LEQEMBI® (lecanemab-irmb)

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for treatment with LEQEMBI (lecanemab-irmb) for Alzheimer's Disease (AD). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Alzheimer's Disease is a neurodegenerative disorder with a complex pathogenesis that primarily affects older adults; it is the most common cause of dementia. *Mild cognitive impairment (MCI)* is the prodromal clinical state prior to dementia where individuals demonstrate cognitive impairment that does not meet the criteria for dementia, but it is more than normal aging.

LEQEMBI is an amyloid beta-directed monoclonal antibody indicated for the treatment of AD. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. The Food and Drug Administration (FDA) approved LEQEMBI in January 2023 under an accelerated approval based on a reduction in amyloid beta plaques. In July 2023, the FDA granted full approval based on a confirmatory trial.

LEQEMBI can cause amyloid related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA is usually asymptomatic, although rarely serious and life-threatening events can occur. Serious intracerebral hemorrhage greater than 1 cm have occurred in patients treated with this class of medications. Patients treated with this class of medications, who are ApoE ε4 homozygotes, have a higher incidence of ARIA, including symptomatic and serious ARIA, compared to heterozygotes and noncarriers.

Coverage guidelines for *KISUNLA™ (donanemab-azbt)* are available **here**

CLINICAL GUIDELINE

Coverage guidelines for LEQEMBI are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an individual assessment of the member and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Initial Authorization

Treatment with LEQEMBI may be considered medically necessary when **ALL** of the following criteria are met:

A. The individual has a diagnosis of early Alzheimer's disease (mild cognitive impairment (MCI) due to AD, or mild Alzheimer's dementia); **AND**

B. The individual is 50 years of age or older; **AND**
C. The individual has confirmed presence of amyloid pathology verified by positron emission tomography (PET) scan or cerebrospinal fluid (CSF) testing; **AND**
D. Treatment is prescribed by or in consultation with a neurologist, geriatrician, or geriatric psychiatrist; **AND**
E. The treating physician and clinical team participates in the CMS National Patient Registry or another CMS-approved study; **AND**
F. The individual must have objective evidence of cognitive impairment at baseline as evidenced by achieving one of the following scores using any of the assessment tools specified below:
    1. Mini-Mental State Exam (MMSE) score of 22-30; **OR**
    2. Clinical Dementia Rating-Global Score (CDR-GS) of 0.5 or 1; **OR**
    3. Montreal Cognitive Assessment (MoCA) score of 17-30; **AND**
G. Testing for ApoE ε4 Homozygote status has been performed prior to initiation of treatment and the implications of genetic test results regarding the risk of developing ARIA has been discussed with the patient and/or caregiver; **AND**
H. The individual has had a recent brain magnetic resonance imaging (MRI) within the last year to assess for pre-existing ARIA or other significant cerebral pathology. The MRI must demonstrate all of the following:
    1. No evidence of other significant pathological findings (e.g., hemorrhages); **AND**
    2. No evidence of other clinically significant lesions that could indicate a dementia diagnosis other than AD; **AND**
I. The individual does not have any of the following:
    1. A bleeding disorder that is inadequately controlled; **OR**
    2. Any other neurologic disorders that may be contributing to cognitive impairment above and beyond that which is caused by AD; **OR**
    3. Any contraindications to amyloid testing (e.g., PET, CSF testing) or to an MRI brain scan (e.g., metallic implants, cardiac pacemaker/defibrillator); **OR**
    4. A history of stroke, transient ischemic attacks (TIA) or seizures documented within the last 12 months; **OR**
    5. Any history of immunologic disease (e.g., lupus erythematosus, rheumatoid arthritis, Crohn's disease) or systemic treatment with immunosuppressants, immunoglobulins, or monoclonal antibodies or their derivatives; **OR**
    6. Current treatment with therapeutic anticoagulation except for aspirin at a prophylactic dose or other antiplatelet agents at standard therapeutic doses (e.g., clopidogrel, prasugrel, ticagrelor); **AND**
J. The individual (and/or caregivers) considering LEQEMBI therapy have been provided with information on the requirements for treatment and expected outcomes, potential side effects, risks (including the risks of ARIA), and burdens related to administration and monitoring; **AND**
K. LEQEMBI will not be used in combination with any other amyloid beta-directed antibodies (e.g., KISUNLA); **AND**
L. The treating physician will follow all other FDA requirements related to dosing, administration, and monitoring. This includes the use of MRI to monitor for ARIA approximately 1 week prior to the 3rd, 5th, 7th, and 14th infusions, and as needed if the individual experiences symptoms suggestive of ARIA.

