

**Louisiana Medicaid**  
**Aducanumab-avwa (Aduhelm™)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for aducanumab-avwa (Aduhelm™).

Additional Point-of-Sale edits may apply.

*Aduhelm™ is indicated for the treatment of Alzheimer's disease. Treatment with Aduhelm™ should be initiated only in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. 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).*

*This agent may have a **Black Box Warning**, and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

## **Approval Criteria**

- The recipient has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia stage of disease; **AND**
- The recipient is 50 years of age or older on the date of the request; **AND**
- The medication is prescribed by a neurologist; **AND**
- Presence of beta-amyloid plaques is verified by one of the following (must be **stated on the request**):
  - Positron emission tomography (PET) scan; **OR**
  - Cerebrospinal fluid (CSF) testing; **AND**
- The prescriber has documented objective evidence of mild cognitive impairment or mild dementia due to Alzheimer's Disease using **BOTH** of the following tests:
  - The recipient has a Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 (score must be **stated on the request**); **AND**
  - The recipient has a Mini-Mental State Exam (MMSE) score of  $\geq 24$  (score must be **stated on the request**); **AND**
- The prescriber has assessed and documented **baseline** disease severity utilizing a validated tool including, but not limited to, the following:
  - Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog-13); **OR**
  - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS); **OR**
  - Clinical Dementia Rating – Sum of Boxes (CDR-SB); **OR**
  - Montreal Cognitive Assessment (MoCA).
- **[name of tool and date of test must be stated on the request]; AND**

- The recipient has no contraindications to magnetic resonance imaging (MRI) and has had a brain MRI within the past 12 months (**date must be specified**) demonstrating all of the following (must be **stated on the request**):
  - No localized superficial siderosis; **AND**
  - Less than 10 brain microhemorrhages; **AND**
  - No brain hemorrhage > 1 cm within the past year; **AND**
- The recipient is not currently taking blood thinners (except  $\leq$  81mg aspirin); **AND**
- The recipient is ambulatory (must be **stated on the request**); **AND**
- The prescriber **states on the request** that the recipient has not had a bleeding disorder or cerebrovascular abnormalities (including, but not limited to, stroke or transient ischemic attack [TIA]) in the last 12 months; **AND**
- The prescriber **states on the request** that other causes of cognitive impairment have been ruled out (including, but not limited to, alcohol/substance abuse, frontotemporal dementia (FTD), Lewy body dementia (LBD), Parkinson's disease dementia, unstable psychiatric illness, and vascular dementia); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The recipient does not have a history of unstable angina, myocardial infarction, advanced chronic heart failure, clinically significant conduction abnormalities or unexplained loss of consciousness within 1 year of treatment initiation; **AND**
  - The recipient has not had a seizure in the past 3 years; **AND**
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

**Duration of initial approval: 6 months (6 infusions)**

#### **Reauthorization Criteria for 7<sup>th</sup> through 11<sup>th</sup> Infusions**

- The recipient continues to meet all initial approval criteria; **AND**
- Prescriber attests that **POSITIVE CLINICAL RESPONSE** to treatment (as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment) has been demonstrated by assessment with the **same validated tool** that was used to establish baseline disease severity [**name of tool and date of test must be stated on the request**]; **AND**
- The prescriber **states on the request** that the recipient has not progressed to the moderate or severe stage of Alzheimer's disease; **AND**
- The recipient has had a brain MRI within the last month prior to the 7<sup>th</sup> infusion demonstrating less than 10 new incident microhemorrhages and less than 2 focal areas of superficial siderosis (**MRI date and findings of any new incident microhemorrhages or focal areas of superficial**

**siderosis must be stated on the request).** \*Note: It is recommended that practitioners use the same MRI device with the same imaging protocol for a given patient whenever possible to assist in comparing the images.\*

#### **Duration of approval for 7<sup>th</sup> through 11<sup>th</sup> infusions: 5 months (5 infusions)**

#### **Reauthorization Criteria for 12<sup>th</sup> and Subsequent Infusions**

- The recipient continues to meet all initial approval criteria; **AND**
- Prescriber attests that **POSITIVE CLINICAL RESPONSE** to treatment (as evidenced by improvement, stability, or slowing in cognitive and/or functional impairment) has been demonstrated by assessment with the **same validated tool** that was used to establish baseline disease severity **[name of tool and date of test must be stated on the request]**; **AND**
- The prescriber **states on the request** that the recipient has not progressed to the moderate or severe stage of Alzheimer's disease; **AND**
- Within one month prior to the 12<sup>th</sup> infusion and annually thereafter, the recipient must have a brain MRI demonstrating less than 10 new incident microhemorrhages and less than 2 focal areas of superficial siderosis **(MRI date and findings of any new incident microhemorrhages or focal areas of superficial siderosis must be stated on the request)**.

#### **Duration of approval for 12<sup>th</sup> and subsequent infusions: 12 months**

#### **References**

Aduhelm (aducanumab-avwa) [package insert]. Cambridge, MA: Biogen Inc; June 2021. <https://www.biogencdn.com/us/aduhelm-pi.pdf>

ClinicalTrials.gov. 221AD301 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's disease (ENGAGE). <https://clinicaltrials.gov/ct2/show/NCT02477800>

ClinicalTrials.gov. 221AD302 Phase 3 Study of Aducanumab (BIIB037) in Early Alzheimer's disease (EMERGE). Last updated May 6, 2021. <https://clinicaltrials.gov/ct2/show/NCT02484547>

<b>Revision / Date</b>	<b>Implementation Date</b>
Policy Created / July 2021	November 2021