COMMUNITY HEALTH CHOICE

December 24, 2024

PRIOR AUTHORIZATION CRITERIA FOR KISUNLA EFFECTIVE FEB. 1, 2025

BACKGROUND

On Jan. 1, 2025, Kisunla will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Kisunla (procedure code J0175) for Medicaid and CHIP, effective for dates of service on or after Feb. 1, 2025.

KEY DETAILS

Kisunla (Donanemab-azbt) is an amyloid-beta directed antibody indicated to treat Alzheimer's disease (AD) by reducing amyloid-beta plaques in clients with mild cognitive impairment or mild dementia stage of disease.

HHSC will consider initial prior authorization approval of Kisunla (Donanemab-azbt) infusion therapy when all of the following criteria are met:

- The client has a confirmed diagnosis of Alzheimer's disease (G30.0, G30.1, G30.8, or G30.9).
- Prescriber attests that other forms of dementia, except Alzheimer's disease, has been ruled out by appropriate lab or other diagnostic testing.
- Prescriber's confirmation of the presence of amyloid beta-plaques.
- Clinical testing must confirm that the client has mild cognitive impairment caused by Alzheimer's disease or a mild stage of Alzheimer's disease.
- Documentation that the client has received a baseline brain-magnetic resonance imaging (MRI) before initiating treatment (within the past year) to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA).
- Prescriber attests to test for ApoE ε4 status and counsel ApoE ε4 homozygotes clients on higher incidence of developing ARIA before initiation of treatment.

The following are monitoring requirements during the Kisunla (donanemab-azbt) treatment period:

- The prescriber must ensure the client is not currently taking any anti-coagulant (except for aspirin at a prophylactic dose or less) or have a history of clotting disorder.
- The prescriber must monitor for amyloid-related imaging abnormalities (ARIA) during the first 24 weeks.
- The prescriber attests to obtaining an MRI before the 2nd, 3rd, 4th and 7th infusion to check for asymptomatic ARIA.
- Clients with severe Amyloid Related Imaging Abnormalities-hemosiderin deposition (ARIA-H) may continue therapy only if radiographic stabilization has been confirmed by a follow-up MRI and supported by clinical evaluation.

For renewal or continuation of Kisunla therapy, clients must meet the following requirements:

- The client continues to meet all the initial authorization approval criteria.
- The client has not progressed to moderate or severe dementia caused by AD.

- The client experienced a positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
- Documentation of MRI (prior to 2nd, 3rd, 4th and 7th infusion) to check for ARIA with Kisunla treatment.
- The client has not experienced any complications or unacceptable toxicities during treatment with Kisunla.

ADDITIONAL INFORMATION

Refer to the Outpatient Drug Services Handbook chapter of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

HHSC approved this updated clinical prior authorization for use by MCOs and will implement criteria for fee-for-service Medicaid on Feb. 1, 2025. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.