Louisiana Medicaid
Donanemab-azbt (Kisunla™)

The *Louisiana Medicaid Donanemab-azbt (Kisunla™) Clinical Authorization Form* should be utilized to request clinical authorization for donanemab-azbt (Kisunla™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Approval Criteria for Initiation of Therapy

- The recipient has a diagnosis of Alzheimer's disease with mild cognitive impairment or mild dementia stage of disease; **AND**
- The recipient is 59 years of age or older on the date of the request; **AND**
- The medication is prescribed by a geriatric psychiatrist, geriatrician or 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 or 1.0 (score must be **stated on the request**); **AND**
    - The recipient has a Mini-Mental State Exam (MMSE) score of ≥20 and ≤28 (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: (**name of tool and date of test must be stated on the request**)
    - Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog-13); **OR**
    - Alzheimer's Disease Assessment Scale – Cognitive Subscale (ADAS-Cog-14); **OR**
    - Repeatable Battery for the Assessment of Neuropsychological Status (RBANS); **OR**
    - Clinical Dementia Rating – Sum of Boxes (CDR-SB); **OR**
    - Montreal Cognitive Assessment (MoCA); **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**):
    - ≤1 area of superficial siderosis; **AND**
    - Four or fewer brain microhemorrhages; **AND**
    - No brain hemorrhage > 1 cm in diameter within the past year; **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.

Duration of approval for initiation of therapy: 1 month (1 infusion)

Approval Criteria for the 2nd Infusion

- 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 1st and 2nd 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 the 2nd infusion: 1 month (1 infusion)

Approval Criteria for the 3rd Infusion

- 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 2nd and 3rd 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 the 3rd infusion: 1 month (1 infusion)

Approval Criteria for 4th through 6th Infusions

- 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 3rd and 4th 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 4th through 6th infusions: 3 months (3 infusions)

Approval Criteria for 7th through 18th Infusions

- 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 18th infusions: 12 months

Approval Criteria for 19th and Subsequent Infusions

- 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 an annual brain MRI 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 19th and subsequent infusions: 12 months

References

ClinicalTrials.gov. A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2). https://clinicaltrials.gov/study/NCT04437511

Kisunla (donanemab-azbt) [package insert]. Indianapolis, IN: Eli Lilly and Company; July 2024. https://uspl.lilly.com/kisunla/kisunla.html#pi

Revision / Date	Implementation Date
Policy Created / August 2024	January 2025