

New Alzheimer's drugs raise hopes and a big question: Who'll pay for them?

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The Alzheimer's Association is stepping up public pressure on the Biden administration, hoping to convince the government to pay for a new class of promising but expensive Alzheimer's drugs.

To date, the advocacy group's campaign has been intense but low-tech, featuring everything from critical statements in the media to a public rally in front of the White House.

But the long-term results of the dispute, whatever they turn out to be, won't be so quaint.

About 6.9 million Americans currently have Alzheimer's, a progressive, [deadly disease](#) that's incredibly expensive to manage, and millions more are expected to be diagnosed as the nation's population ages up. Many Alzheimer's patients need years of care as they lose their [cognitive abilities](#), and the three drugs in question, Leqembi, Aduhelm and Donanemab, show signs of slowing that mental decline for a few months to a year—at an [annual cost](#) of \$25,000 to \$30,000.

For families of people affected by Alzheimer's, federal insurance could be essential for getting the drugs and the window of normal living they might provide. For working-age taxpayers asked to foot the bill, that same insurance could start in the billions and run up for decades.

So far, the Centers for Medicare & Medicaid Services (CMS), the federal agency that sets coverage policies for the biggest federal insurance programs and often influences the private insurance market, has balked. Agency officials note that the three drugs aren't insurable, for now, because they've been granted "accelerated," not "traditional" approval from the Food and Drug Administration, and because the drugs haven't yet demonstrated that they are "essential" for patients.

At least one of those conditions could change in early summer. The FDA is slated to issue a decision on granting full, traditional approval to Leqembi as soon as July 6. Many observers suggest that ruling eventually could pave the way for getting all three drugs to market.

Until that ruling is announced, officials with the Alzheimer's Association say they plan more protests—including one in Los Angeles in June—as a way to remind officials from CMS, and inside the White House, that the public is watching.

"We're looking to make sure the voice of people who might benefit are heard. In March, we held a rally in front of the White House. Between

now and July we'll do this around the country," said Dr. Joanne Pike, president and chief executive of the Alzheimer's Association.

Few of those voices are louder than Tony Gonzales'. The 49-year-old from Santa Maria has been working with the Alzheimer's Association since last year, when he was diagnosed with mild cognitive impairment, which he says in his case is a precursor to Alzheimer's. On May 10, he testified to Congress about why the drugs should be insured by the government.

"Americans living with Alzheimer's disease are entitled to FDA-approved therapies, just as are people with conditions like cancer, heart disease and HIV/AIDS," Gonzales told the House Ways and Means Health Subcommittee.

"People are losing the opportunity; they're losing days, weeks, months and memories. ... And it is unacceptable."

Gonzales said this week that he views medical bureaucracy—which, in this case, dictates that he is too young to participate in clinical trials for any of the three Alzheimer's drugs—as a life-or-death issue.

"I'm not an angry guy," Gonzales said. "But every part of this, even when I was on the grass at the White House yelling at the president, has been healing for me.

"Any reasoning behind CMS' stance on this has left me," he added. "From a political or practical view, this doesn't make sense."

Public comments from CMS officials suggest the agency agrees.

Last month, CMS Administrator Chiquita Brooks-LaSure told Congress that Medicare will cover Leqembi if, in July, the FDA approves it for

broader use. "When FDA approves the drug, whichever populations they say it is appropriate for, that will be the basis of which people will get the drug."

This week, a CMS spokesman issued a follow-up statement reiterating that position, and suggesting the Alzheimer's Association's public opinion campaign isn't falling on deaf ears.

"CMS always appreciates people raising their voices, and encourages public participation and comments on the agency's work. We remain committed to helping people obtain timely access to treatments proven to meaningfully improve care and outcomes for people living with Alzheimer's disease."

Still, other details surrounding the debate—about the drugs and the costs; even about the bureaucracy blocking Gonzales and others from treatment—suggest the question isn't so clear cut.

For one thing, testing so far suggests the drugs only slow—but don't reverse—cognitive decline. That means only a small, subgroup of Alzheimer's patients might be helped; those who have been medically diagnosed with Alzheimer's but aren't yet showing profound symptoms. The vast majority of patients get a confirmed diagnosis only after the disease has progressed beyond the point where the drugs might be effective.

However, researchers believe that dynamic might change if the drugs are approved by the FDA and insurance makes them widely available.

"Right now, a lot of doctors are reluctant to diagnose Alzheimer's because, when they do, they don't have options," said Dr. April Thames, a psychiatry professor at UCLA's Brain Research Institute who studies Alzheimer's disease.

"(But) if the drugs were insured, and the doctors had something to give those patients, that wouldn't be the case."

Another issue is that all three drugs fall into a new class of treatment; immunotherapies that use the body's own chemistry to fight the proteins known to be key to harming a patient's brain functions. Though promising, researchers note that the category has no track record, meaning testing must be rigorous before unleashing it on the public.

There's also a question of cost.

This month, health researchers at UCLA issued a report saying coverage for just Leqembi would run Medicare from \$2 billion to \$5 billion a year. That's based on projections of 86,000 to 216,000 patients using the drug. Last year, UCLA issued a cost projection for Aduhelm that ranged from \$7 billion to \$37 billion a year based on the idea that a quarter of people on Medicare might eventually be using the drug.

Also, the drugs in question carry a risk of serious side effects, including brain swelling and bleeding. While those threaten health outcomes for patients, they also boost the amount those patients spend for outpatient medical services.

Last year, published studies suggested outpatient services related to Alzheimer's drugs could run \$6,600 a year for people who don't have extended Medicare coverage. Also last year, in anticipation of Alzheimer's drugs hitting the market, Medicare boosted its premiums for certain medical services by about 15%.

And all of those costs are just part of a bigger equation.

The Alzheimer's Association recently published a simple menu of costs that can be incurred by a family caring for a person with Alzheimer's:

Adult daycare is about \$83 a day. A non-medical home health aide providing five, eight-hour days of help runs about \$1,145 a week. Assisted living facilities that include care for people with Alzheimer's run, on average, \$57,289 a year, while a private room in a nursing home is about \$115,000 a year.

Though many of those costs currently aren't covered by federal insurance, they suggest a \$25,000-a-year drug that staves off those expenses might save money.

Some observers also point out that the current debate over Alzheimer's drug insurance is a glimpse of the kind of public policy questions that figure to become common as America's population ages up.

The number of Americans who are 65 or older is projected to jump from about 1 in 7 today to 1 in 4 by the mid-2040s. As that happens, questions about everything from Social Security to immigration will have to balance the growing needs of older people with the ongoing needs of working-age taxpayers.

But Alzheimer's researchers like Thames, and Alzheimer's Association leader Pike, also suggest that the debate over covering these particular drugs is about science.

Money will lead to more research, they say, and more research will lead to better drugs in the future.

"These (three) drugs are the first treatments that have shown benefits of treating the underlying cause of Alzheimer's," said association leader Pike.

"They aren't trying to find a cure; we don't believe this is a cure," she added. "But what we do know it's a first step. And first steps lead to

second steps."

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