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The real costs of the new Alzheimer's drug, most of which will fall to taxpayers

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The first drug purporting to slow the advance of Alzheimer's disease is likely to cost the U.S. health care system billions annually even as it remains out of reach for many of the lower-income seniors most likely to suffer from dementia.

Medicare and Medicaid patients will make up 92% of the market for lecanemab, according to Eisai Co., which sells the drug under the brand name Leqembi. In addition to the company's $26,500 annual price tag for the drug, treatment could cost U.S. taxpayers $82,500 per patient per year, on average, for genetic tests and frequent brain scans, safety monitoring, and other care, according to estimates from the Institute for Clinical and Economic Review, or ICER. The FDA gave the drug full approval July 6. About 1 million Alzheimer's patients in the U.S. could qualify to use it.

Patients with early Alzheimer's disease who took lecanemab in a major clinical trial declined an average of five months slower than other subjects over an 18-month period, but many suffered brain swelling and bleeding. Although those side effects usually resolved without obvious harm, they apparently caused three deaths. The great expense of the drug and its treatment raises questions about how it will be paid for, and who will benefit.

"In the history of science, it's a significant achievement to slightly slow down progression of dementia," said John Mafi, a researcher and associate professor of medicine at the David Geffen School of Medicine at UCLA. "But the actual practical benefits to patients are very marginal, and there is a real risk and a real cost."

To qualify for Leqembi, patients must undergo a PET scan that looks for amyloid plaques, the protein clumps that clog the brains of many Alzheimer's patients. About 1 in 5 patients who took Leqembi in the major clinical test of the drug developed brain hemorrhaging or swelling, a risk that requires those taking the drug to undergo frequent medical checkups and brain scans called MRIs.

In anticipation of additional costs from the Leqembi drug class, the Centers for Medicare & Medicaid Services in 2021 increased monthly

premiums for Medicare patients by 15%, and premiums may rise again in 2024 after a slight decline this year.

Such increases can be a significant burden for many of the 62 million Medicare subscribers who live on fixed incomes. "Real people will be affected," Mafi said. He contributed to a study that estimated lecanemab and related care would cost Medicare $2 billion to $5 billion a year, making it one of the most expensive taxpayer-funded treatments.

In its analysis, ICER suggested that Leqembi could be cost-effective at an annual price of $8,900 to $21,500. In an interview, David Rind, ICER's chief medical officer, said $10,000 to $15,000 a year would be reasonable. "Above that range doesn't seem like a good place," he said.

Whatever its price, patients may be delayed getting access to Leqembi because of the relative shortage of specialists capable of managing the drug, which will require genetic and neuropsychological testing as well as the PET scan to confirm a patient's eligibility. A similar drug, Eli Lilly's donanemab, is likely to win FDA approval this year.

Already there are long waits for the testing needed to assess dementia, Mafi said, noting that one of his patients with mild cognitive impairment had to wait eight months for an evaluation.

Such testing is not readily at hand because of the paucity of effective treatment for Alzheimer's, which has helped to make geriatrics a relatively unappealing specialty. The United States has about a third as many dementia specialists per capita as Germany, and about half as many as Italy.

"Time is of the essence" for the neuropsychological testing, Mafi said, because once a patient's cognitive ability declines below a certain threshold, they become ineligible for treatment with the drug, which was

tested only in patients in the earliest stages of the disease.

Mafi's study estimates that patients without supplemental Medicare coverage will have to pay about $6,600 out-of-pocket for each year of treatment. That could put it out of reach for many of the 1 in 7 "dual eligible" Medicare beneficiaries whose income is low enough to simultaneously qualify them for state Medicaid programs. Those programs are responsible for about 20% of physician bills for drug infusions, but they don't always cover the full amount.

Some practitioners, such as cancer centers, cover their Medicaid losses by receiving higher rates for privately insured patients. But since almost all lecanemab patients are likely to be on government insurance, that "cross-subsidization" is less of an option, said Soeren Mattke, director of the Center for Improving Chronic Illness Care at the University of Southern California.

This poses a serious health equity issue because "dual eligibles are low-income patients with limited opportunities and education, and at higher risk of chronic illnesses including dementia," Mattke said in an interview. Yet many doctors may not be willing to treat them, he said. "The idea of denying access to this group is just appalling."

Eisai spokesperson Libby Holman said the company was reaching out to specialists and primary care physicians to make them aware of the drug, and that reimbursement options were improving. Eisai will provide the drug at no cost to patients in financial need, she said, and its "patient navigators" can help lock down insurance coverage.

"A lot of clinicians are excited about the drug, and patients are hearing about it," said David Moss, chief financial officer of INmune Bio, a company that has another Alzheimer's drug in development. "It's a money center for infusion centers and MRI operators. It provides

reasons for patients to come into the office, which is a billing thing."

Outstanding doubts about Leqembi and related drugs have given urgency to efforts to monitor patient experiences. CMS is requiring Leqembi patients to be entered into a registry that tracks their outcomes. The agency has established a registry, but the Alzheimer's Association, the leading advocacy group for dementia patients, is funding its own database to track those being treated, offering physician practices $2,500 to join it and up to $300 per patient visit.

In a letter to CMS on July 27, a group of policy experts said CMS should ensure that any and all Leqembi registries create and share data detailed enough for researchers and FDA safety teams to obtain a clear picture of the drug's real-world profile.

The anti-amyloid drugs like lecanemab have created a polarized environment in medicine between those who think the drugs are a dangerous waste of money and those who believe they are a brilliant first step to a cure, said ICER's Rind, who thinks lecanemab has modest benefits.

"People are as dug in on this as almost anything I've ever seen in medicine," he said. "I don't think it's healthy."

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