Louisiana Medicaid
Alzheimer's Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for non-preferred Alzheimer's agents (except Aduhelm™).

The *Louisiana Medicaid Aducanumab-avwa (Aduhelm™) Clinical Authorization Form* should be utilized to request clinical authorization for aducanumab-avwa (Aduhelm™).

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** 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 for Non-Preferred Alzheimer's Agents (Except Aduhelm™)

Approval Criteria for Initial and Reauthorization Requests

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
    - The prescriber states that the recipient is currently using the requested medication; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - 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 and reauthorization approval: 12 months

Approval Criteria for Aduhelm™

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).

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 ≥ 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~~ 5 brain microhemorrhages; **AND**
    - No brain hemorrhage > 1 cm within the past year; **AND**
- The recipient is not currently taking blood thinners (except ≤ 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**
- If the request is for a non-preferred agent - **ONE** of the following is required:
    - The recipient has had a *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has a *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **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: 46 ~~6~~ months (46 ~~6~~ infusions)

Reauthorization Criteria for 57 ~~7~~th through 611 ~~11~~th 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 between the 4th and 5th infusions that does not demonstrate the following: (**MRI date and findings are stated on the request**)
    - Moderate or severe ARIA-E radiographic findings; **OR**
    - Moderate or severe ARIA-H radiographic findings; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate any ARIA-H clinical symptoms; **AND**

- The prescriber **states on the request** that the recipient does not demonstrate moderate or severe ARIA-E clinical symptoms.
- ~~The recipient has had a brain MRI within the last month prior to the 7th 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 5~~7~~th through 6~~11~~th infusions: 2~~5~~ months (2~~5~~ infusions)

Reauthorization Criteria for 7th through 8th 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 between the 6th and 7th infusions that does not demonstrate the following: (**MRI date and findings are stated on the request**)
    - Moderate or severe ARIA-E radiographic findings; **OR**
    - Moderate or severe ARIA-H radiographic findings; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate any ARIA-H clinical symptoms; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate moderate or severe ARIA-E clinical symptoms.

Duration of approval for 7th through 8th infusions: 2 months (2 infusions)

Reauthorization Criteria for 9th through 11th 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 between the 8th and 9th infusions that does not demonstrate the following: (**MRI date and findings are stated on the request**)
    - Moderate or severe ARIA-E radiographic findings; **OR**
    - Moderate or severe ARIA-H radiographic findings; **AND**

- The prescriber **states on the request** that the recipient does not demonstrate any ARIA-H clinical symptoms; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate moderate or severe ARIA-E clinical symptoms.

Duration of approval for 9th through 11th infusions: 3 months (3 infusions)

Reauthorization Criteria for 12th 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**
- The recipient has had a brain MRI between the 11th and 12th infusions, and annually thereafter, that does not demonstrate the following: (**MRI date and findings are stated on the request**)
    - Moderate or severe ARIA-E radiographic findings; **OR**
    - Moderate or severe ARIA-H radiographic findings; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate any ARIA-H clinical symptoms; **AND**
- The prescriber **states on the request** that the recipient does not demonstrate moderate or severe ARIA-E clinical symptoms.
- ~~Within one month prior to the 12th 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 12th and subsequent infusions: 12 months

References

Aduhelm (aducanumab-avwa) [package insert]. Cambridge, MA: Biogen Inc; ~~July~~February ~~2023~~1. https://www.biogencdn.com/us/aduhelm-pi.pdf

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; https://www.clinicalkey.com/pharmacology/

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

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. Pharmacotherapy: A Pathophysiologic Approach, 10e New York, NY: McGraw-Hill; https://accesspharmacy.mhmedical.com/book.aspx?bookid=1861

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Separated "Select Therapeutic Classes (Established)" into individual therapeutic class documents / November 2019	January 2020
Aduhelm™ policy created / July 2021	November 2021
Combined Aduhelm™ criteria with Alzheimer's Agents non-preferred therapeutic category; formatting changes / October 2021	January 2022
Modified Aduhelm™ reauthorization criteria to reflect updated MRI monitoring parameters, updated references / May 2023	October 2023