Clinical Policy: Aducanumab-avwa (Aduhelm)

Reference Number: KY. CP.PHAR.468
Effective Date: 04.18.22
Line of Business: Medicaid
Last Review Date:

Coding Implications
Revision Log

Description
Aducanumab-avwa (Aduhelm™) is a monoclonal antibody targeting amyloid beta.

FDA Approved Indication(s)
Aduhelm is indicated for the treatment of Alzheimer's disease (AD). Treatment with Aduhelm should be initiated in patients with mild cognitive impairment or mild dementia stage of the 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 is approved under accelerated approval based 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).

Policy/Criteria

It is the policy of WellCare of Kentucky as directed by the Kentucky Cabinet for Health and Family Services that Aduhelm is medically necessary for its FDA-approved indication.

I. Initial Approval
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Initial approval is for 6 months.

- Prescribed by or in consultation with a Neurologist, Geriatrician, Geropsychiatric specialist OR AD Specialist. If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests.

- Provider attestation that the member has a diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia associated with AD disease dementia.

- Confirmation of beta-amyloid plaques verified by one of the following
  - Positron emission tomography (PET) scan OR
  - Lumbar puncture for cerebrospinal fluid (CSF) testing

- Prescriber has assessed and documented baseline disease severity utilizing one of the following scores (within the past 6 months):
  - Mini-Mental Status Exam (MMSE) score ≥ 24
  - Montreal Cognitive Assessment (MoCA) ≥ 15

- Documentation the member has concurrent or historic trial and failure of 2 or more of the following: Alzheimer's drug therapies [Donepezil (Aricept), Galantamine (Razadyne), Rivastigmine (Exelon)]

- Documentation within medical record member does not have ANY of the following:
  - Member does NOT have any medical or neurological condition (other than Alzheimer's Disease) that might be a contributing cause of the subject's cognitive impairment, specifically ruling out ALL of the following:
    - vascular dementia; and
    - lewy body dementia; and
    - frontotemporal dementia; and
    - dementia in down's syndrome; and
    - Parkinson's disease dementia; and

  - Member has NOT had a Transient Ischemic Attack (TIA), stroke or unexplained loss of consciousness in the past 1 year

  - Member does NOT have a history or known seropositivity for human immunodeficiency virus (HIV).

  - Member does NOT have any of the following neurological or psychiatric conditions:
    - uncontrolled seizure disorder; and
    - uncontrolled mood disorder, anxiety disorder, or psychosis

  - Member does NOT have any of the following cardiovascular conditions:
    - uncontrolled hypertension; and
    - coronary artery disease, including unstable angina and myocardial infarction; and
    - heart failure; and
    - arrythmia; and
    - clinically significant carotid atherosclerosis and/or peripheral arterial disease; and

  - Member does NOT have any contraindications to brain magnetic resonance imaging (MRI) or PET scans

  - Member does NOT have any significant cerebrovascular disease as established by brain MRI showing any of the following (within the past year prior to starting treatment):
    - acute or sub-acute hemorrhage; and
    - prior macro-hemorrhage or prior subarachnoid underlying structural or vascular hemorrhage; and
    - greater than four microhemorrhages; and
    - cortical infarct; and
    - greater than one lacunar infarct; and

- superficial siderosis; and
- history of diffuse white matter disease

- Member is NOT currently taking blood thinners (except for aspirin at a prophylactic dose < 325mg/day)

- Member NOT have any uncontrolled clinically significant chronic medical conditions (e.g. liver disease, kidney disease, pulmonary disease, autoimmune disease requiring chronic immunosuppression, malignant neoplasm, active chronic infection [HCV], poorly controlled diabetes mellitus).

