

PHARMACY POLICY STATEMENT Ohio Medicaid

DRUG NAME

Aduhelm (aducanumab-

STATUS	Prior Authorization Required

Aduhelm, a monoclonal antibody that targets amyloid plaque buildup in the brain, was initially approved by the FDA in June 2021. It is indicated for Alzheimer's disease patients with mild cognitive impairment or mild dementia stage of disease. Aduhelm is the first drug approved to slow the progression of Alzheimer's. There has been significant controversy surrounding the accelerated approval of this product, including conflicting results from the phase 3 clinical trials EMERGE and ENGAGE, and concerns regarding safety outcomes.

Aduhelm (aducanumab) will be considered for coverage when the following criteria are met:

Alzheimer's Disease

For *initial* authorization:

- 1. Member is at least 50 years of age; AND
- 2. Medication must be prescribed by or in consultation with a neurologist or geriatrician; AND
- 3. Member has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia as evidenced by <u>ALL</u> of the following assessments:
 - a) MMSE score¹⁰ of at least 21, and
 - b) CDR-GS score equal to 0.5, and
 - c) <u>At least one</u> of the following:
 - i) MoCA score of at least 18,
 - ii) QDRS score between 2 and 5,
 - iii) REDAMS/160.001iceaof 03:50 3r11e7 on f5110/107avar99.91199131;1al7foleasccSof (e)-5.8e 5

- 6. Member has undergone a complete physical and neurological exam to comprehensively <u>rule out</u> all other possible causes of neurocognitive decline including but not limited to:
 - a) Any medication potentially causing cognitive impairment must have been stopped for at least 4 weeks with continued cognitive symptoms,
 - b) Currently uncontrolled psychiatric condition (including alcohol or substance abuse),
 - c) Parkinson's disease,
 - d) Lewy body dementia,
 - e) Vascular dementia (such as from a stroke); AND



- 7. Member is not taking any blood thinners (exception: low dose aspirin).
- 8. **Dosage allowed/Quantity limit:** After initial titration (see below), the recommended maintenance dose is 10 mg/kg every 4 weeks as an IV infusion.

For reauthorization:

1. Member has had a follow up assessment to determine that they have <u>not progressed</u> to moderate/severe dementia, as concluded by at lvtA(u)5n3 -0.001 Tc 0.001 Tdvwo(ED)]TJ0 Tc 0 T5528.09 0 Tc



- Alexander GC, Emerson S, Kesselheim AS. Evaluation of Aducanumab for Alzheimer Disease: Scientific Evidence and Regulatory Review Involving Efficacy, Safety, and Futility. JAMA. 2021;325(17):1717-1718. doi:10.1001/jama.2021.3854
- Haeberlein SB, von Hehn C, Tian Y, Chalkias S, et al. EMERGE and ENGAGE Topline Results: Two Phase 3 Studies to Evaluate Aducanumab in Patients With Early Alzheimer's Disease. Presented at: Clinical Trials on Alzheimer's Disease - 12th Conference (CTAD 2019). Dec 4th - Dec 7th, 2019; San Diego, CA, USA. JA(C2)(LTP)(10)(60.0)

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