# TX CLINICAL CRITERIA & PROCEDURE

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| **CRITERIA NAME:** Lecanemab-irmb (Leqembi®) | **CRITERIA ID:** TX.CC.PHAR.27 |
| **BUSINESS UNIT:** Superior HealthPlan | **FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims |
| **EFFECTIVE DATE:** 11/01/2023 | **PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate |
| **REVIEWED/REVISED DATE:** 11/10/2023, 4/3/2024 | |
| **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 lecanemab-irmb (Leqembi®).

**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:**
MRI = magnetic resonance imaging
ARIA = Amyloid Related Imaging Abnormalities
ARIAH = Amyloid Related Imaging Abnormalities – hemosiderin deposition

**POLICY:**
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of Lecanemab-irmb (Leqembi®); procedure code: J0174.

**Exclusion:** This clinical prior authorization applies to Medicaid clients only. Dual eligible clients must follow the Medicare National Coverage Determination policy guidelines for monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

*Description/Mechanism of Action:*
Lecanemab-irmb (Leqembi®) is an amyloid-beta directed antibody indicated to treat Alzheimer's disease (AD) by reducing amyloid-beta plaques.

*FDA Approved Indication(s):*
Lecanemab-irmb (Leqembi®) is indicated for the treatment of Alzheimer's disease (AD). Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials.

**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 (AD) (must meet all):**

1. The client has a confirmed diagnosis of Alzheimer's disease (AD) (diagnosis codes: G30.0, G30.1, G30.8 or G30.9).
2. Prescriber attestation that other forms of dementia, except Alzheimer's disease has been ruled out by appropriate lab and/or other diagnostic testing.
3. Prescriber's confirmation of amyloid beta-plaques presence.
4. Documentation of clinical testing that confirms the client has mild cognitive impairment caused by Alzheimer's disease or mild dementia stage of 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 to the following monitoring requirements during Leqembi treatment period:
    - Prescriber must monitor for Amyloid Related Imaging Abnormalities (ARIA) during the first 14 weeks of treatment;
    - Prescriber must obtain an MRI prior to the 5th, 7th and 14th infusion to check for ARIA;
    - Prescriber must attest that clients with severe Amyloid Related Imaging Abnormalities – hemosiderin deposition (ARIAH) will only continue therapy if radiographic stabilization has been confirmed by a follow-up MRI and supported by clinical evaluation.

**Approval duration: 6 months**

**II. Continued Therapy**

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

1. The client continues to meet all initial prior authorization approval criteria.
2. The client has not progressed to moderate to severe dementia caused by AD.
3. The client has 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 brain MRI prior to 5th, 7th and 14th infusion to check for ARIA with Leqembi treatment.
5. The client has not experienced any complications or unacceptable toxicities during treatment with Leqembi.

**Approval duration: 6 months**

**REFERENCES:**
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook
Leqembi Package Insert; Eisai Inc.; July 2023

**ATTACHMENTS:**

**REVISION LOG**

| REVISION TYPE | REVISION SUMMARY | DATE APPROVED & PUBLISHED |
|---|---|---|
| New Policy | | 11/01/2023 |
| Ad Hoc Review | For Initial Therapy - removed criteria: 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, to align with TMHP manual<br>For Continued Therapy – adjusted criteria steps 1 and 5 to align with TMHP Manual; updated approval duration to 6 months | 11/10/2023 |
| Ad Hoc Review | Updated to TX.CC.PHAR format template<br>Added Centene copyright statement | 4/3/2024 |