

Medicare will cover new class of Alzheimer's drugs if fully approved by FDA, with limits

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Medicare will soon cover a new class of Alzheimer's drugs if they



receive full approval from the U.S. Food and Drug Administration, with some key limits.

Along with being full approved, <u>drug makers</u> will also have to gather and keep data in a registry showing how the drugs are working in the real world, the U.S. Centers for Medicare and Medicaid Services announced Thursday.

"Alzheimer's disease takes a toll on not just the people suffering from the disease but also on their loved ones and caregivers in a way that almost no other illness does. CMS has always been committed to helping people obtain timely access to innovative treatments that meaningfully improve care and outcomes for this disease," CMS Administrator Chiquita Brooks-LaSure said in a <u>statement</u> announcing the change. "If the FDA grants traditional approval, CMS is prepared to ensure anyone with Medicare Part B who meets the criteria is covered."

The drugs in question—Lecanemab (Leqembi) and Aduhelm—have already been given <u>accelerated approval</u> to "fill an unmet medical need" while <u>drug</u> makers continue research on their effectiveness and safety. But neither drug has have received full, traditional approval.

Not everyone was thrilled with the idea of collecting real-world data in a registry.

In a <u>statement</u>, the Alzheimer's Association called the registry requirement "an unnecessary barrier," adding that the registry "should not be a requirement for coverage" of an FDA-approved treatment.

But the CMS said there is a "strong precedent" for using registries.

About 6 million Americans live with Alzheimer's disease, which affects memory and cognitive abilities. There is no cure.



More information: The U.S. Centers for Disease Control and Prevention has more on <u>Alzheimer's disease</u>.

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