SENTARAHEALTH PLAN

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Leqembi™ (lecanemab) IV (J0174) (Medical)

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

- **Maximum Dose – 10 mg/kg once every 2 weeks** (single-dose vial for injection): 200 mg/2 mL, 500 mg/5 mL
- Leqembi is administered as an intravenous (IV) infusion via a 0.2 micron in-line filter over approximately one hour.

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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 (6 doses of infusion only)

- ❑ Prescribed by or in consultation with a neurologist

AND

- ❑ Member must be 50 years of age or older

AND

- ❑ 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)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5
  - ❑ Mini-Mental State Exam (MMSE) score of 24-30
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13, ADAS-Cog 14] score of 17
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]

AND

- ❑ 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)**

AND

- ❑ 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)

AND

- ❑ Provider must submit documentation of beta-amyloid protein deposition, as evidenced by a positive amyloid positron emission tomography (PET) scan or CSF measurement assessment Aß (1-42)

AND

- ❑ 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
  - ❑ Less than 10 brain microhemorrhages
  - ❑ No localized superficial siderosis

AND

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- ❑ 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)

AND

- ❑ Member has **NOT** had a stroke, transient ischemic attack (TIA) or unexplained loss of consciousness in the past 12 months

AND

- ❑ Member is **NOT** currently receiving anti-platelet agents (with the exception of prophylactic aspirin), anticoagulants (e.g., Factor Xa inhibitors), or anti-thrombins (e.g., heparin)

AND

- ❑ Member does **NOT** have impaired renal or liver function

AND

- ❑ 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

AND

- ❑ Member has **NOT** had a clinically significant and unstable psychiatric illness in the past six months

Continuation of Therapy: 6 months
Members with < 5 total infusions: up to the 4th total infusion
Members with < 6 total infusions: up to the 7th total infusion
Members with > 12 total infusions: 6 infusions per PA approval
If infusion is missed, recommended to resume at the same dose as soon as possible. Infusions are administered once every 2 weeks.

- ❑ Member continues to meet all initial authorization criteria

AND

- ❑ Member has responded to therapy compared to pretreatment baseline confirmed by improvement, stability, slowing cognitive and /or functional impairment or there has not been a clinically meaningful cognitive deterioration by **ONE** of the following assessments **(must submit documentation)**:
  - ❑ Clinical Dementia Rating-Global score (CDR-GS) of 0.5
  - ❑ Mini-Mental State Exam (MMSE) score of 24-30
  - ❑ Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13, ADAS-Cog 14]
  - ❑ Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive Impairment version [ADCS-ADL-MCI]

AND

- ❑ Member has **NOT** progressed to moderate or severe dementia

AND

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- ❑ 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

AND

- ❑ Member has received the follow-up MRI for monitoring of Amyloid Related Imaging Abnormalities edema (ARIA-E) or hemosiderin (ARIA-H) at the following timeframes **(must submit results)**:
  - ❑ Pre-5th infusion
  - ❑ Pre-7th infusion
  - ❑ Pre-14th infusion

AND

- ❑ 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

OR

- ❑ 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

OR

- ❑ Results from MRI must meet **ONE** of the following for members with radiographic evidence of amyloid related 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

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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

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.

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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.

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

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References:

1. van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in early Alzheimer's disease. *N Engl J Med*. 2023;388(1):9-21.
2. 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. *Alzheimer's Res Ther*. 2021;13(1):80.
3. Leqembi™ intravenous infusion [prescribing information]. Nutley, NJ: Eisai; January 2023.
4. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2023 January 8]. Available from: https://clinicaltrials.gov/. Search term: lecanemab.
5. Liu KY, Schneider LS, Howard R. The need to show minimum clinically important differences in Alzheimer's disease trials. *Lancet Psychiatry*. 2021;8(11):1013-1016.
6. Arvanitakis Z, Shah RC, Bennett DA. Diagnosis and management of dementia: a review. JAMA. 2019;322(16):1589-1599.
7. Langa, LM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review.
8. 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: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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.