New Alzheimer's drug is first to show it slows disease. But It's facing a rocky rollout

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Eisai Co.'s breakthrough Alzheimer's drug—the first to show it slows the

brain-destroying disease—is facing a rocky rollout as doctors grapple with logistical issues, insurance uncertainties and complicated safety testing requirements.

The same day Eisai's Leqembi received full US approval, Medicare officials said the government health program for the elderly will pay for it. But that doesn't mean patients will be able to get the $26,500-a-year treatment quickly. Doctors at top medical centers said they're still trying to coordinate required testing, reimbursement and a real-world monitoring system of patients' side effects and cognitive status.

"I'm not even sure we know all the steps right now," said Constantine Lyketsos, director of the the Memory and Alzheimer's Treatment Center at Johns Hopkins Medicine in Baltimore.

The need for therapy is urgent and widespread: More than 6 million Americans have Alzheimer's, a number projected to roughly double by 2060 as the population ages. A significant portion with mild disease might be eligible for Leqembi, and Eisai expects global sales of more than $7 billion in fiscal 2030.

"It's a game-changer," that may be followed by other, better drugs, said Anna Nordvig, a neurologist at the New York-Presbyterian and Weill Cornell Medicine Alzheimer's Disease and Memory Disorders Program.

Eisai said Leqembi's launch is progressing well, with coverage from both Medicare and Medicaid, the health program for low-income people, along with other payers. The company is providing health-care professionals with information about the drug and its use in Alzheimer's, it said by email.

Long Wait

Interest appears strong, said Lawrence Honig, director of the Center of Excellence for Alzheimer's Disease at Columbia University Medical Center, and he's started writing prescriptions. Dementia specialists at Columbia University Irving Medical Center are getting daily calls and messages about the drug, said Honig, who earlier conducted studies of Leqembi.

But for most patients, the wait is likely to be weeks or longer. Lyketsos foresees rolling out Leqembi at Hopkins in September at the earliest. Doctors at Mayo Clinic in Rochester, Minnesota, said they won't start wide use of the drug until the fall, after they work out procedures for administering it. Other centers plan to pilot it on relatively small numbers of patients until they're sure the drug and tests are routinely covered by insurers. Jefferies analysts estimate that just 3,000 patients will be on Leqembi by year-end.

Betsy Groves, a 74-year-old retired clinical social worker from Cambridge, Massachusetts, with early-stage Alzheimer's, hopes to be one of them. She's expecting to start on Leqembi after her next neurology appointment that's scheduled for October.

Groves said she isn't particularly worried about the side effects. They can be significant, such as swelling and bleeding in the brain that's usually asymptomatic, and turn life-threatening in rare cases. Patients must weigh that against the modest slowing of the disease that the drug offers.

"Our folks are saying, 'We're not impressed with the benefit and we worry about the risk,'" Lyketsos said. So far, he said, most of his eligible patients are opting against Leqembi.

To qualify, patients need to undergo cognitive and functional tests, as well as a specialized amyloid brain scan that hasn't been widely covered

by insurance until now. Alternatively, they can undergo a spinal tap, but some patients find these unpleasant, and they give less information than the scan.

That's just the start. Patients need a separate scan to establish brain status before starting on the drug. They'll need three more MRI scans in about the first six months of treatment to monitor for early signs of side effects. And the FDA advises testing for a gene called APOE4 that could signal a far greater risk of brain swelling or bleeding.

Learning Curve

As many as five medical specialists—from genetic counselors to nuclear medicine specialists to neuropsychologists—may need to weigh in before a patient can get the drug, said David Knopman, a neurologist and Alzheimer's expert at Mayo. His facility will only treat patients who live close enough to be evaluated quickly if side effects develop.

"There are a whole bunch of things we have to do to give the drugs safely," said Paul Schulz, a neurologist at McGovern Medical School at UTHealth in Houston. It's almost like a complicated cancer treatment, and for the average neurologist, "there is a big learning curve."

Until the insurance situation is settled, Schulz said he'll use the drug on a handful of patients to make sure there aren't unexpected reimbursement problems.

Once patients have cleared those hurdles, they have to start infusions, a new experience for most Alzheimer's doctors, according to Allison Lapins, a neurologist at Northwestern University Feinberg School of Medicine. Hospitals will need to find biweekly slots at busy infusion centers.

A task force of Northwestern doctors has been meeting since January to devise procedures for safely using Leqembi, Lapins said. They want to train nurses who administer it to check for subtle symptoms of brain swelling. Northwestern will require gene testing and won't give the drug to patients with two APOE4 gene copies. Patients on blood thinners that may boost the risk of brain bleeding will also be excluded, she said.

"It is extremely complicated" to use the drug, Lapins said. She still expects a deluge of patients as more people who've been diagnosed in the early stages start to come in for treatment.