AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Leqembi Iqlik™ (lecanemab-irmb) (Pharmacy)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Requested Medication is ONE of the following:

- ❑ New Start
- ❑ Continuation of therapy – provide therapy start date: _____

Recommended Dosage:

- Initial: SUBQ: 500 mg once weekly for 18 months. After 18 months, may continue the initial regimen or switch to a maintenance regimen.
- **NOTE**: After 18 months, treatment with 10 mg/kg once every two weeks may be continued, or a transition to the maintenance dosing regimen of either 10 mg/kg once every 4 weeks or a subcutaneous dose of 360mg once weekly may be considered.
- **NOTE**: In patients who are on stable maintenance therapy for 18 months, clinical judgment will be used in considering whether to continue treatment or permanently discontinue. In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment from Leqembi, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Complete the following if the member has completed a minimum of 18 months of treatment with Leqembi IV meeting all the initial approval criteria
  - ❑ Documentation of the first and last Leqembi IV infusion dates must be submitted. Please provide both the date and dose of administration:
    - First Leqembi IV infusion date and dose: _____
    - Last Leqembi IV infusion date and dose: _____
    - Please note that any active Leqembi IV authorizations under the medical benefit will be discontinued.
- ❑ Prescribed by or in consultation with a neurologist
- ❑ Member must be 50-90 years of age or older
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ALL** the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5 to 1.0
  - ❑ CDR Memory Box score of at least ≥ 0.5
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ONE** of the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Mini-Mental State Exam (MMSE) score of 22-28
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13] score of ≥18
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]
  - ❑ Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16
- ❑ Member has/is experiencing signs and symptoms of mild cognitive impairment characterized by skills that affect memory (i.e., inability to make sound decisions, judge time, sequence, steps needed to complete a complex task) **(must submit chart note documentation)**
- ❑ Provider must submit chart notes supporting that other differential diagnoses have been ruled out (e.g., dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), vascular dementia, pseudodementia due to mood disorder, vitamin B12 deficiency, encephalopathy)
- ❑ Provider must submit documentation of beta-amyloid protein deposition, as evidenced by **ONE** of the following:
  - ❑ Positive amyloid positron emission tomography (PET) scan
  - ❑ Cerebrospinal fluid (CSF) measurement positive assessment Aß (1-42)

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- ❑ Provider must submit documentation that meets **ONE** of the following requirements regardingapolipoprotein E ε4 (ApoE ε4) testing and its implications for treatment:
  - ❑ Member has been tested prior to treatment to assess apolipoprotein E ε4 (ApoE ε4) status (e.g., homozygote, heterozygote, or noncarrier) and the prescriber has informed the patient that those who are homozygotes have a higher incidence of developing ARIA
  - ❑ Genotype testing has not been performed and the prescriber has informed the patient that it cannot be determined if they are apolipoprotein E ε4 (ApoE ε4) homozygotes and, therefore, if they are at higher risk for developing ARIA
- ❑ Provider attests that counseling has been provided on the risk of amyloid-related imaging abnormalities (ARIA-E and ARIA-H) and member and/or caregiver are aware to monitor for headache, dizziness, visual disturbances, nausea and vomiting
- ❑ A brain magnetic resonance imaging (MRI) will be reviewed after 1, 2, 3 and 6 months of treatment
- ❑ Member must have undergone a recent (within the last year) brain magnetic resonance imaging (MRI) demonstrating **ALL** the following **(must submit MRI results)**:
  - ❑ No brain hemorrhage > 1 cm within the past year
  - ❑ No more than 4 brain microhemorrhages (defined as 10mm or less at the greatest diameter)
  - ❑ No localized superficial siderosis
  - ❑ No evidence of vasogenic edema
- ❑ Member does **NOT** have any relevant brain hemorrhage, bleeding disorder, cerebrovascular abnormalities, or recent (within the prior year) cardiovascular condition (e.g., unstable angina, myocardial infarction, advanced CHF, or clinically significant conduction abnormalities)
- ❑ Member has **NOT** had a stroke, transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months
- ❑ Members receiving antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) prior to initiating treatment with Leqembi **MUST** have been on a stable dose for at least 4 weeks
- ❑ Member does **NOT** have impaired renal or liver function
- ❑ Member has **NOT** had a clinically significant and unstable psychiatric illness in the past six months
- ❑ Leqembi Iqlik™ will **NOT** be used concurrently with other anti-amyloid immunotherapies (i.e. donanemab, Leqembi™ IV)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ALL** the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5 to 1.0
  - ❑ CDR Memory Box score of at least ≥ 0.5

