hang over the agency. The proposal would exclude from the clinical trials any people with intellectual and developmental disabilities, like Down syndrome, and many chronic conditions. A requirement that qualifying trials meet diversity requirements does not satisfy some advocates.

Gretchen Wartman, vice president for policy and program at the National Minority Quality Forum, called the decision "problematic" during an Alliance for Aging Research briefing.

"I can summarize our concerns by stating that, in an intolerably cynical

and disingenuous manner, they are weaponizing the result of a history of bias and betrayal of particular population cohorts to justify bias toward and betrayal of a particular patient cohort," she said.

Both the Alliance for Aging Research and the National Minority Quality Forum count Biogen among their corporate sponsors.

Looking back and ahead

The final decision in April will cap a lengthy saga that started when the FDA approved the drug under the accelerated pathway last June. The agency's advisory board recommended it be rejected from the traditional pathway, and three members quit over the FDA's decision.

Acting FDA Commissioner Janet Woodcock eventually requested an independent review of the approval. The Federal Trade Commission and the Securities and Exchange Commission are conducting separate investigations into the company's approval and marketing of the drug.

Few doctors are prescribing the drug so far. The public backlash prompted Biogen to slash the annual price in half, from $56,000 to $28,200. Aduhelm brought in just $3 million in revenue for 2021, and the company has reportedly undergone layoffs.

The debate over experimental treatments will likely continue, regardless of how the Aduhelm story concludes. Lawmakers are attempting to create another multibillion-dollar health research agency at President Joe Biden's behest that would be responsible for advancing "platform technologies" to help speed innovative therapies to market.

Amyloid treatments are one example of the type of research the agency could conduct, former Defense Advanced Research Projects Agency official Geoffrey Ling recently told the Energy and Commerce Health

Subcommittee. The agency could work with private companies, "so that they can better use the data that's available to make it better and easier for them to conduct their clinical trials," he said.

That could save money, he said, and "determine more quickly what, in fact, is the benefit."

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