Reauthorization

<u>Continuation of treatment with LEQEMBI may be considered medically necessary at six-month intervals if:</u>

A. The individual is continuing to benefit from treatment as evidenced by objective, validated tests

used longitudinally for assessment. The expected benefit is slowing of cognitive and functional decline; improvement of current clinical state is not anticipated (a signed letter from the individual's ordering physician is required); **AND**

B. All MRI scans performed per recommended protocol to monitor for ARIA demonstrate that:
    a. The individual shows no evidence of ARIA or if ARIA is present, it is mild, and the individual is asymptomatic; **AND**
    b. The individual does not have unresolved moderate or severe ARIA; **AND**
C. The individual has not manifested severe symptoms (e.g., seizures, stroke-like manifestations) in the presence of ARIA.

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization is required for LEQEMBI. Requests for coverage of LEQEMBI are reviewed in accordance with procedures in place for reviewing requests for physician-administered drugs. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review prior authorization requests:

1. Fully completed State of Connecticut, Department of Social Services HUSKY Health Program Leqembi Prior Authorization Request form (to include physician's order and signature);
2. For all Initial requests, clinical documentation supporting the medical necessity of treatment with Leqembi should include the following:
    A. Medical record documentation confirming:
        a. Diagnosis of early Alzheimer's disease (mild cognitive impairment (MCI) due to AD, or mild Alzheimer's dementia; **AND**
        b. Results of PET imaging or CSF testing confirming presence of amyloid pathology; **AND**
        c. Results from at least one dementia rating scale outlined in the Clinical Guideline section of this policy confirming cognitive impairment at baseline; **AND**
        d. Results from the most recent brain MRI scan; **AND**
        e. Results from ApoE ε4 testing; **AND**
    B. Signed provider attestation confirming the following:
        a. Implications of ApoE ε4 genetic test results regarding the risk of developing ARIA has been discussed with the patient and/or caregiver; **AND**
        b. The individual does not have any of the following:
            - A bleeding disorder that is inadequately controlled; **OR**
            - Any other neurologic disorders that may be contributing to cognitive impairment above and beyond that which is caused by AD; **OR**
            - Any contraindications to amyloid testing (e.g., PET, CSF testing) or to an MRI brain scan (e.g., metallic implants, cardiac pacemaker/defibrillator); **OR**
            - A history of stroke, transient ischemic attacks (TIA) or seizures documented within the last 12 months; **OR**
            - Any history of immunologic disease (e.g., lupus erythematosus, rheumatoid

arthritis, Crohn's disease) or systemic treatment with immunosuppressants, immunoglobulins, or monoclonal antibodies or their derivatives; **OR**
- Current treatment with therapeutic anticoagulation except for aspirin at a prophylactic dose or other antiplatelet agents at standard therapeutic doses (e.g., clopidogrel, prasugrel, ticagrelor); **AND**

c. The individual (and/or caregivers) considering LEQEMBI therapy have been provided with information on the requirements for treatment and expected outcomes, potential side effects, risks (including the risks of ARIA), and burdens related to administration and monitoring; **AND**
d. LEQEMBI will not be used in combination with any other amyloid beta-directed antibodies (e.g., KISUNLA); **AND**
e. The treating physician will follow all other FDA requirements related to dosing, administration, and monitoring. This includes the use of MRI to monitor for ARIA approximately 1 week prior to the 3rd, 5th, 7th, and 14th infusions, and as needed if the individual experiences symptoms suggestive of ARIA.

3. For reauthorization requests:
   A. A letter from ordering physician documenting the benefits patient is receiving from treatment; **AND**
   B. Results from the most recent brain MRI scan as outlined in the FDA requirements
4. Other information as requested by CHNCT.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for LEQEMBI for individuals covered under the HUSKY Health Program on or after February 01, 2024.

LIMITATIONS
Not Applicable

CODES:

Code	Description
J0174	Injection, lecanemab-irmb, 1mg

DEFINITIONS
1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited

Benefit programs, collectively.

6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
9. **Prior authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

