HEARTLAND DAILY NEWS

Promising Alzheimer's Drug Under Attack for Cost

AnneMarie Schieber

July 6, 2021

The U.S. Food and Drug Administration (FDA) is under attack for approving a $56,000 a year treatment for Alzheimer's disease because clinical data had yet to demonstrate the drug's efficacy.

In response, the FDA pulled back its initial approval and asked the manufacturer to narrow its intended use. On July 8, Biogen, the company that makes the drug, Adulhem (aducanumab) said the drug should only be used on patients with mild impairment.

The FDA approved Biogen's Aduhelm (aducanumab) under its "accelerated approval pathway" because "it provides a meaningful therapeutic advantage over existing treatments," despite the disapproval of its advisory panel.

The FDA stated approving the drug using a "surrogate endpoint" made sense.

"Alzheimer's disease is a devastating illness that can have a profound impact on the lives of people diagnosed with the disease as well as their loved ones," said Patrizia Cavazzoni, M.D. the director of the FDA's Center for Drug Evaluation and Research. "Currently available therapies only treat symptoms of the disease; this treatment option is the first therapy to target and affect the underlying disease process of Alzheimer's. As we have learned from the fight against cancer, the accelerated approval pathway can bring therapies to patients faster while spurring more research and innovation."

A New Approach

Aduhelm takes a first-of-a-kind approach to slowing down Alzheimer's by reducing the buildup of amyloid plaque in the brain. Alzheimer's affects 6.2 million Americans and Aduhelm is the first treatment to win approval in 20 years.

Although amyloid plaque is a condition highly associated with Alzheimer's, it is not clear if removing it will slow down progression of the disease. The Bio Industry Organization reports that while there are 33 trials of drugs aimed at reducing amyloid plaque, 52 others have failed.

However, the cost of Aduhelm is what is getting the most attention. Sen. Ron Wyden (D-OR), who heads the powerful Senate Finance Committee, tweeted it is "unconscionable to ask seniors and taxpayers to pay $56,000 a year for a drug that has yet to be proven effective."

The patient activist group Public Citizen stated Aduhelm could "potentially bankrupt the Medicare program" and is calling for three top officials at the FDA to resign.

FDA Approval Process

The dispute over price misses a fundamental problem with FDA's drug approval process, says Jeffrey Singer, M.D., a surgeon and senior fellow at the Cato Institute. In a blog on the Cato website, Singer suggests that if all drugs were approved on safety alone, Aduhelm might not be getting the pushback it is now.

"Prior to 1962, drug makers were required to convince the FDA their product was safe to consume and met the FDA's criteria for providing product information, use, and dosage on their labels," Singer writes. "But the 1962 Kefauver-Harris Amendments to the Food Drug and Cosmetic Act of 1938 added the additional burden of proving the drug's efficacy in treating the condition for which it was developed. Efficacy requirements add years to the approval process."

In the real world, physicians can experiment with approved drugs for uses other than what the drug was originally approved.

"An estimated 20 percent of prescriptions are for off-label use," Singer writes. "It is reasonable to wonder why, after doctors wait several years to get permission from the FDA to treat their patients with a drug for condition 'A,' the FDA in principle trusts doctors to use their clinical judgment, based on their knowledge, experience, and analysis of real-world trials, to treat conditions B thru Z. Why not skip the efficacy component of the approval process and speed things up?"

The Cost Factor

Under federal law, Medicare is obligated to cover approved drugs and prohibited from negotiating prices.

"Biogen (the manufacturer of Aduhelm) can charge whatever it wants," Singer told *Health Care News*. "The brouhaha over Aduhelm is, at the end of the day, all of Congress's making. Why have laws requiring Medicare to cover virtually every FDA approved drug and not be able to negotiate?"

On the other hand, private insurance companies have no obligation to cover the drug and can negotiate the price with the manufacturer, a point Congress should heed, Singer says.

"When patients have more skin in the game, they'll be more judicious about using Aduhelm," Singer said. "With private insurance, the insurance company will need the prescriber to speak to the company's physician advisor and get authorization to use the drug, having to convince the advisor why it makes sense for the health plan to cover it.

"Why have the FDA insist on efficacy when, at the end of the day, it will be clinicians who will make that decision, one way or the other, on their own?" Singer said.

Cost-Saving Measures

If Aduhelm shows significant success in slowing down Alzheimer's, it could save taxpayers billions of dollars. The estimated total cost of treating Alzheimer's Disease in 2020 was $305 billion, according to an August 2020 report by the American Journal of Managed Care, and could rise to $1 trillion as the population ages.

If Aduhelm proves to be successful, competition from new therapies could bring the cost down.

"If Aduhelm doesn't prove to be effective, doctors won't prescribe it," states a June 21 Wall Street Journal editorial.

Weeks after the FDA approved Aduhelm, Eli Lilly announced it will seek accelerated approval for its Alzheimer's treatment, donanemab. The treatment is just entering Phase 3 trials.