## 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

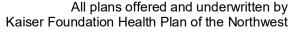
Non-Formulary **donanemab** (**Kisunla**) requires a clinical review. Appropriateness of therapy will be based on the following criteria:

# 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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Revised: 12/12/24 Effective: 02/20/25





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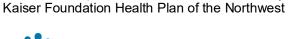
## Donanemab (Kisunla)

<u>Continued use criteria</u>: 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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