Aduhelm™ (aducanumab-avwa)  
(Intravenous)

Document Number: IC-0610

Last Review Date: 06/06/2022  
Date of Origin: 07/01/2021  
Dates Reviewed: 07/2021, 06/2022

I. Length of Authorization

- Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:
   - Aduhelm 170 mg/1.7 mL (100 mg/mL) solution in a single-dose vial: 1 vial every 28 days
   - Aduhelm 300 mg/3 mL (100 mg/mL) solution in a single-dose vial: 4 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:
   - Infusions 1 & 2: 57 billable units (115 mg) every 28 days
   - Infusions 3 & 4: 172 billable units (345 mg) every 28 days
   - Infusions 5 & 6: 345 billable units (690 mg) every 28 days
   - Infusion 7 and beyond: 575 billable units (1,150 mg) every 28 days

III. Initial Approval Criteria \(^{1,5,6,9}\)

Coverage is provided in the following conditions:

- Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., Mini-Mental Status Exam [MMSE], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.): AND

- Patient does not have any of the following within 1 year of treatment initiation: pre-treatment localized superficial siderosis, 10 or more brain microhemorrhages, or brain hemorrhage >1 cm: AND

Universal Criteria \(^{1,6,6,9}\)

- Must be prescribed by, or in consultation with, a specialist in neurology or gerontology; AND
• Patient has received a baseline brain magnetic resonance imaging (MRI) prior to initiating treatment (within one year prior – unless the patient has a more recent exacerbation, traumatic event [e.g., falls, etc.], or co-morbidity necessitating an evaluation within one month preceding initiation) and periodically throughout therapy (see prescribing information for schedule of MRI scans): AND

• Patient has not had a stroke or transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months: AND

• Patient does not have any relevant brain hemorrhage, bleeding disorder, cerebrovascular abnormalities, or recent (within the prior year) cardiovascular condition (e.g., unstable angina, myocardial infarction, advanced CHF, or clinically significant conduction abnormalities): AND

• Patient does not have a clinically significant and unstable psychiatric illness in the past 6 months: AND

• Patient is not currently receiving anti-platelet agents (with the exception of prophylactic aspirin), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin): AND

• Patient does not have a history of alcohol or substance abuse in the preceding year: AND

Alzheimer’s Disease (AD) †1,2,5,6

• Patient has mild cognitive impairment (MCI) due to AD or has mild Alzheimer’s dementia (there is insufficient evidence in moderate or severe AD) as evidenced by all of the following:
  o Clinical Dementia Rating (CDR)-Global Score of 0.5
  o Objective evidence of cognitive impairment at screening
  o MMSE score between 24 and 30 (inclusive)
  o Positron Emission Tomography (PET) scan is positive for amyloid beta plaque

• Other conditions mimicking, but of non-Alzheimer’s Dementia etiology, have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], normal pressure hydrocephalus, etc.)

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ф Orphan Drug

IV. Renewal Criteria 1,5,6

Coverage may be renewed based upon the following criteria:

• Patient continues to meet the universal and other indication-specific relevant criteria identified in section III: AND

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: amyloid related imaging abnormalities-edema (ARIA-E), severe hypersensitivity reactions, etc.: AND

• Patient has responded to therapy compared to pretreatment baseline as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment in one or more
of the following (not all-inclusive): ADAS-Cog 13; ADCS-ADL-MCI; MMSE; CDR-SB, etc.;

- Patient has not progressed to moderate or severe AD: **AND**
- Patient has received a pre-5th, 7th, 9th, **AND** 12th infusion MRI for monitoring of Amyloid Related Imaging Abnormalities—edema (ARIA-E) and Amyloid Related Imaging Abnormalities—hemosiderin (ARIA-H) microhemorrhages: **AND**

**ARIA-E**
- Patient is asymptomatic or mildly symptomatic with mild radiographic severity* on MRI: **OR**
- Patient is asymptomatic or mildly symptomatic with moderate to severe radiographic severity* on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve: **OR**
- Patient has moderate to severe symptoms with mild to severe radiographic severity* on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve

**ARIA-H**
- Patient is asymptomatic with mild radiographic severity* on MRI: **OR**
- Patient is asymptomatic with moderate radiographic severity* on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve: **OR**
- Patient is symptomatic with mild to moderate radiographic severity* on MRI **AND** administration will be suspended until MRI demonstrates radiographic resolution and symptoms, if present, resolve: **AND**
  - Clinical judgment will be used in considering whether to continue treatment or permanently discontinue

- Patient must continue maintenance therapy at the recommended dosage of 10 mg/kg every four weeks (Note: clinical efficacy was demonstrated only at the highest dose, therefore doses below 10 mg/kg are not supported and will not be approved)

<table>
<thead>
<tr>
<th>*ARIA Type 1</th>
<th>Radiographic Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td>ARIA-E</td>
<td>FLAIR hyperintensity confined to sulcus and or cortex/subcortical white matter in one location &lt; 5 cm</td>
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</tbody>
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**ADUHELM™ (aducanumab-avwa) Prior Auth Criteria**

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V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Aduhelm Dosage</th>
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<tbody>
<tr>
<td>Alzheimer's Disease (AD)</td>
<td></td>
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<tr>
<td>IV Infusion (every 4 weeks)</td>
<td></td>
</tr>
<tr>
<td>Infusions 1 &amp; 2</td>
<td>1 mg/kg</td>
</tr>
<tr>
<td>Infusions 3 &amp; 4</td>
<td>3 mg/kg</td>
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<tr>
<td>Infusions 5 &amp; 6</td>
<td>6 mg/kg</td>
</tr>
<tr>
<td>Infusion 7 &amp; beyond</td>
<td>10 mg/kg</td>
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</table>

- After an initial titration (see dosing schedule below), the recommended dosage of Aduhelm is 10 mg/kg and administered as an intravenous (IV) infusion over approximately one hour every four weeks and at least 21 days apart.

- Obtain recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment. Obtain MRIs prior to the 5th infusion (first dose of 6 mg/kg), 7th infusion (first dose of 10 mg/kg), 9th infusion (third dose of 10 mg/kg), and 12th infusion (sixth dose of 10 mg/kg).

- If an infusion is missed, resume administration at the same dose as soon as possible, infusions are to be administered every 4 weeks and at least 21 days apart.

VI. Billing Code/Availability Information

HCPCS Code:
- J0172 – Injection, aducanumab-avwa, 2 mg; 1 billable unit = 2 mg

NDC:
- Aduhelm 170 mg/1.7 mL (100 mg/mL) solution in a single-dose vial: 64406-0101-xx
- Aduhelm 300 mg/3 mL (100 mg/mL) solution in a single-dose vial: 64406-0102-xx

VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
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<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>G30.0</td>
<td>Alzheimer's disease with early onset</td>
</tr>
<tr>
<td>G30.1</td>
<td>Alzheimer's disease with late onset</td>
</tr>
<tr>
<td>G30.9</td>
<td>Alzheimer's disease, unspecified</td>
</tr>
<tr>
<td>G31.84</td>
<td>Mild cognitive impairment, so stated</td>
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</tbody>
</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

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<th>Contractor</th>
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<tbody>
<tr>
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<td>Noridian Healthcare Solutions, LLC</td>
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<tr>
<td>Jurisdiction</td>
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<td>--------------</td>
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</tr>
<tr>
<td>F (2 &amp; 3)</td>
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<tr>
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<td>15</td>
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<td>CGS Administrators, LLC</td>
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