Medicare's strict Alzheimer's policy raises ante for drugmakers

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The U.S. Medicare program's decision to tightly limit coverage for the first drug meant to slow the course of Alzheimer's disease has raised the stakes for companies trying to make the next one.

First up are Eisai Co. and Roche Holding AG, which will release data from final-stage trials of their respective lecanemab and gantenerumab treatments later this year. Next will be Eli Lilly & Co., whose donanemab results are expected in the middle of next year. Each of the companies will be trying to reach a bar that has never been met: showing clear evidence that they can alter the course of Alzheimer's in a way that's meaningful to patients.

The big studies from the three companies should finally deliver a definitive answer as to whether clearing patients' brains of amyloid, a protein associated with the disease, helps slow cognitive decline. In its decision on Thursday, the Centers for Medicare and Medicaid Services pledged broad reimbursement for Alzheimer's medicines that win traditional approval from the Food and Drug Administration. That could mean billions of dollars in sales and a long-awaited treatment option for a disease that affects more than 6 million Americans, many of whom are elderly.

"The CMS coverage memo has sobering implications for Eli Lilly, Roche and other amyloid antibody developers hoping for full Medicare coverage after an FDA approval," Bloomberg Intelligence analysts Marc Engelsgjerd and Sam Fazeli said Friday.

The new drugs face tough odds. Biogen Inc.'s Aduhelm, which was billed as a breakthrough when regulators granted it accelerated approval last year, shows what happens when an Alzheimer's drug can't demonstrate clear benefits. Medicare's policy effectively ruins Aduhelm's prospects of becoming commercially viable, and Biogen may have to cut its losses and shift gears.

Like Aduhelm, the new drugs aim to remove amyloid protein that accumulates in the brains of Alzheimer's patients. But the link between amyloid buildup and cognitive decline years later is murky. Scientists

still don't agree whether this approach can slow the progression of the memory-wasting disease and meaningfully help patients.

Lilly, Roche and Eisai will need to decide how they want to move their treatments forward. Aduhelm came to the U.S. market under the FDA's "accelerated approval" program, which can expedite drugs for serious conditions based on measurements that are thought to predict clinical benefit. Others are following the same approach. Eisai and Lilly both plan to ask for accelerated approval. Biogen and Eisai worked together on Aduhelm and the new drug.

But Medicare's strict stance on treatments that receive this kind of approval raises questions about how successful these drugs can become. Even amyloid-targeting drugs that receive traditional approval will need to track patients in a follow-up study, albeit in a less onerous way, to make sure the medicines wind up having a tangible benefit.

Lilly already delayed its filing because of reimbursement uncertainty. In a statement following news of Medicare's policy, the company vowed to fight for broader coverage. Roche said it still plans to seek standard regulatory approval based on its late-stage data. Eisai said it expects to finish its accelerated approval application in the next few months. If its data later this year are positive, the company said Medicare could reconsider its coverage policy if its drug wins FDA approval.