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Aduhelm Medicare National Coverage Final Decision

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Aduhelm® Medicare National Coverage Final Decision

Background

Aduhelm (aducanumab), Biogen's controversial Alzheimer's disease (AD) treatment, has been awaiting a Medicare National Coverage Decision (NCD) since its Food and Drug Administration (FDA) approval in June 2021. In the absence of a national coverage policy, local Medicare Administrative Contractors decide drug coverage for a Medicare patient on a claim-by-claim basis. In January 2022, Centers for Medicare and Medicaid Services (CMS) released a proposed NCD allowing Medicare coverage of Aduhelm under a Coverage with Evidence Development (CED) program. In February 2022, the National Association of Medicaid Directors commented on the proposed coverage decision for Aduhelm requesting that under a CED, CMS should allow states the flexibility to apply the same coverage in their Medicaid programs.

Thus far, the uptake of Aduhelm has remained minimal, with prescribers citing safety and efficacy concerns in addition to cost as limiting factors. In late December 2021, Biogen announced the company was reducing the wholesale acquisition cost of Aduhelm by 50% (to $28,200) at the yearly maintenance dose to encourage uptake and patient access.

CMS Final Decision

On April 7, 2022, CMS released a final decision memorandum regarding the Medicare coverage of approved monoclonal antibodies that target amyloid for the treatment of AD — including Aduhelm. Presently, Aduhelm is the only monoclonal antibody directed against amyloid beta approved by the FDA for the treatment of AD. The finalized NCD will cover Aduhelm through a CED only for Medicare patients enrolled in qualifying clinical trials. Medicare patients participating in these trials would be eligible to receive coverage of the drug, related services, and other routine costs. The CMS decision is specific to patients who have a clinical diagnosis of mild cognitive impairment due to AD or mild dementia with a confirmed presence of plaque on the brain, consistent with the FDA label. In the event the FDA updates the label, CMS would reevaluate the coverage policy.

Following feedback from the proposed decision, CMS made an important distinction in the final CED decision. The final CED decision allows for flexibility in a less rigorous study design for some monoclonal antibodies that target amyloid for the treatment of AD.

- Drugs in this class with evidence of efficacy from a change in a surrogate endpoint (e.g., amyloid reduction) or considered as reasonably likely to predict clinical benefit may be covered in a FDA or National Institutes of Health approved trial(s).
- Drugs in this class that are FDA-approved based upon evidence of efficacy from a direct measure of clinical benefit may be covered in CMS-approved prospective comparative studies. Study data for CMS approved prospective comparative studies may be collected in a registry.

Medicaid Implications

CMS offered the following clarification for states regarding Medicaid coverage of Aduhelm and other drugs in the class for dual eligible enrollees:

> **When drugs included in the NCD are not covered by Medicare Part B under the terms of the NCD, CMS considers them Part D drugs. Medicaid does not pay for Part D drugs for full-benefit dually eligible individuals, regardless of whether they are enrolled in a Part D plan. This means that when the drugs included in the NCD are not covered by Part B under the terms of the NCD, regardless of whether a full benefit dually eligible individual's Part D plan actually covers the drugs, Medicaid will not cover them.**

Simply put, CMS is instructing states to not cover Aduhelm for individuals eligible for Medicare Part D.

For Medicaid-only individuals, CMS reiterated that states are required to cover Aduhelm when the drug is used for a medically accepted indication. State Medicaid programs could subject Aduhelm to utilization management techniques, such as prior authorization, and medical necessity criteria. CMS also reiterated that as a covered outpatient drug, Aduhelm manufacturers are required to pay rebates, as appropriate, when dispensed and paid for under the state plan, including for dual enrollees.

References

- CMS Finalizes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease
- Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease
- NAMD Comments on Medicare's Proposed Coverage Determination for Alzheimer's Drug
- CMS Proposes Medicare Coverage Policy for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease
- Biogen Announces Reduced Price for ADUHELM® to Improve Access for Patients with Early Alzheimer's Disease
- Cost and controversy are limiting use of new Alzheimer's drug
- Change of Aduhelm Price by Biogen is Only a Step Toward Equitable Access to Treatments for Alzheimer's Disease
- Alzheimer's Association Statement on CMS Draft Decision

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