Generic Name: Donanemab

Therapeutic Class or Brand Name: Kisunla™

Applicable Drugs: Click or tap here to enter text.

Preferred: N/A

Non-preferred: N/A

Date of Origin: 11/18/2024

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 for cerebrospinal fluid (CSF) testing $A\beta_{42}$, $A\beta_{42}/A\beta_{40}$ ratio, tau/$A\beta_{42}$ ratio

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

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

ii. Mini-Mental State Examination (MMSE) score of 20 to 28

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 donanemab.

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 donanemab.

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

F. Documentation confirming that genetic testing for ApoE ε4 has been offered to the patient.

II. Minimum age requirement: 60 years

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

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the 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, serious infection of the brain, 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.
- Pregnant or breastfeeding individuals.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 700 mg IV infusion every 4 weeks for the first three doses, followed by 1400 mg every 4 weeks thereafter

APPROVAL LENGTH

- **Authorization:** 6 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 2nd, 3rd, 4th, and 7th infusions. If radiographically observed ARIA occurs, treatment recommendations are based on type, severity, and presence of symptoms. See Appendix Tables 3, 4, and 5 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. 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 4. 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 of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.

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

Table 5. 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 until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; consider MRI to assess for resolution 2 to 4 months after initial detection. May resume dosing based on clinical judgment.

[b] Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment to consider whether to continue treatment or permanently discontinue treatment with Kisunla.

REFERENCES

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3. Petersen RC, Lopez O, Armstrong MJ, et al. Practice guideline update summary: Mild cognitive impairment: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology. 2018;90(3):126-135. doi:10.1212/WNL.0000000000004826
4. Dementia: Assessment, management and support for people living with dementia and their careers. London: National Institute for Health and Care Excellence (NICE); June 2018.
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6. Han L, Cole M, Bellavance F, McCusker J, Primeau F. Tracking cognitive decline in Alzheimer's disease using the mini-mental state examination: a meta-analysis. Int Psychogeriatr. 2000;12(2):231-247. doi:10.1017/s1041610200006359
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.