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- ❑ Member has a confirmed diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's dementia (there is insufficient evidence in moderate or severe Alzheimer's disease) based on **ONE** of the following dementia rating scales **(must submit baseline documentation)**:
  - ❑ Mini-Mental State Exam (MMSE) score of 22-28
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13] score of ≥18
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]
  - ❑ Montreal Cognitive Assessment (MoCA) score of greater than or equal to 16
- ❑ Member has **NOT** progressed to moderate or severe dementia
- ❑ Provider continues to monitor member for the occurrence of any medical or neurological conditions (other than Alzheimer's disease) that may be a contributing cause to the member's cognitive impairment
- ❑ Member has received the follow-up MRI for monitoring of Amyloid Related Imaging Abnormalities edema (ARIA-E) or hemosiderin (ARIA-H) within the following timeframes **(must submit results)**:
  - ❑ After 1 month of treatment
  - ❑ After 2 months of treatment
  - ❑ After 3 months of treatment
  - ❑ After 6 months of treatment
- ❑ Member must meet **ONE** of the following:
  - ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid **related imaging abnormalities edema (ARIA-E):**
    - ❑ Member has had no new ARIA-E
    - ❑ Member has mild ARIA-E on MRI **AND** ARIA-E is asymptomatic (no clinical symptoms)
    - ❑ Member has had moderate or severe ARIA-E on MRI **AND** ARIA-E is asymptomatic (no clinical symptoms) **AND** the ARIA-E is stable
    - ❑ Member has had mild, moderate or severe ARIA-E on MRI **AND** ARIA-E resulted in mild, moderate or severe clinical symptoms **AND** the ARIA-E is stable
  - ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid related imaging abnormalities microhemorrhage (ARIA-H):
    - ❑ Member has had 1 to 4 new incident microhemorrhage(s) **AND** microhemorrhages are asymptomatic (no clinical symptoms)
    - ❑ Member has had 5 to 9 new incident microhemorrhages **AND** microhemorrhages are asymptomatic (no clinical symptoms) **AND** the microhemorrhages have been stabilized
    - ❑ Member has had 1 to 9 new incident microhemorrhages **AND** microhemorrhages resulted in mild, moderate or severe clinical symptoms **AND** the microhemorrhages have been stabilized

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- ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid r**elated imaging abnormalities superficial siderosis (ARIA-H):**
  - ❑ Member has had no new incident areas of superficial siderosis
  - ❑ Member has had 1 new incident area of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms)
  - ❑ Member has had 2 new incident areas of superficial siderosis **AND** superficial siderosis is asymptomatic (no clinical symptoms) **AND** the superficial siderosis has been stabilized
  - ❑ Member has had 1 to 2 new incident areas of superficial siderosis **AND** superficial siderosis resulted in mild, moderate or severe clinical symptoms **AND** the superficial siderosis has been stabilized

Appendix/General Information

ARIA MRI Classification Criteria

ARIA Type	Radiographic Severity		
	Mild	**Moderate**	**Severe**
ARIA-E	FLAIR hyperintensity confined to sulcus and/or cortex/subcortical white matter in one location < 5cm	FLAIR hyperintensity 5 to 10 cm, or more than 1 site of involvement, each measuring <10 cm	FLAIR hyperintensity measuring > 10cm, often with significant subcortical white matter and/or sulcal involvement. One or more separate sites of involvement may be noted
ARIA-H microhemorrhage	≤ 4 new incident microhemorrhages	5 to 9 new incident microhemorrhages	10 or more new incident microhemorrhages
ARIA-H superficial siderosis	1 focal area of superficial siderosis	2 focal areas of superficial siderosis	>2 focal areas of superficial siderosis

