

## PHARMACY POLICY STATEMENT North Carolina Marketplace resultsfrom the phase 3 clinical trials EMERGE and El

DRUG NAME	Aduhelm (aducanumab-avwa)	
BILLING CODE	J3590	
BENEFIT TYPE	Medical	
SITE OF SERVICE ALLOWED	Home/Office/Outpatient	
STATUS		

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

**Alzheimer's Disease** 



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.

If all the above requirements are met , the medication will be approved for 6 months

## 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 <u>at least two</u> of the following cognitive tests:
  - a) MMSE score of at least 19,
  - b) CDR-GS score of 1.0 or less,
  - c) CDR-SB score of 9.0 or less,
  - d) MoCA score of at least 18,
  - e) QDRS score of 12 or less; AND
- 2. Prior to the 7th infusion (first dose of 10 mg/kg) and 12th infusion (sixth dose of 10 mg/kg), repeat MRI must be completed to evaluate for amyloid related imaging abnormalities-edema (ARIA-E), which can be observed on MRI as brain edema, and amyloid related imaging abnormalities-hemosiderin deposition (ARIA-H), which includes microhemorrhage. Discontinuation is warranted in those with severe symptomatic ARIA<sup>10</sup>, radiographically severe ARIA-H, and as otherwise outlined in the prescribing information.

If all the above requirements are met, the medication will be approved for an additional 6 months.



- 7. Sevigny J, Chiao P, Bussière T, et al. The antibody DGXFDQXPDE UHGXFHV \$ SODTXHV LQ \$C disease. Nature. 2016;537(7618):50-56. doi:10.1038/nature19323
- Lin GA, Whittington MD, Synnott PG, McKenna A, Campbell J, Pearson SD, Rind DM. Aducanumab for Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, May 5, 2021. <u>https://icer.org/assessment/alzheimersdisease-2021/</u>.
- Ackley SF, Zimmerman SC, Brenowitz WD, et al. Effect of reductions in amyloid levels on cognitive change in randomized trials: instrumental variable meta-analysis. BMJ. 2021;372:n156. Published 2021 Feb 25. doi:10.1136/bmj.n156
- 10. Cummings, J., Aisen, P., Apostolova, L.G. et al. Aducanumab: Appropriate Use Recommendations. J Prev Alzheimers Dis (2021). https://doi.org/10.14283/jpad.2021.41

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