

Clinical Oversight Review Board (CORB) Criteria for Prescribing Donanemab (Kisunla)

Notes:

- ApoE ε4 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
- * Aspirin 81 mg is appropriate as long as patient has indication for use

Non-Formulary **donanemab (Kisunla)** 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) ε4 homozygous, they are NOT currently taking antithrombotic or antiplatelet medications*
- Patient does NOT meet any of the following:
 - Vascular dementia
 - Relevant brain hemorrhage or cerebrovascular abnormalities seen on MRI
 - Bleeding disorder or platelet abnormality
 - Significant renal (creatinine clearance less than 30 mL/min) or significant liver function abnormalities
 - Concomitant use of other monoclonal antibodies
 - Known history of human immunodeficiency virus (HIV)
- Patient has been reviewed by the Kaiser Permanente Interregional Consultative Physician Panel, with recommendation to use medication

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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
- Lack of response to therapy based on physician evaluation of cognition and functional assessments

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