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Recommendations for Dosing Interruptions in Patients with Amyloid Related Imaging Abnormalities (ARIA)

Table 1: Dosing Recommendations for Patients with ARIA-E

Clinical Symptom Severity[1]	ARIA-E Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[2]	Suspend dosing[2]
Mild	May continue dosing based on clinical judgment	Suspend dosing[2]	
Moderate or Severe	Suspend dosing[2]		

[1] Mild: discomfort noticed, but no disruption of normal daily activity.
Moderate: discomfort sufficient to reduce or affect normal daily activity.
Severe: incapacitating, with inability to work or to perform normal daily activity.
[2] Suspend until MRI demonstrates radiographic resolution and symptoms, if present, resolve; consider a follow-up MRI to assess for resolution 2 to 4 months after initial identification. Resumption of dosing should be guided by clinical judgment.

Table 2: Dosing Recommendations for Patients with ARIA-H

Clinical Symptom Severity	ARIA-H Severity on MRI		
	Mild	**Moderate**	**Severe**
Asymptomatic	May continue dosing	Suspend dosing[1]	Suspend dosing[2]
Symptomatic	Suspend dosing[1]	Suspend dosing[1]	

[1] Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; resumption of dosing should be guided by clinical judgment; consider a follow-up MRI to assess for stabilization 2 to 4 months after initial identification.
[2] Suspend until MRI demonstrates radiographic stabilization and symptoms, if present, resolve; use clinical judgment in considering whether to continue treatment or permanently discontinue LEQEMBI.

In patients who develop intracerebral hemorrhage greater than 1 cm in diameter during treatment with LEQEMBI, suspend dosing until MRI demonstrates radiographic stabilization and symptoms, if present, resolve. Use clinical judgement in considering whether to continue treatment after radiographic stabilization and resolution of symptoms or permanently discontinue LEQEMBI.

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Appendix/General Information

Dementia Rating Scales

Type of dementia rating scale	Description	Rate
Clinical Dementia Rating-Global score (CDR-GS)	Useful for characterizing and tracking a patient's level of impairment/dementia	• 0 = normal • 0.5 = very mild dementia • 1 = mild dementia • 2 = moderate dementia • 3 = severe dementia
Mini-Mental State Exam (MMSE)	Series of questions asked by a health professional designed to test a range of everyday mental skills.	• 25 to 30 suggest normal cognition • 20 to 24 suggests mild dementia • 13 to 20 suggests moderate dementia • less than 12 indicates severe dementia
Alzheimer's Disease Assessment Scale- Cognitive Subscale [ADAS- Cog-13, ADAS-Cog 14]	Series of questions scaled for five cognitive domains such as immediate memory, delayed memory, attention, language, visuospatial ADAS-Co 14 include executive function	• ADAS-Cog 13 scale range from to 0 to 85 • ADAS-Cog 14 range from 0 to 90 • Higher scores indicate greater cognitive impairment
Alzheimer's Disease Cooperative Study- Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS- ADL- MCI]	Series of questions to assess the performance of basic and instrumental activities of daily living.	• ADCS-ADL-MCI range from 0 to 53 • Lower score indicate poorer functional performance
Montreal Cognitive Assessment (MoCA)	Series of questions to assess multiple cognitive domains such as orientation, memory, language, attention, visuospatial and executive function	• Normal: 26 and above • Mild Cognitive Impairment: 19-25 • Mild Dementia: 11-21 • *16.2= MoCA average score for Alzheimer's Disease

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References:

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3. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.
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8. Arvanitakis Z, Shah RC, Bennett DA. Diagnosis and management of dementia: a review. JAMA. 2019;322(16):1589-1599.
9. Langa, LM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review.
10. Lin GA, Whittington MD, Wright A, Agboola F, Herron-Smith S, Pearson SD, Rind DM. Beta-Amyloid Antibodies for Early Alzheimer's Disease: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, December 22, 2022.

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~11/20/2025;~~ **9/24/2026**
REVISED/UPDATED/REFORMATTED: ~~12/5/2025;~~ **10/15/2026**