FDA Approves Alzheimer's-fighting Drug Leqembi

The Food and Drug Administration (FDA) has granted full approval to Leqembi, a drug developed by Japanese pharmaceutical company Eisai, for the treatment of mild dementia and other symptoms associated with early Alzheimer's disease.

Leqembi is the first medication to demonstrate modest effectiveness in slowing cognitive decline in Alzheimer's patients.

The FDA initially provided conditional approval to Leqembi in January based on preliminary findings that showed the drug's ability to clear the brain plaque associated with Alzheimer's disease.

The drug's effectiveness was further validated in a larger study involving 1,800 patients, which demonstrated a five-month delay in memory and thinking decline among those receiving the treatment compared to those receiving a placebo.

FDA's neurology drug director, Teresa Buracchio, stated that the confirmatory study provided evidence of the drug's safety and efficacy in treating Alzheimer's disease. However, the prescribing information for Leqembi will include a warning about potential side effects, including brain swelling and bleeding, although such risks are also associated with other plaque-targeting Alzheimer's drugs.

The approval of Leqembi holds significant implications for Medicare and other insurance plans, as it now paves the way for coverage of the drug for Alzheimer's patients. Medicare, the primary health coverage provider for the majority of Americans with Alzheimer's, had previously withheld coverage

pending the FDA’s full approval.

Concerns were raised about the financial burden of new plaque-targeting Alzheimer’s drugs like Leqembi on Medicare, given that the cost of a year’s supply of the drug amounts to around $26,500 for biweekly intravenous administrations.

Medicare administrator Chiquita Brooks-LaSure has confirmed that the program will immediately begin reimbursing for Leqembi following its FDA approval. However, additional requirements will be implemented, including the enrollment of Medicare recipients in a federal registry to monitor the drug’s real-world safety and effectiveness.

While Medicare coverage will now be available for Leqembi, the process of initiating patients on the drug may take time.

Doctors will need to verify the presence of the specific brain plaque targeted by Leqembi, and healthcare professionals will require training to administer the drug correctly. Ongoing monitoring through repeated brain scans will also be necessary to detect any potential adverse effects. These additional services and procedures may incur additional costs for hospitals and medical clinics.

Eisai estimates that approximately 100,000 Americans could be diagnosed with Alzheimer’s and eligible for treatment with Leqembi by 2026.

The drug, co-marketed with Biogen, has shown a slight delay in disease progression, as measured on cognitive scales. While some experts argue that the observed difference may be too subtle for patients and their families to notice, federal health advisers have deemed it meaningful and recommended full FDA approval of the drug during a public meeting in June.

New York Times bestselling author Dr. Con Colbert’s book Healthy Brain Zone shows how to reverse memory loss and reduce risks of dementia and Alzheimer’s.

Colbert says the key ingredient to fighting memory loss, dementia and Alzheimer’s isn’t in prescriptions or unnatural treatments, but in “a healthy, gut-friendly diet,” and understanding the brain-gut connection with the nutritional and dietary choices that support it.

More and more, science is proving that a healthy digestive system is the key to a healthy brain and body, Colbert writes.

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