TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Donanemab-azbt (Kisunla®)	**CRITERIA ID:** TX.CC.PHAR.47
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 02/01/2025	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 02/03/2025	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for donanemab-azbt (Kisunla®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

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

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of donanemab-azbt (Kisunla®); procedure code: J0175.

Description/Mechanism of Action:
Donanemab-azbt (Kisunla®) is an amyloid-beta directed antibody.

FDA Approved Indications:
Donanemab-azbt (Kisunla®) is indicated for the treatment of Alzheimer's disease (AD).

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Alzheimer's Disease (must meet all):

1. The client has a confirmed diagnosis of Alzheimer's disease (diagnosis codes: G30.0, G30.1, G30.8, G30.9).
2. Prescriber attestation that other forms of dementia, except Alzheimer's disease, has been ruled out by appropriate lab or other diagnostic testing.
3. Prescriber's confirmation of the presence of amyloid beta-plaques.
4. Documentation of clinical testing that confirms the client has mild cognitive impairment caused by Alzheimer's disease or a mild stage of Alzheimer's disease.

5. 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).
6. Prescriber attestation that the client has been tested for ApoE ε4 status and ApoE ε4 homozygotes clients have been provided counseling on higher incidence of developing ARIA before initiation of treatment.
7. Prescriber attestation to the following monitoring requirements during the Kisunla treatment period:
    - 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.
    - Prescriber must monitor for amyloid-related imaging abnormalities (ARIA) during the first 24 weeks.
    - Prescriber attestation to obtaining an MRI before the 2nd, 3rd, 4th and 7th infusion to check for symptomatic (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.

Approval Duration: 6 months

II. Continued Therapy:

B. Alzheimer's Disease (must meet all):

1. The client continues to meet all the initial authorization approval criteria.
2. The client has not progressed to moderate or severe dementia caused by AD.
3. The client experienced a positive clinical response to therapy as demonstrated by no increase in amyloid plaque or radiographic stabilization as compared to baseline.
4. Documentation of MRI (prior to 2nd, 3rd, 4th and 7th infusion) to check for ARIA with Kisunla treatment.
5. The client has not experienced any complications or unacceptable toxicities during treatment with Kisunla.

Approval Duration: 6 months

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document		02/01/2025
Ad Hoc Review	For initial therapy, updated criteria step 6 to: Prescriber attestation that the client has been tested for ApoE ε4 status and ApoE ε4 homozygotes clients have been provided counseling on higher incidence of developing ARIA before initiation of treatment.	02/03/2025