# POLICY – MPP – ADUHELM (ADUCANUMAB-AVWA)

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| **Department/Team** | Medical Management/Medical Payment Policy (MPP) |
| **Approval By** | HQUM |
| **Approval Date** | December 27, 2021 |
| **Effective Date** | May 2, 2022 |
| **Line of Business** | ☒ CCC+ ☐ Exchange<br>☒ Medallion 4.0<br>☒ D-SNP<br>☐ MAPD |

**PURPOSE**

This policy outlines guidelines and criteria for coverage determination of Aduhelm (aducanumab-avwa) injection for intravenous use for the treatment of Alzheimer's Disease.

**DESCRIPTION**

Alzheimer's disease is the most common cause of dementia among older adults. It is currently ranked as the sixth leading cause of death in the United States. More than 25 million people in the world today are affected by dementia, most suffering from Alzheimer's Disease. It is common for most people to have mixed dementia. Symptoms include memory loss, language problems, and unpredictable behavior. Dementia can be caused by abnormal brain clumps, called amyloid plaques, and tangled bundles of fibers, called neurofibrillary, or tau tangles. These plaques and tangles in the brain are considered some of the main features of Alzheimer's Disease.

Aduhelm (aducanumab-avwa) is an amyloid beta-directed antibody indicated for treatment of Alzheimer's disease. The indication was approved under accelerated approval base on reduction in amyloid beta plaques observed in patients treated with Aduhelm. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

**DEFINITIONS**

Mild Cognitive Impairment (MCI): the stage between the expected cognitive decline of normal aging and the more serious decline of dementia. It's characterized by problems with memory, language, thinking or judgment.

Dementia: Dementia is diagnosed when there are cognitive or behavioral (neuropsychiatric) symptoms that interfere with the ability to function at work or usual activities, represent a decline from previous levels of functioning and performance; and are not explained by delirium or major psychiatric disorder.

**GUIDELINES/INSTRUCTIONS**

**SCOPE**: This policy specifically addresses the use of intravenous infusion of Aduhelm in the treatment of Alzheimer's Disease.

**POSITION:** FDA approved treatment for mild to moderate Alzheimer's Disease for members who meet prior authorization criteria described below.

**Initial Approval Criteria**

1. Must be prescribed by, or in consultation with a specialist in neurology **AND**
2. Must be ≥ 50 years of age or older **AND**
3. Must meet all the criteria for MCI due to probable AD or mild AD dementia according to The National Institute on Aging – Alzheimer's Association (NIA-AA) criteria (see McKhann et. al, reference below ), and must have the following:
    a. MCI due to AD a Clinical Dementia Rating-Global (CDR-GS) score of 0.5, and a Mini-Mental Status Exam (MMSE) score between 24 and 30 **OR**
    **b.** Mild AD dementia CDR-GS score of 0.5 or 1, and an MMSE score between 20 and 25 **OR**
    **c.** Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index score of 85 or below **AND**
4. Chart notes submitted support signs and symptoms of mild cognitive impairment characterized by skills that affect member (i.e., ability to make sound decisions, judge time, sequence, steps needed to complete a complex task) **AND**
5. Chart notes submitted rule out other differential diagnoses such as (dementia with Lewy bodies, frontotemporal dementia, vascular dementia, B12 deficiency, encephalopathy, etc.) AND
6. Patient has received a baseline brain MRI prior to initiation of treatment within one year. Also, MRIs needed to be obtained prior the 7$^{th}$ infusion and 12$^{th}$ infusion. **AND**
7. Dementia caused by or related to beta amyloid plaque evident by positive PET scan **AND**
8. Patient has not had any of the following within 1 year of treatment initiation
    a. Pre-treatment localized superficial siderosis
    b. 10 or more micro brain microhemorrhages
    **c.** Brain hemorrhage ≥ 1cm **AND**
9. Patient is not currently receiving anti-platelet agents, anticoagulants, or anti-thrombin; (exception of aspirin prophylaxis)

**Reauthorization Criteria**

1. Patient has responded to therapy compared to pretreatment baseline shown by improvement, stability, or slowing of progression of disease as evident of documentation of:
    a. CDR-GS score of 0.5 **OR**
    **b.** MMSE score between 24 and 30 **OR**
    **c.** RBANS memory index of 85 or below **AND**
2. Brain MRI studies conducted prior to 7$^{th}$ infusion and if 10 or more new incident microhemorrhages or > 2 focal areas of superficial siderosis (radiographic severe ARIA-H) is observed, treatment may be continued with caution ONLY after a clinical evaluation and a

follow-up MRI demonstrates radiographic stabilization.

**Exclusion Criteria**

1. Any uncontrolled medical or neurodegenerative condition that could be contributing to cognitive impairment
2. Clinically unstable psychiatric illness in the past 6 months
3. Transient ischemic attack or stroke or any unexplained loss of consciousness within 12 months of treatment initiation.
4. Impaired renal or liver function
5. Members who have Human Immunodeficiency Virus (HIV)
6. Alcohol or substance abuse in the past year
7. Any contraindications to brain magnetic resonance imaging (MRI) or PET scans
8. Significant systematic illness or infection in the past 30 days

**Initial Approval 6 months (6 doses)**

**Renewal Approval (4 months, once patient has received MRI prior to 7th infusion)**

**Maintenance Approval after 12 infusions for 6 months (6 infusions per approval period after patient has received MRI prior to 12th infusion)**

**DOSAGE:**

| IV Infusion (every 4 weeks) | ADUHELM Dosage (administered over approximately one hour) |
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| Infusion 1 and 2 | 1 mg/kg |
| Infusion 3 and 4 | 3 mg/kg |
| Infusion 5 and 6 | 6 mg/kg |
| Infusion 7 and beyond | 10 mg/kg |

After an initial titration, the recommended dosage of ADUHELM is 10 mg/kg.
ADUHELM is administered as an intravenous (IV) infusion via a 0.2 or 0.22 micron in-line filer over approximately one hour every four weeks and at least 21 days apart.

**CODING:**

**HCPCS**

J3590 or J3490 unclassified biologics (newly FDA approved medication)

**ICD-10 Diagnosis**

G30 Alzheimer's disease

**REFERENCES**

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2. Aduhelm [package insert]. Cambridge, MA; Biogen Inc; July 2021

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 July 3, 2021

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5. Cummings J. Aducanumab: Appropriate use recommendations. Alzheimer's Dementia.2021;1-3.

6. McKhann, Guy M et al. "The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease." *Alzheimer's & dementia : the journal of the Alzheimer's Association* vol. 7,3 (2011): 263-9. doi:10.1016/j.jalz.2011.03.005 Accessed October 7, 2021 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3312024/

| Related Documents |
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| Revision History | | |
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| **Date** | **By** | **Description** |
| 9/23/2021 | Joseph Kupiec, PharmD | Original creation of policy |
| 11/11/2021 | Joseph Kupiec, PharmD | Additions of exclusion criteria and approval by P&T Committee |

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