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Alzheimer's drugs that could slow cognitive decline achieve unanimous endorsement and expanded coverage

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The Buzz This Week

June is Alzheimer's and Brain Awareness Month, an opportunity to better understand Alzheimer's disease and other dementias. This year there have been significant developments in the coverage and approval of new Alzheimer's drugs.

Notably, on June 9, expert advisors to the U.S. Food and Drug Administration (FDA) unanimously recommended expanding the approval of Lecanemab (marketed as Leqembi), an Alzheimer's disease treatment developed by Japan's Eisai and its U.S. partner Biogen. The panel concluded that the drug showed clinical benefits in slowing cognitive decline based on data from a late-stage trial. The data revealed that Leqembi not only treats symptoms but also alters the progression of the disease by 5 to 6 months.

Leqembi's initial FDA approval came through an accelerated pathway in January. This initial approval allows the drug to launch based on preliminary results, before patient benefit is confirmed. During this phase, the drug is only available to patients enrolled in the clinical trial and those able to pay the out-of-pocket cost of \$26,500 annually. However, the FDA is expected to make a final decision regarding traditional approval of Leqembi by July 6, though the agency is not obligated to follow the recommendations put forth by the panel.

In a related development, Eli Lilly's new drug in the same class, Donanemab, has shown promising results and could receive traditional FDA approval by early 2024.

Earlier this month, the Centers for Medicare and Medicaid Services (CMS) announced plans to provide broad coverage for this new class of Alzheimer's drugs for enrollees who meet coverage criteria once the drugs receive traditional approval from the FDA. CMS will also continue to require physicians prescribing

these drugs to participate in registries to gather real-world data on their effectiveness. The U.S. Department of Veterans Affairs (VA) has taken a different approach from Medicare's current stance on coverage, announcing in March plans to cover Leqembi for veterans in early stages of the disease.

Why It Matters

More than 55 million people worldwide live with dementia, and Alzheimer's is the leading cause of cognitive decline. Although these new drugs only delay cognitive decline by several months, they could still have a meaningful impact on patients' quality of life.

"The progress we've seen in this class of treatments, as well as the diversification of potential new therapies over the past few years, provides hope to those impacted by this devastating disease," said Maria Carrillo, PhD, Chief Science Officer for the Alzheimer's Association.

Even as new medications are developed that may slow disease progression, the shortage of specialists (including geriatricians, neurologists, and radiologists) poses significant challenges for the 6.7 million people in the U.S. currently living with Alzheimer's. This number is projected to grow to 13 million by 2050. The shortage of providers, compounded by limited testing capacity, consequently creates extensive waiting periods for newly diagnosed patients before receiving the necessary care and potential access to these breakthrough drugs.

While promising, the new drugs also have potential side effects and impacts that must be carefully considered. The drugs may cause brain swelling and bleeding. Another significant factor to consider is the pricing of the drug. Insurers will need to decide whether and how to cover these drugs. Medicare's decision about how it will cover the new drugs will be crucial, given that it covers most of the senior population. The high cost of the medication could pose a challenge for many individuals with Medicare, even though they have coverage. The median income of Medicare beneficiaries is approximately \$30,000 per person.

This issue becomes more significant considering that older Hispanic and Black adults in the U.S. have higher rates of dementia and lower incomes compared to white beneficiaries. In addition, individuals from these marginalized populations are often diagnosed at the later stages of the disease—and the new medicine targets those with early onset Alzheimer's. The high cost of Leqembi treatment may raise concerns as it could potentially limit access for Black and Hispanic beneficiaries who cannot afford it, exacerbating existing racial disparities when it comes to Alzheimer's.

Other concerns exist about inequitable access. For instance, while the clinical trial for Leqembi had the most diverse set of participants for an Alzheimer's treatment to date, it still did not provide sufficient evidence to determine whether the drug is effective for Black people. Additionally, those who live in rural areas are at a disadvantage because the availability of PET scans, a diagnostic tool for Alzheimer's, is limited and primarily concentrated in larger cities.

Overall, the approval of Leqembi represents a step forward in Alzheimer's treatment, but questions remain about its true clinical significance, equitable access, and cost-effectiveness.

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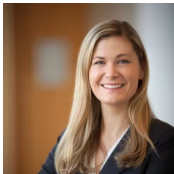
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