- Member does NOT have a recent history (within last year) of the following:
  - use of illicit narcotic medication
  - alcohol or substance use disorder

- Prescriber attests to the following:

  - Dose will not exceed the following (must meet all):
    - Infusion 1 and 2: 1 mg/kg per 4 weeks
    - Infusion 3 and 4: 3 mg/kg per 4 weeks
    - Infusion 5 and 6: 6 mg/kg per 4 weeks

  - Follow-up MRI will be obtained at the following time frame:
    - Week 14 (after 4th infusion, prior to the first 6 mg/kg dose); and
    - Week 22 (after 6th infusion, prior to first 10 mg/kg dose); and
    - Week 30 (after 8th infusion, prior to third 10 mg/kg dose); and
    - Week 42 (after 11th infusion; prior to sixths 10 mg/kg dose); and
    - Every six months thereafter

  - Member and/or authorized representative (e.g., power of attorney, invoked health care proxy) has been informed of the known and potential risks and lack of established clinical benefit associated with Aduhelm treatment

II. Continuation of Therapy:

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. Continuation of approval is for 1 year.

- Documentation member is able to tolerate the 10mg/kg dosing.
- Documentation of a follow-up MRI:
  - Week 14 (after 4th infusion, prior to the first 6 mg/kg dose); and
  - Week 22 (after 6th infusion, prior to first 10 mg/kg dose); and
  - Week 30 (after 8th infusion, prior to third 10 mg/kg dose); and
  - Week 42 (after 11th infusion; prior to sixths 10 mg/kg dose); and
  - Every six months thereafter

- Evaluation for amyloid-related imaging abnormalities and provider documentation clearly indicates which of the following from each category applies to the member:

    - Amyloid-related imaging abnormalities-hemosiderin (ARIA-H), microhemorrhages:
        - Member has no new incident microhemorrhage; or
        - Member has had one to four new incident microhemorrhage(s) and microhemorrhages are asymptomatic (no clinical symptoms); or
        - Member has had five to nine new incident microhemorrhage(s) and microhemorrhages are asymptomatic (no clinical symptoms) and the microhemorrhages have been stabilized; or
        - Member has had one to nine new incident microhemorrhage(s) and microhemorrhages, which have resulted in mild, moderate or severe clinical symptoms and the microhemorrhages have been stabilized; AND

    - Amyloid-related imaging abnormalities (ARIA-H), superficial siderosis
        - Member has no new incident areas of superficial siderosis; or
        - Member has had one new incident area of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms); or
        - Member has had two new incident areas of superficial siderosis and superficial siderosis is asymptomatic (no clinical symptoms) and the superficial siderosis has been stabilized; or
        - Member has had one to two new incident areas of superficial siderosis, which resulted in mild, moderate or severe clinical symptoms and the superficial siderosis have been stabilized; AND

    - Amyloid-related imaging abnormalities-edema (ARIA-E)
        - Member has no new ARIA-E; or
        - Member has mild ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms); or
        - Member has moderate or severe ARIA-E on MRI and ARIA-E is asymptomatic (no clinical symptoms) and the ARIA-E is stable; or
        - Member has had one to two new incident areas of superficial siderosis, which resulted in mild, moderate or severe clinical symptoms and the superficial siderosis have been stabilized

- Provider attests that the member does not have an emergence of any of the below listed conditions OR provides clinical rationale for continued use of Aduhelm with the noted change in clinical status:

    - Member has not developed any of the following conditions:
        - Initiation of anticoagulation; and

- Development of an active immune medicated/autoimmune condition (e.g., Crohn's disease, myasthenia gravis, aplastic anemia, meningitis/encephalitis); and
- Initiation of immunomodulatory medication (e.g., cancer immunotherapies, rituximab, azathioprine); and
- Development of other neurologic condition (e.g. intracerebral bleeds, traumatic injury, stroke); or

- A copy of the MMSE or MoCA (within three months of renewal) documenting the member has not had disease progression by one of the following:
  - MMSE $\geq$ 24; or
  - MoCA $\geq$ 15; or
  - MMSE < 24 or MoCA < 15 and
  - Rate of decline was slower than expected (< two points/year)

Coding Implications

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HCPCS Codes	Description
J0172	Injection, aducanumab-avwa, 2 mg

Reviews, Revisions, and Approvals	Date	Approval Date
State approved for all MCOs to implement		4/18/22
State removed off-label criteria		5/9/22

References

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6. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's Disease (EMERGE). Clinical trials.gov

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