Generic Name: Lecanemab

Applicable Drugs: Leqembi™

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/22/2023

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:

A. Alzheimer's disease

i. Documented presence of amyloid beta pathology with one of the following:

1. Positron emission tomography (PET) scan
2. Lumbar puncture of cerebrospinal fluid (CSF) testing t-tau $A\beta_{1-42}$

B. Documentation of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease (AD) dementia and meets ALL of the following i to iv:

i. Clinical Dementia Rating-Global (CDR-G) score of 0.5 to 1.0

ii. CDR Memory Box score of > 0.5

iii. Mini-Mental State Examination (MMSE) score of 22 to 30

iv. Objective evidence of impairment in episodic memory documented as at least 1 standard deviation below age-adjusted mean in the Wechsler Memory Scale IV – Logical Memory II (WMS-IV LMII).

C. Documented brain MRI within the last year showing no localized superficial siderosis, fewer than 4 brain microhemorrhages, and no brain hemorrhages that are greater than 1 cm in diameter.

D. Documentation of one of the following i or ii:

i. Patient has been maintained on a stable dose of AD medication(s) (ie, acetylcholinesterase inhibitors, memantine, or both) for a duration of at least 12 weeks and agrees not to alter dose or medication regimen while taking lecanemab.

ii. Patient is AD treatment naïve and agrees not to initiate treatment with AD medication(s) (ie, acetylcholinesterase inhibitors, memantine, or both) for at least 12 months after initiating lecanemab.

E. Documentation of the patient's baseline activities of daily living (ADLs) and instrumental activities of daily living (IADLs).

II. Documentation that the patient is enrolled in a qualifying clinical trial and the clinical trial protocol is provided for review.

III. Request is for a medication with the appropriate FDA labeling and dosage, or its use is supported by current clinical practice guidelines.

IV. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Dementia due to other causes (ie, Lewy body dementia, Parkinson's disease dementia, frontotemporal dementia, dementia in down's syndrome, HIV-associated dementia, vascular dementia, etc).
- Patients with risk factors for intracerebral hemorrhage: prior cerebral hemorrhage > 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, and severe small vessel or white matter disease.
- History of transient ischemic attacks, stroke, or seizures in the previous 12 months.
- Patients using anticoagulants who are not at an optimized dose and stable for at least 4 weeks.
- History of clinically significant and unstable psychiatric illness in the previous 6 months.
- Pregnant or breastfeeding individuals.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 10 mg/kg IV infusion every 2 weeks

APPROVAL LENGTH

- **Authorization:** 3 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective including all of the following:
    I. Documentation of the patient's clinical progress, including current ADLs, and IADLs.

II. Documentation of positive response to therapy compared to pretreatment baseline with improvement, stability, or slowing in cognitive and/or functional impairment in MMSE and CDR-G scores.

III. No evidence of moderate AD or progression to moderate AD as evidenced by:

a. CDR-G score of 2 or 3

b. MMSE score of < 21

IV. Documentation of MRI prior to the 5th, 7th, and 14th infusions. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms. See Appendix Tables 4, 5, and 6 for ARIA Classification Criteria and dose interruption recommendations.

APPENDIX

Table 1. Clinical Dementia Rating- Global (CDR-G)

Score	Staging Category
0	No dementia
0.5	Questionable dementia
1	Mild dementia
2	Moderate dementia
3	Severe Dementia

Table 2. Mini-Mental State Examination (MMSE)[a]

Score	Staging Category
30	No dementia
26 to 29	Questionable dementia
21 to 25	Mild dementia
11 to 20	Moderate dementia
0 to 10	Severe dementia

[a] On average, the MMSE score of a person with Alzheimer's declines about 3.3 points per year.

Table 3. Wechsler Memory Scale IV – Logical Memory II (WMS-IV LMII)

Age (years)	1 standard deviation below age-adjusted mean
50 to 64	≤ 15
65 to 69	≤ 12
70 to 74	≤ 11
75 to 79	≤ 9
80 to 90	≤ 7

Table 4. ARIA MRI Classification Criteria

ARIA type	Radiographic Severity		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortex white matter in one location < 5 cm	FLAIR hyperintensity 5 to 10 cm in single greatest dimension, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity >10 cm with associated gyral swelling and sulcal effacement. One or more separate/ independent sites of involvement may be noted.
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	> 2 focal areas of superficial siderosis

Table 5. Dosing Recommendations for Patients with ARIA-E

Clinical Symptom Severity[a]	ARIA-E Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[b]	Suspend dosing[b]
Mild	May continue dosing based on clinical judgment	Suspend dosing[b]	
Moderate or Severe	Suspend dosing[b]		

[a] Mild: discomfort noted, but no disruption to normal daily activity. Moderate: discomfort that reduces or affects normal daily activity Severe: incapacitating, with inability to work or to perform normal daily activity

[b] Suspend dosing until MRI demonstrates radiographic resolution and symptoms resolve; consider MRI to assess resolution 2 to 4 months after initial detection. May resume dosing based on clinical judgment.

Table 6. Dosing Recommendations for Patients with ARIA-H

Clinical Symptom Severity[a]	ARIA-H Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[a]	Suspend dosing[b]
Symptomatic	Suspend dosing[a]	Suspend dosing[a]	

[a] Suspend dosing until MRI demonstrates radiographic resolution and symptoms resolve; consider MRI to assess resolution 2 to 4 months after initial detection. May resume dosing based on clinical judgment.

[b] Suspend dosing until MRI demonstrates radiographic resolution and symptoms resolve; use clinical judgment to consider whether to continue treatment or permanently discontinue treatment with Leqembi.

REFERENCES

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