MetroPlus Health

# Policy and Procedure

| Title: Aduhelm (Aducanumab-avwa) | Division: Medical Management<br>Department: Pharmacy, Utilization Management |
|---|---|
| Approval Date: 1/28/2022 | LOB: Medicaid, Medicare, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP, UltraCare |
| Effective Date: 1/28/2022 | Policy Number: UM-MP327 |
| Review Date: 1/28/2022, 6/27/2022 | Cross Reference Number: |
| Retired Date: | Page 1 of 7 |

1. **POLICY DESCRIPTION:**
   Alzheimer's Disease - Amyloid Directed Monoclonal Antibody, Aduhelm

2. **RESPONSIBLE PARTIES:**
   Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. **DEFINITIONS:**
   Aduhelm is indicated for the treatment of Alzheimer's Disease. Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication was approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Aduhelm.

4. **POLICY – FDA APPROVED INDICATIONS**
   A. **Alzheimer's Disease**
      Aduhelm will be considered medically necessary when the following conditions of coverage have been met:

      **Initial Request:**
      a. Patient has a diagnosis of Alzheimer's with documentation of disease history from prescriber **AND**
      b. Aduhelm is prescribed by or in consultation with a psychiatrist, neurologist, or Neuropsychiatrist **AND**
      c. Patient is 50 years or older **AND**
      d. Dosing is performed according to FDA regulations (no more than 6 doses)
         i. Dose 1 and 2: 1 mg/kg every 4 weeks
         ii. Dose 3 and 4: 3 mg/kg every 4 weeks
         iii. Dose 5 and 6: 6 mg/kg every 4 weeks

         **AND**
      e. Documentation of magnetic resonance imaging within the past year showing **ALL** of the below:
         i. No localized superficial siderosis
         ii. Less than 10 brain microhemorrhages
         iii. No brain hemorrhage greater than 1 cm within one year

         **AND**

f. Patient has objective evidence of cognitive impairment at baseline (see Appendix A)
**AND**
g. Patient has mild dementia or mild cognitive impairment confirmed by **BOTH** of the following scores within the past 6 months:
    i. Clinical Dementia Rating (CDR) – Global Score of 0.5 or 1 (see Appendix B)
    **AND**
    ii. Mini-Mental Examination Status (MMSE) score of 20 - 30 (see Appendix C)
**AND**
h. One of the following:
    i. Confirmed presence of beta-amyloid plaques by Positron emission topography (PET) scan or other neuroimaging; i.e. brain biopsy
    **OR**
    ii. An beta-amyloid 42/40 ratio (AB42/AB40 ratio) $\leq$ 0.25 confirmed by Cerebrospinal fluid (CSF) testing
**AND**
i. The following causes of dementia have been ruled out:
    i. Frontotemporal lobar dementia
    ii. Dementia with Lewy Bodies
    iii. Vascular dementia
    iv. Huntington's disease
    v. HIV dementia complex
    vi. Creutzfeldt-Jakob disease
**AND**
j. Patient has been previously treated with Alzheimer's drug therapies (i.e: donepezil, galantamine, memantine, rivastigmine)

*Approved for 6 months*

**Renewal Request:**

a. Initial conditions of coverage have been met
b. Individual doses cannot exceed 10 mg/kg
c. Member has been evaluated for evidence of severe amyloid-related imaging abnormalities (ARIA) on MRI prior the 7$^{th}$ dose (first dose of 10 mg/kg). (See Appendix D)
    i. 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 (i.e., no increase in size or number of ARIA-H).

*Approved for 6 months*

**5. LIMITATIONS/ EXCLUSIONS:**

a. Suspected neurodegenerative etiology of cognitive impairment other than Alzheimer's disease (AD), including but not limited to frontotemporal lobar degeneration (FTLD), vascular dementia, or Lewy body disease (i.e., meeting consensus criteria for possible or probable dementia with Lewy bodies.
b. Requirement for therapeutic anticoagulation (e.g., anticoagulants, antiplatelets), except for aspirin at a prophylaxis dose or less (no more than 325 mg daily).
c. Stroke, transient ischemic attack (TIA), or unexplained loss of consciousness within the past year.
d. Brain hemorrhages, cerebrovascular disorders, or bleeding disorders within the past 6 months.
e. Unstable angina, myocardial infarction, or advanced chronic heart failure within the past year.
f. HIV infection or significant systemic infection within the past 30 days

**6. APPLICABLE PROCEDURE CODES:**

| CPT | Description |
|---|---|
| J0172 | Injection, aducanumab-avwa, 2 mg |

**7. APPLICABLE DIAGNOSIS CODES:**

| CODE | Description |
|---|---|
| G30.9 | Alzheimer's disease, unspecified |

**8. APPENDICES**

**Appendix A: Summary of clinical and cognitive evaluation for mild cognitive impairment due to Alzheimer's Disease**

- Cognitive concern reflecting a change in cognition reported by patient or information or clinician (i.e. historical or observed evidence of decline over time)
- Objective evidence of impairment in one or more cognitive domains, typically including memory (i.e., formal or bedside testing to establish level of cognitive function in multiple domains)
- Preservation of independence in functional abilities
- Not demented

**Appendix B: Clinical Dementia Rating (CDR) Scale**

The CDR is obtained through semi-structured interviews of patients and informants with cognitive functioning rated on a 5-point scale in the following domains: memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care. The score relates to the member's level of dementia:

- 0 = Normal
- 0.5 = Very Mild Dementia
- 1 = Mild Dementia
- 2 = Moderate Dementia
- 3 = Severe Dementia

**Appendix C: Mini-Mental Status Exam (MMSE)**

The MMSE is scored on a 30-point scale, with items that assess orientation (temporal and spatial; 10 points), memory (registration and recall; 6 points), attention/concentration (5 points), language (verbal and written, 8 points), and visuospatial function (1 point). The score relates to the member's level of dementia:

- 25 - 30 suggest normal cognition
- 20 – 24 suggests mild dementia
- 13 – 20 suggests moderate dementia
- Less than 12 suggests severe dementia

**Appendix D: ARIA MRI Classification Criteria**

| ARIA Type | Radiographic Severity |
|---|---|

| | Mild | Moderate | Severe |
|---|---|---|---|
| ARIA-E | FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location < 5 cm | FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring < 10 cm | FLAIR hyperintensity measuring > 10 cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted. |
| ARIA-H Microhemorrhage | 4 or fewer new incident microhemorrhages | 5 to 9 new incident microhemorrhages | 10 or more new incident microhemorrhages |
| ARIA-H Superficial Siderosis | 1 focal area of superficial siderosis | 2 focal areas of superficial siderosis | More than 2 focal areas of superficial siderosis |

## 9. REFERENCES:


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**REVISION LOG:**

| REVISIONS | DATE |
|---|---|
| Creation date: | 1/28/2022 |
| Updated HCPCS code | 6/27/22 |

| Approved: | Date: | Approved: | Date: |
|---|---|---|---|
| Glendon Henry — Digitally signed by Glendon Henry Date: 2022.06.28 11:03:08 -04'00' | | Sanjiv Shah MD — Digitally signed by Sanjiv Shah MD Date: 2022.07.06 17:31:54 -04'00' | |
| **Glendon Henry, MD**<br>**Senior Medical Director** | | **Sanjiv Shah, MD**<br>**Chief Medical Officer** | |

## Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.
All coding and website links are accurate at time of publication.
MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.