

Clinical Oversight Review Board (CORB) Criteria for Prescribing Lecanemab (Leqembi)

Non-Formulary **lecanemab (Leqembi)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria and criteria for *new members* entering Kaiser Permanente already taking the medication who have not been reviewed previously:

- Prescribed by a neurologist
- Patient has a diagnosis of early dementia or mild cognitive impairment due to Alzheimer's disease
- Patient is age 50 to 90 years old
- Positive beta-amyloid and p-tau via spinal tap
- Body mass index (BMI) is greater than 17 but less than 35
- If patient is Apolipoprotein (ApoE) ϵ 4 homozygous, they are NOT currently taking antithrombotic or antiplatelet medications
- Patient does NOT meet any of the following:
 - Vascular dementia
 - Experienced a stroke, transient ischemic attack, or a seizure in the last 12 months
 - Bleeding disorder or platelet abnormality
 - Abnormal renal or liver function
 - Use of other monoclonal antibodies
 - Known history of human immunodeficiency virus (HIV)
 - Life expectancy of less than one year
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

Continued use criteria: Continued use will be contingent upon demonstrated response to therapy (to be reviewed every 12 months while on treatment). **Discontinuation is recommended in the following situations:**

- Patient has progressed to moderate dementia
- Patient has missed more than two consecutive doses, or more than two doses in a 6-month period
- Lack of response to therapy based on physician evaluation of cognition and functional assessments

Notes:

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- ApoE ϵ 4 homozygous: ApoE gene provides instructions for making a protein called apolipoprotein E. Having two copies of this gene (homozygous) was shown to increase risk of brain swelling or brain bleeding on lecanemab.
- Beta-amyloid: main component of the amyloid plaques found in the brains of people with Alzheimer's disease
- Phosphorylated tau (p-tau) is a key biomarker of Alzheimer's disease and can detect the earlier stages of Alzheimer's disease

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