US FDA Approves Lecanemab Drug for Alzheimer's Disease

The Alzheimer's Association enthusiastically welcomes today's U.S. Food and Drug Administration (FDA) action to grant the accelerated approval of Leqembi™ (lecanemab) (Eisai/Biogen) for the treatment of patients in mild cognitive impairment (MCI) or mild dementia stage of Alzheimer's disease and with confirmation of amyloid beta. While this is a milestone achievement for people eligible for the treatment, their families and the research community, without Centers for Medicare & Medicaid Services (CMS) and insurance coverage of this treatment and others in its class, access for those who could benefit from the newly-approved treatment will only be available to those who can pay out-of-pocket.

"What the FDA did today in granting accelerated approval to Leqembi was the right decision. But what CMS is doing by severely restricting coverage for approved treatments is unprecedented and wrong," said Joanne Pike, DrPH, Alzheimer's Association president and chief executive officer. "The FDA carefully reviewed the evidence for Leqembi before granting approval. CMS, in sharp contrast, denied coverage for Leqembi months ago before it had even reviewed this drug's evidence. CMS has never done this before for any drug, and it is clearly harmful and unfair to those with Alzheimer's. Without access to and coverage of this treatment and others in its class, people are losing days, weeks, months - memories, skills and independence. They're losing time."

Each day without access to the drug, the Alzheimer's Association estimates more than 2,000 individuals aged 65 or older may transition from mild dementia due to Alzheimer's to a more advanced stage of the disease where they may no longer be eligible for Leqembi and the other antibodies targeting amyloid currently being tested. In an unprecedented decision, CMS issued a National Coverage Determination (NCD) on April 7, 2022, declaring that Leqembi and other treatments in the same class were not "reasonable and necessary" before reviewing the evidence for these future treatments. The Alzheimer's Association has submitted a formal request asking CMS to remove the requirement that Medicare beneficiaries be enrolled in a research study in order to receive coverage of FDA-approved Alzheimer's treatments.

"The unquestionably positive data from the clinical studies of Leqembi indicate that thorough removal of beta amyloid from the brain leads to clinical benefit," said Maria C. Carrillo, Ph.D., Alzheimer's Association chief science officer. "This treatment can change the course of Alzheimer's in a meaningful way for people in the early stages of the disease, allowing more time to participate in daily life and live independently."

"The decision to use this treatment should lie in the hands of the individual living with the disease and their family, in consultation with their doctor," Carrillo added.

The prescriber information for Leqembi acknowledges the need for real-world evidence and long-term safety data collection. Participation in the Alzheimer's Association's Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) by clinicians and patients is encouraged by the FDA in the prescribing information.

"ALZ-NET is a prime example of the Alzheimer's Association's commitment to improve care and clinical readiness, and support innovative drug discovery," Carrillo said. "The goal of ALZ-NET is to improve patient care and inform Alzheimer's treatment practices, including helping us better understand and remediate health disparities, by tracking how people from all backgrounds and communities respond to novel FDA-approved Alzheimer's therapies."

Leqembi was approved through the FDA's accelerated approval pathway, which grants earlier approval to drugs that treat serious conditions and fill an unmet medical need. In December 2022, Congress passed legislation to preserve and strengthen this important regulatory pathway. The company has already completed the confirmatory Phase 3 trial required by the FDA to stay on the market. The trial met its primary endpoint, reducing clinical decline by 27% compared to placebo after 18 months of treatment. The company announced they will submit to the FDA for traditional approval very shortly.

"People living with this fatal disease today do not have time to wait for a miracle drug or cure," said Pike. "While we continue efforts to discover new targets and test new treatments, people living with Alzheimer's deserve the opportunity to discuss and make the choice with their doctor if an FDA-approved treatment that offers benefits is right for them."

If you or a loved one is experiencing memory changes, the Alzheimer's Association strongly encourages speaking with a health care provider for a thorough evaluation and, diagnosis and to discuss treatment options. For more information on diagnosis or to find a local health care provider, visit the Alzheimer's Association at *alz.org*, or the Helpline 24/7 at 800.272.3900.

"We are proud of what the Alzheimer's Association has done to accelerate the drug development process, so that individuals will have access to more effective treatments faster," Carrillo said. "This second new drug approval, and sustained progress in the research field, is due to years of investment, unrelenting dedication, and working toward our vision of a world without Alzheimer's and all other dementia."

Alzheimer's - a progressive, degenerative and fatal brain disease - is the most common cause of dementia. For the Alzheimer's Disease Facts and Figures, an annual report released by the Alzheimer's Association please visit *alz.org/facts*. Support and information from the Alzheimer's Association are available for free anytime, day or night for individuals with Alzheimer's disease and their caregivers at 800.272.3900. Some North Carolina statistics from the report are:

- An estimated 6.5 million Americans age 65 and older are living with Alzheimer's dementia, including 180,000 North Carolina residents, a number estimated to grow to as many as 210,000 by 2025.
- Nationally, more than 11 million caregivers of people with Alzheimer's disease or other dementias. In North Carolina, 356,000 caregivers provide a total of 514 million hours of unpaid care, valued at a total of $7.3 billion.
- One in three seniors dies with Alzheimer's or other dementia.
- Nearly two-thirds of those with Alzheimer's - 3.9 million - are women.
- Older non-Hispanic Blacks and Hispanic Americans are disproportionately more likely than older whites to have Alzheimer's or other dementias.

Cheraw Arts Commission Weekly Theatre Classes for Kids

The Cheraw Arts Commission will offer weekly evening Theatre Classes for children ages 4th grade & up. Younger children ages 1st -3rd grades will need to audition to participate in the classes. The classes will be held on Mondays from 5:30-6:30pm at the Theatre on the Green in Cheraw beginning January 23. Additional Thursday classes will start in March in preparation for the production.

There will be a total of 23 classes that will run from January through April ending with the musical production of Disney's The Jungle Book KIDS on April 28 & 29. The classes will concentrate on basic acting skills that include improvisation, theatre games, blocking shows, production/stage assistance, and voice projection. Participants will be introduced to stage makeup application, audition techniques and learn songs and dance routines. Laney Rogers will provide instruction for the weekly classes and serve as director for the production.

Cost for the 23 classes is $30 per month for a total of $90. Registration will be conducted at the Cheraw Community Center – 200 Powe Street from 8:30am-5:00pm on Mondays-Fridays. Call the Cheraw Arts Commission 843.537.8420 x 12 for additional information.