Prior Authorization Group Description	**Kisunla**
Drugs	Kisunla (donanemab-azbt)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	Patients with moderate to severe Alzheimer's Disease (AD) Patients with neurodegenerative disease caused by a condition other than AD
Required Medical Information	See "Other Criteria"
Age Restrictions	Age 60-85 years
Prescriber Restrictions	Prescriber must be a neurologist
Coverage Duration	For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months For reauthorization: if all of the conditions are met, the request will be approved for 6 months.
Other Criteria	**Initial Authorization** • Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o Clinical Dementia Rating Global (CDR-G) score of 0.5-1.0 o Mini-Mental State Examination (MMSE) score ≥ 20 and ≤ 28 o Montreal Cognitive Assessment (MoCA) score of ≥16 • The request is for an FDA approved dose • Documentation of BOTH of the following: o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan or cerebrospinal fluid testing o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan • Physician has assessed baseline disease severity utilizing an objective measure/tool (i.e., integrated Alzheimer's Disease Rating Scale [iADRS], Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog], Alzheimer's Disease Cooperative Study-instrumental Activities of Daily Living [ADCS-iADL], Clinical Dementia Rating-Sum of Boxes [CDR-SB], etc.) • No recent (past 1 year) history of stroke, seizures or transient ischemic attack (TIA), or findings on neuroimaging that indicate an increased risk for intracerebral hemorrhage **Reauthorization** • The request is for an FDA approved dose • Patient continues to have a diagnosis of MCI caused by AD or mild AD dementia consistent with Stage 3 or Stage 4 Alzheimer's disease as evidenced by at least one of the following: o CDR-G score of 0.5-1.0

Revision/Review Date: 11/2024	○ MMSE score of 20-28 ○ MoCA score of ≥16 • Provider attestation of safety monitoring and management of amyloid related imaging abnormalities (ARIA) and intracerebral hemorrhage, as recommended per the manufacturer's prescribing information • Documentation that member has experienced clinical benefit from the medication (i.e., stabilization or decreased rate of decline in symptoms from baseline on CDR-SB, iADRS, ADAS-Cog, or ADCS-iADL scales) • No recent (past 1 year) history of stroke, seizures or TIA **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**