1. A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease (Clarity AD). ClinicalTrials.gov identifier: NCT03887455. Updated October 14, 2025. Accessed October 30, 2025. https://clinicaltrials.gov/study/NCT03887455
2. A Study to Evaluate Safety, Tolerability, and Efficacy of Lecanemab in Subjects With Early Alzheimer's Disease ClinicalTrials.gov identifier: NCT01767311. Updated January 22, 2025. Accessed October 30, 2025. https://clinicaltrials.gov/study/NCT01767311.
3. Alzheimer's Association. 2023 Alzheimer's Disease Facts and Figures. Alzheimers Dement. 2023;19(4). DOI 10.1002/alz.13016.
4. Berry DA, Dhadda S, Kanekiyo M, et al. Lecanemab for Patients With Early Alzheimer Disease: Bayesian Analysis of a Phase 2b Dose-Finding Randomized Clinical Trial. *JAMA Netw Open.* 2023;6(4):e237230. Published 2023 Apr 3. doi:10.1001/jamanetworkopen.2023.7230
5. Centers for Medicare & Medicaid Services. (2022, June 6). Fact sheet - Centers for Medicare & Medicaid Services. www.cms.gov. https://www.cms.gov/files/document/fact-sheet-june-2023.pdf. Accessed on August 3, 2023
6. Centers for Medicare & Medicaid Services Medicare Coverage Database. National Coverage Determination: Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. April 7, 2022. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1. Accessed on August 28, 2023
7. Cummings, J., Apostolova, L., Rabinovici, G.D. et al. Lecanemab: Appropriate Use Recommendations. *J Prev Alzheimers Dis* 10, 362–377 (2023).
8. Dhadda S, Kanekiyo M, Li D, et al. Consistency of efficacy results across various clinical measures and statistical methods in the lecanemab phase 2 trial of early Alzheimer's disease. *Alzheimers Res Ther*. 2022;14(1):182. Published 2022 Dec 9. doi:10.1186/s13195-022-01129-x
9. Honig LS, Sabbagh MN, van Dyck CH, et al. Updated safety results from phase 3 lecanemab

study in early Alzheimer's disease [published correction appears in Alzheimers Res Ther. 2024 Jul 10;16(1):159. doi: 10.1186/s13195-024-01507-7]. *Alzheimers Res Ther*. 2024;16(1):105. Published 2024 May 10. doi:10.1186/s13195-024-01441-8
10. Institute for Clinical and Economic Review - Lecanemab for Early Alzheimer's Disease: Effectiveness and Value. Evidence Summary. April 17, 2023. Available at: https://analytics.icer.org/report-snapshots/64. Accessed on August 2, 2023
11. LEQEMBI [package insert]. Nutley, NJ: Eisai Inc.; Revised August 2025.
12. McDade E, Cummings JL, Dhadda S, et al. Lecanemab in patients with early Alzheimer's disease: detailed results on biomarker, cognitive, and clinical effects from the randomized and open-label extension of the phase 2 proof-of-concept study. *Alzheimers Res Ther*. 2022;14(1):191. Published 2022 Dec 21. doi:10.1186/s13195-022-01124-2
13. Office of the Commissioner. (2023, July 6). FDA converts novel Alzheimer's disease treatment to traditional approval. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval#:~:text=Action%20Follows%20Confirmatory%20Trial%20to%20Verify%20Clinical%20Benefit&text=Today%2C%20the%20U.S.%20Food%20and,confirmatory%20trial%20verified%20clinical%20benefit. Accessed on August 3, 2023
14. Press D, Buss SS. Amyloid-targeted therapies for the treatment of Alzheimer disease. In: UpToDate, DeKosky ST, Wilterdink JL (Eds). Wolters Kluwer. Updated October 31, 2025. Accessed November 4, 2025.
15. Press D, Buss SS. Treatment of Alzheimer's Disease. In: *UpToDate*, DeKosky ST, Schmader KE, Wilterdink JL (Eds). Wolters Kluwer. Updated October 31, 2025. Accessed November 4, 2025.
16. Swanson CJ, Zhang Y, Dhadda S, et al. A randomized, double-blind, phase 2b proof-of-concept clinical trial in early Alzheimer's disease with lecanemab, an anti-Aβ protofibril antibody. *Alzheimers Res Ther*. 2021;13(1):80. Published 2021 Apr 17. doi:10.1186/s13195-021-00813-8
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PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	December 2023	Approved at the October 11, 2023 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee On December 13, 2023. Approved by DSS on January 03, 2024.
Update	September 2024	ADUHELM (aducanumab) removed from policy, drug was discontinued in November 2024. KISUNLA (donanemab-azbt) added. Criteria regarding participation in the CMS National Patient Registry or another CMS-approved study added based on the CMS National Coverage Determination. Age criteria and criteria regarding previous stroke, TIA, seizures and anticoagulation moved to medication-specific sections. Code J0172 removed, J0175 added and references updated. Approved at the October 9, 2024 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on

		December 16, 2024. Approved by DSS on December 27, 2024.
Update	November 2025	KISUNLA removed from policy and separated out into its own policy. Added some background on Alzheimer's disease. Additional exclusion criteria regarding any history of immunologic disease added. Added requirement to conduct MRI prior to the 3rd dose in accordance with prescribing information update. Updated procedure section adding a requirement for provider attestation. Updated references. Reviewed and approved at the December 10, 2025 CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on December 15, 2025. Approved by DSS on December 26, 2025.