Medical Policy

Aduhelm™ (aducanumab-avwa)	
MEDICAL POLICY NUMBER	Med_Clin_Ops_078
ORIGINAL EFFECTIVE DATE	July 19, 2021
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Aduhelm™ (aducanumab-avwa) therapy.

POLICY

Aduhelm™ (aducanumab-avwa) is not considered medically necessary due to insufficient evidence of therapeutic value. Aducanumab-avwa does not meet the definition of medical necessity for all indications including, but not limited to, Alzheimer's disease, cognitive impairment due to Alzheimer's disease, Alzheimer's disease related dementia, as a clinical benefit has not been established.

LIMITATIONS/EXCLUSIONS

1. Aduhelm is considered experimental and investigational for all indications and is therefore not covered.
2. Medicare benefit

a. Coverage of the Aduhelm is contingent upon patient enrollment in a qualifying clinical trial (FDA-approved randomized controlled trial, CMS approved study, or study supported by the NIH).
b. Any other use is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit and is NOT covered.

BACKGROUND

Adacanumab-avwa is a recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. Adacanumab-avwa indicated for the treatment of Alzheimer's disease in those with mild cognitive impairment or mild dementia as studied in clinical trials.

This indication was approved under an accelerated approval based on a reduction in amyloid beta plaques observed in patients treated with adacanumab-avwa. The relationship between clearance of beta amyloid in the brain and clinical improvement has not been demonstrated. Use of adacanumab-avwa may result in ARIA, including bleeding into brain tissue (in clinical trials, at least one death has been attributed to this).

NOTE: An FDA advisory committee determined efficacy data on was inconclusive given the discordant results from clinical trials.

DEFINITIONS

1. ADUHELM (aducanumab-avwa) injection is a preservative-free, sterile, clear to opalescent, and colorless to yellow solution. ADUHELM is supplied one vial per carton as follows:
    a. 170 mg/1.7 mL (100 mg/mL) single-dose vial (with red flip cap) – NDC 64406-101-01
    b. 300 mg/3 mL (100 mg/mL) single-dose vial (with blue flip cap) – NDC 64406-102-02

CODING

Applicable NDC Codes	
64406-0101-01	ADUHELM (aducanumab-avwa) injection 170 mg/1.7 mL (100 mg/mL) single-dose vial
64406-0102-02	ADUHELM (aducanumab-avwa) injection 300 mg/3 mL (100 mg/mL) single-dose vial

Applicable Procedure Code	
J3590	Unclassified biologics (When utilized for Aduhelm [aducanumab-avwa])

Applicable ICD-10 Codes	
G30	Alzheimer's disease
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset

G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified

EVIDENCE BASED REFERENCES

1. Product Information: ADUHELM(TM) intravenous injection, aducanumab-avwa intravenous injection. Biogen, Inc (per FDA), Cambridge, MA, 2021.
2. Sevigny J, Chiao P, Bussière T, et al. The antibody aducanumab reduces Aβ plaques in Alzheimer's disease. Nature. 2016 Sep 1;537(7618):50-6. doi: 10.1038/nature19323. Update in: Nature. 2017 Jun 21;546(7659):564.
3. Biogen. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Available from: https://clinicaltrials.gov/ct2/show/NCT02484547?term=NCT02484547&draw=2&rank=1. Accessed November 22, 2021.
4. Biogen. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (ENGAGE). Available from: https://clinicaltrials.gov/ct2/show/NCT02477800?term=NCT02477800&draw=2&rank=1. Accessed November 22, 2021.
5. Lin GA, Whittington MD, Synnott PG, et al. Aducanumab for Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, May 5, 2021. https://icer.org/assessment/alzheimers-disease-2021/.

POLICY HISTORY

Original Effective Date	July 19, 2021
Revised Date	January 1, 2022 – Aduhelm's (aducanumab-avwa) is now considered investigational/experimental and is therefore not medically necessary under all lines of business. P&T Approved. May 24, 2022 – Added clarifying language to scenarios for coverage under the Medicare Part B benefit per CMS guidance. P&T Approved. March 1, 2023 – Adopted by MA UMC January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)