MEDICAL COVERAGE POLICY	
SERVICE:	**Lecanemab-irmb (Leqembi®)**
Policy Number:	**301**
Effective Date:	**09/01/2025**
Last Review:	**08/11/2025**
Next Review:	**08/11/2026**

Important note: *Unless otherwise indicated, medical policies will apply to all lines of business. Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.*

SERVICE: Lecanemab-irmb (Leqembi®)

PRIOR AUTHORIZATION: **Required**

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) 200.3 Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD).

For Medicaid plans, please confirm coverage as outlined in the Texas Medicaid Provider Procedures Manual | TMHP (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

Baylor Scott & White Health Plan (BSWHP) may consider lecanemab (Leqembi®) medically necessary when documentation is submitted showing ALL of the following criteria are met:

Initial requests:

1. Member has a diagnosis of Alzheimer's disease (AD); **AND**
2. The medication is prescribed by or in consultation with a neurologist, geriatric psychiatrist, or geriatrician; **AND**
3. Member age is 50 to 90 years; **AND**
4. The member must have a documented diagnosis of mild cognitive impairment (MCI) due to AD or mild dementia stage of AD as confirmed by both:
    a. One or more of the following cognitive tests with scores:
        i. MMSE (Mini-Mental State Exam) score 21-30
        ii. CDR-GS (Clinical Dementia Rating-Global Scale) score = 0.5 or 1
        iii. MoCA (Montreal Cognitive Assessment) score ≥16

    AND

    b. Amyloid beta (Aβ) deposits consistent with a diagnosis of AD as confirmed by one of the following (must submit a copy of imaging results or diagnostic immunoassay):
        i. Amyloid PET; **OR**
        ii. Lumbar puncture: CSF assay with results consistent with diagnosis of Alzheimer's disease. Biomarkers include but are not limited to: A-beta 42 peptide (Aβ42), phospho-tau (P-tau) and total tau (T-tau) proteins, ATI index (Aβ42/ T-tau)

    AND

5. Specialist has ruled out other conditions or causative factors that could be viewed as AD (ex. Lewy body dementia, cerebrovascular disease, Parkinson's disease, vitamin B12 deficiency, etc.); **AND**
6. Prior to lecanemab administration, member must be on stable dose if taking the following drugs:
    a. AD symptomatic treatment (ex. donepezil, rivastigmine, galantamine, memantine) for 12 weeks
    b. Anticoagulant therapy (ex. enoxaparin, warfarin, Eliquis, Pradaxa, Xarelto), for 4 weeks

    AND
7. Apolipoprotein E ε4 genetic testing performed to assess risk of amyloid-related imaging abnormalities (ARIA), i.e. brain swelling and bleeds; **AND**
8. Risks of ARIA discussed with member or caregiver; **AND**
9. Lecanemab will be dosed and administered according to FDA approved labeling; **AND**

10. The member does NOT have any of the following:
    a. Submitted baseline MRI (within 1 year) with any of the following:
        i. More than four microhemorrhages (≤ 10 mm at greatest diameter)
        ii. A single microhemorrhage > 10 mm at greatest diameter
        iii. An area of superficial siderosis
        iv. Evidence of vasogenic edema
        v. Evidence of cerebral contusion, encephalomalacia, aneurysms, vascular malformations, or infection lesions
        vi. Evidence of multiple lacunar infarcts or stroke involving a major vascular territory, severe small vessel, or white matter disease
        vii. Space occupying lesions
        viii. Brain tumors (meningiomas or arachnoid cysts an < 10 mm at greatest diameter are not exclusionary)
    b. Any medical or neurological condition (other than AD) that might be a contributing cause of cognitive impairment
    c. Seizures, stroke, or transient ischemic attack (TIA) in the past 12 months
    d. History of cerebrovascular abnormalities
    e. Bleeding disorder not under adequate control (ex. platelet count < 50,000 or INR > 1.5 for patients not on warfarin)

    AND
11. Lecanemab will not be used in combination with any other amyloid beta-directed antibodies (ex. aducanumab)

