ALASKA MEDICAID
Prior Authorization Criteria

Leqembi™
(lecanemab-irmb)

FDA INDICATIONS AND USAGE[1]

Leqembi™ is an amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with Leqembi™ should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with Leqembi™. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

APPROVAL CRITERIA[1,2,3,4]

1. Patient is 50 years of age or older **AND**;
2. Prescribed by or in consultation with a neurologist **AND**;
3. Patient has the diagnosis of Alzheimer's disease **AND**;
4. Patient has the presence of beta-amyloid plaques verified by either a positron emission tomography (PET) scan or cerebrospinal fluid (CSF) testing **AND**;
5. Patient must have a documented brain magnetic resonance imaging (MRI) within the last year showing no localized superficial siderosis, has less than 4 brain microhemorrhages, and no brain hemorrhages that are greater than 1 cm in the past year **AND**;
6. Must have objective evidence of cognitive impairment at screening **AND**;
7. Patient has a Clinical Dementia Rating (CDR) global score of 0.5 or 1 **AND**;
8. Patient has a Mini-Mental State Exam (MMSE) of greater than or equal to 22 **AND**;
9. Other known causes of dementia have been ruled out (e.g. vascular dementia, Parkinson's disease dementia, etc.)

DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR**;
2. Patient is taking any blood thinners, other than aspirin 81mg or less **OR**;
3. Patient has had a brain hemorrhage, bleeding disorder, or cerebrovascular abnormalities in the last 6 months **OR**;
4. Patient has a significant systematic illness or infection in past 30 days **OR**;
5. Patient has a history of unstable angina, myocardial infarction, advanced chronic heart failure, or clinically significant conduction abnormalities within 1 year prior to Screening

CAUTIONS[1]

- Amyloid Related Imaging Abnormalities (ARIA): Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with Leqembi™. If a patient experiences symptoms which could be suggestive of ARIA, clinical evaluation should be performed, including MRI testing if indicated.
- The most common adverse reactions include infusion reactions, ARIA-Edema, headache, ARIA-H microhemorrhage, and ARIA-H superficial siderosis.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 6 months if:
  - MRI has been obtained prior to the 5th dose and shows no increase in size or number of ARIA. **AND**;
  - Documented evidence the patient is responding positively, has slowed the rate of cognitive decline, and evidence of no adverse reactions.
  - Additional MRI's will be required prior to the 7th and 14th doses to continue to screen for evidence of ARIA

QUANTITY LIMIT

- 10mg/kg infused over one hour once every two weeks
- HCPCS: J3590

REFERENCES / FOOTNOTES:

1. Leqembi (lecanemab-irmb) [prescribing information]. Nutley, NJ: Eisai Inc; January 2023
2. van Dyck C, Swanson C, et al.; Lecanemab in Early Alzheimer's Disease. N Engl J Med 2022 DOI: 10.1056/NEJMoa2212948. Available at: https://nejm.org/doi/full10.1056/NEJMoe2212948
3. Berry DA, Berry S, Gordon R, Kramer LD, Cummings JL.; Alzheimers Res Ther. 2021 Apr 17;13(1):80. DOI: 10.1186/s13195-021-00813-8
4. Institute for Clinical and Economic Review: Draft Evidence Report – Beta-Amyloid Antibodies for Early Alzheimer's Disease. December 22, 2022. Available at: https://icer.org/wp-content/uploads/2021/12/ICER_Alzheimers-Disease_Draft-Report_12222022-1.pdf. Accessed January 17, 2023.