Louisiana Medicaid
Lecanemab-irmb (Leqembi™)

The *Louisiana Medicaid Lecanemab-irmb (Leqembi™) Clinical Authorization Form* should be utilized to request clinical authorization for lecanemab-irmb (Leqembi™).

Additional Point-of-Sale edits may apply.

*This agent 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

- 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 or 1.0 (score must be **stated on the request**); **AND**
    - The recipient has a Mini-Mental State Exam (MMSE) score of ≥ 22 (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**):
    - No localized superficial siderosis; **AND**
    - Four or fewer brain microhemorrhages; **AND**
    - No brain hemorrhage > 1 cm in diameter within the past year; **AND**
- The recipient is not currently taking blood thinners (except ≤ 81mg aspirin); **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: (See Alzheimer's Agents – Cholinesterase Inhibitors on the PDL/NPDL for list of preferred agents)
    - 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 has not had a seizure in the past 12 months; **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: 2 months (4 infusions)

Reauthorization Criteria for 5th through 6th 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.

Duration of approval for 5th through 6th infusions: 1 month (2 infusions)

Reauthorization Criteria for 7th through 13th 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 13th infusions: 14 weeks (7 infusions)

Reauthorization Criteria for 14th 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 13th and 14th 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.

Duration of approval for 14th and subsequent infusions: 12 months

References

ClinicalTrials.gov. A Study to Evaluate Safety, Tolerability, and Efficacy of Lecanemab in Subjects With Early Alzheimer's Disease. https://clinicaltrials.gov/ct2/show/NCT01767311

Leqembi (lecanemab-irmb) [package insert]. Nutley, NJ: Eisai Inc; July 2023. https://www.leqembi.com/-/media/Files/Leqembi/Prescribing-Information.pdf?hash=3d7bf1a2-5db2-4990-8388-81086f415676

Revision / Date	Implementation Date
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