Wellmark

Pharmacy trend ALERT

What's trending?

A new treatment option is now available for patients diagnosed with Alzheimer's disease. Labeled as Aduhelm™, this amyloid directed antibody slows the progression of Alzheimer's disease by reducing amyloid beta plaque in the brain. It was granted a fast-track designation and approved by the accelerated approval pathway and FDA on June 7, 2021.

Further clinical trials need to be conducted to assess clinical benefit, which has only been demonstrated in one of the two phase 3 clinical trials.

Alzheimer's disease is a type of dementia that progressively destroys memory and thinking skills. The rate at which the disease can progress varies. Disease progression is irreversible, and the cause is not fully understood, but it's hypothesized the cause is multifactorial and results from a combination of genetic, environmental, and lifestyle factors. It's currently characterized by changes in certain biomarkers such as amyloid plaques and neurofibrillary tangles (NFTs) in the brain, and these are thought to result in the depletion of neurons and their connections.

More than six million Americans are currently living with Alzheimer's, according to the Alzheimer's Association®. It's approximated that one in three seniors die with Alzheimer's or another dementia. Most of the individuals that are affected are 65 years or older. The CDC ranks it as the 6th leading cause of death in the United States.

Aduhelm (aducanumab-avwa), which is an amyloid beta-directed antibody, received FDA approval for the treatment of Alzheimer's on June 7. It is the first treatment approved for Alzheimer's disease since 2003. Aduhelm is also considered a novel treatment because it targets the underlying pathophysiology of the disease (amyloid beta plaque). The previously available drug therapies could only temporarily mitigate symptoms but could not slow clinical decline of patients.

It was granted fast-track designation and was approved via the accelerated approval pathway. Fast-track designation is given to treatments that can fill an unmet medical need and can allow patients to receive important new drugs earlier. Drugs are given accelerated approval pathways when they can show an

effect on a surrogate endpoint that could predict clinical benefit, even if clinical benefit hasn't been established. In the case of Aduhelm, it showed a significant dose- and time-dependent reduction of amyloid plaques, however, only one of the two phase 3 clinical trials met the primary endpoint and showed reduction in clinical decline. Because it was approved via the accelerated approval pathway, the manufacturer, Biogen, is required to conduct a new randomized, controlled clinical trial to establish clinical benefit of the drug. Failure to do so may result in the FDA withdrawing its approval of the drug.

The estimated wholesale acquisition cost (WAC) is $4,312 per infusion for a 74-kg patient, which would lead to approximately a yearly cost of $56,000 at the maintenance dose.

Wellmark's management strategy

Wellmark is projecting up to 650 members could be eligible for treatment with Aduhelm.

As with all newly FDA-approved drugs, Wellmark has conducted a thorough clinical review of the safety and efficacy of Aduhelm.

Aduhelm was presented to our pharmacy and therapeutics (P&T) committee in July, and the P&T committee voted to not cover Aduhelm under medical due to insufficient evidence to demonstrate clinical effectiveness. The P&T will review and evaluate any new evidence as it becomes available.

The Wellmark Pharmacy and Therapeutics (P&T) Committee

The pharmacy world is a constantly changing landscape as new drugs and treatments become available.

A team of local doctors and pharmacists reviews new and existing drugs and selects medications for the Wellmark Drug List based on safety and efficacy. They also evaluate drugs on how their effectiveness compares to similar drugs used treat the same condition, which helps determine their tier.

The P & T committee considers such things as:

- Need for a new drug therapy
- Effectiveness
- Costs
- Medical necessity

The goal is always to use unbiased, third-party research and clinical data along with committee members' collective expertise to select drugs that reduce overall health care costs without sacrificing effectiveness.

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