<u>Renewal requests:</u>

1. MRI conducted prior to the 5th, 7th, and 14th infusions to monitor for amyloid-related imaging abnormalities (ARIA), i.e. brain swelling and bleeds; **AND**
2. Member must not have any of the following:
    a. Started new medications that increase risk for ARIA (ex. tPA use since last authorization, antiplatelets, anticoagulants) without documented discussion of ARIA risk and plans for monitoring

   b. Missed more than two consecutive doses or more than two doses in a 6-month period
   c. Any medical or neurological condition (other than AD) that might be a contributing cause of cognitive impairment
   d. Seizures, stroke, or transient ischemic attack (TIA) in the past 12 months
   e. History of cerebrovascular abnormalities
   f. Bleeding disorder not under adequate control (ex. platelet count < 50,000 or INR > 1.5 for patients not on warfarin)

AND

3. Clinical documentation must be submitted showing cognition scores have not worsened to moderate or advanced disease as defined by one or more of the following cognitive tests (must submit the same cognition tests used for initial approval):
   a. MMSE (Mini-Mental State Exam) score 20 or lower
   b. CDR-GS (Clinical Dementia Rating-Global Scale) score greater than 1
   c. MoCA (Montreal Cognitive Assessment) score < 16

AND

4. Manageable or no side effects

Authorization duration – 6 months

BSWHP considers lecanemab for the treatment of all other indications to be experimental and investigational because the effectiveness of this strategy has not been established.

BACKGROUND:

Alzheimer's disease (AD) is an irreversible and incurable neurodegenerative disorder that is characterized by progressive memory loss and cognitive decline. AD manifests as impairment in a broad spectrum of cognitive processes, typically presenting with an insidious decline in verbal and nonverbal memory, and gradually progressing to deficits in recognition, language, semantics, attention, executive function, visuoperceptual and spatial abilities, and sensory and motor skills. The pathogenesis of AD is not yet fully understood. Amyloid beta (Aβ) accumulation is considered to be a hallmark of early onset of AD; it is also proposed to be an activator for aggregation of phosphorylated tau. As such, amyloid beta is predicted to be a potentially efficient target for drug/biologic therapy.

Lecanemab (Leqembi®) is indicated for treatment of Alzheimer's Disease (AD) to be initiated in patient with mild cognitive impairment or mild dementia stage of disease. The FDA approved it under the accelerated approval pathway based on a phase 2 study (which showed reduced accumulation of Aβ plaque and slowing of clinical decline. The Clarity AD confirmatory trial showed Lecanemab appeared to slow disease progression by about one-quarter, and caused the brain edema (ARIA-E) in one of eight participants. The slower decline translates to a five- to six-month delay in disease progression.

The Centers for Medicare & Medicaid Services (CMS) covers Food and Drug Administration (FDA) approved monoclonal antibodies directed against amyloid for the treatment of AD when furnished in accordance with Section B under coverage with evidence development (CED) for patients who have a clinical diagnosis of mild cognitive impairment (MCI) due to AD or mild AD dementia, both with

confirmed presence of amyloid beta pathology consistent with AD. The CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. CMS's decision to use CED is because no trial involving any intervention, alone or combined, has yet demonstrated a meaningful improvement in health outcomes for patients treated with anti-amyloid monoclonal antibodies for the treatment of AD.

CODES:

Important note: *Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.*

CPT Codes:	
HCPCS Codes:	J0174 Injection, lecanemab-irmb, 1 mg
ICD10 codes:	Z00.6 Encounter for examination for normal comparison and control in clinical research program G30.0 Alzheimer's disease w/early onset G30.1 Alzheimer's disease w/late onset G30.8 Other Alzheimer's disease G30.9 Alzheimer's disease, unspecified G31.84 mild cognitive impairment, so stated
ICD10 Not covered:	

POLICY HISTORY:

Status	Date	Action
New	08/24/2023	New policy
Updated	08/12/2024	Applied new format and layout. Add CMS NCD hyperlink. Reworded lumbar puncture criteria for clarity.
Updated	08/11/2025	Updated initial and renewal request heading and consolidated authorization durations. Added requirement of submitted documentation and FDA dosing criteria. Updated experimental and investigational language. Background section simplified.

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications based upon the evolution of the published clinical evidence. Should additional scientific studies become available, and they are not included in the list, please forward the reference(s) to BSWHP so the information can be

reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

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Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid plans are offered through Scott and White Health Plan in the Central Managed Care Service Area (MRSA) and STAR and CHIP plans are offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs.