Leqembi

HMSAMCD- Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Patient's Phone Number: _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Additional Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*ft* _____*inches*

Indicate where the drug is being dispensed:

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

Indicate where the drug is being administered:

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What is the ICD-10 code? _____

Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512

CVS Caremark Specialty Programs ● 2969 Mapunapuna Place ● Honolulu, HI 96819
Phone: 1-808-254-4414 ● Fax: 1-866-237-5512 ● www.caremark.com

Criteria Questions:

1. What is the diagnosis?
❒ Alzheimer's disease, *Continue to #2*
❒ Other, please specify: _____, *Continue to #2*

2. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to #26*
❒ No, *Continue to #3*

3. Have other forms of suspected neurodegenerative etiology other than Alzheimer's disease been ruled out, including but not limited to frontotemporal lobar degeneration (FTLD) or Lewy body disease (i.e., meeting consensus criteria for possible or probable dementia with Lewy bodies)?
❒ Yes, *Continue to #4*
❒ No, *Continue to #4*

4. Is the patient concurrently using antithrombotic medications (e.g., aspirin, other antiplatelets, or anticoagulants)?
❒ Yes, *Continue to #5*
❒ No, *Continue to #6*

5. Has the been on a stable dose of antithrombotic medications for at least 4 weeks prior to initiation of the requested medication?
❒ Yes, *Continue to #6*
❒ No, *Continue to #6*

6. Does the patient have a history of transient ischemic attacks (TIA), stroke, or seizures within the past 12 months?
❒ Yes, *Continue to #7*
❒ No, *Continue to #7*

7. Does the patient have a bleeding disorder that is not under adequate control (including a platelet count <50,000 or international normalized ratio [INR] > 1.5)?
❒ Yes, *Continue to #8*
❒ No, *Continue to #8*

8. Will the requested drug be used in combination with any other amyloid beta-directed antibodies (e.g., aducanumab)?
❒ Yes, *Continue to #9*
❒ No, *Continue to #9*

9. Is this medication being prescribed by or in consultation with a geriatrician, neurologist, psychiatrist, or neuropsychiatrist?
❒ Yes, *Continue to #10*
❒ No, *Continue to #10*

10. Is the patient 50 years of age or older?
❒ Yes, *Continue to #13*
❒ No, *Continue to #11*

11. Has genetic testing been completed to confirm the patient has a genetic mutation in the amyloid precursor protein (APP), presenilin-1 (PSEN1), or presenilin-2 (PSEN2)? ***ACTION REQUIRED****: If Yes, please attach testing results documenting a mutation in the amyloid precursor protein (APP), presenilin-1 (PSEN-1) or preseline-2 (PSEN2)*
❒ Yes, *Continue to #13*
❒ No, *Continue to #12*

12. Is there clinical documentation to support the patient has early onset Alzheimer's disease? ***ACTION REQUIRED****: If Yes, please attach clinical documentation supporting early onset Alzheimer's disease*
❒ Yes, *Continue to #13*
❒ No, *Continue to #13*

13. Does the patient have mild cognitive impairment due to Alzheimer's disease (AD) or mild Alzheimer's disease (AD)? ***ACTION REQUIRED****: If Yes, please attach medical records or chart notes documenting diagnosis of mild impairment due to Alzheimer's disease (AD) or mild Alzheimer's disease (AD)*
❒ Yes, *Continue to #14*
❒ No, *Continue to #14*

14. Does the patient have objective evidence of cognitive impairment at baseline?
❒ Yes, *Continue to #15*
❒ No, *Continue to #15*

15. Based on clinical and cognitive evaluation of the patient, which of the following characteristics does the patient exhibit as objective evidence of mild cognitive impairment at baseline?
❒ Objective evidence of impairment in one or more cognitive domains, typically including memory (i.e., formal or bedside testing to establish level of cognitive function in multiple domains), *Continue to #16*
❒ Cognitive concern reflecting a change in cognition reported by patient or information or clinician (i.e., historical or observed evidence of decline over time), *Continue to #16*
❒ Preservation of independence in functional abilities, *Continue to #16*
❒ Not demented, *Continue to #16*
❒ All of the above, *Continue to #16*
❒ None of the above, *Continue to #16*

16. Which of the following assessment tools have been completed at baseline?
❒ Clinical Dementia Rating Global Score (CDR-GS), *Continue to #17*
❒ Mini-Mental Status Examination (MMSE), *Continue to #18*
❒ Montreal Cognitive Assessment (MoCA), *Continue to #19*
❒ None of the above

17. What is the patient's Clinical Dementia Rating Global Score (CDR-GS)? ***ACTION REQUIRED****: Please attach baseline assessment tool for the Clinical Dementia Rating Global score (CDR-GS)*
❒ 0, *Continue to #20*
❒ 0.5, *Continue to #20*
❒ 1, *Continue to #20*
❒ 2 or more, *Continue to #20*
❒ Unknown, *Continue to #20*

18. What is the patient's Mini-Mental Status Examination (MMSE) score? ***ACTION REQUIRED****: Please attach baseline assessment tool for the Mini-Mental Status Exam (MMSE)*
❒ Less than 21, *Continue to #20*
❒ 21-30, *Continue to #20*
❒ Unknown, *Continue to #20*

19. What is the patient's Montreal Cognitive Assessment (MoCA) Score? ***ACTION REQUIRED****: Please attach baseline assessment tool for the Montreal Cognitive Assessment Score (MoCA)*
❒ Greater than or equal to 16, *Continue to #20*
❒ 15 or less, *Continue to #20*
❒ Unknown, *Continue to #20*

20. Has the patient had a positron emission tomography (PET) scan confirming the presence of amyloid pathology? ***ACTION REQUIRED****: If Yes, please attach baseline PET scan results*
❒ Yes, *Continue to #22*
❒ No, *Continue to #21*

21. Has a lumbar puncture been completed to confirm at least one of the following detected in cerebrospinal fluid (CSF) as determined by lab assay? ***ACTION REQUIRED****: If Yes, please attach lumbar puncture results*
❒ Yes, presence of elevated phosphorylated tau (P-tau) protein and/or elevated total tau (T-tau) protein and reduced beta amyloid-42 (AB42), *Continue to #22*
❒ Yes, low AB42/AB40 ratio, *Continue to #22*
❒ Yes, elevated P-Tau/AB42 ratio, *Continue to #22*
❒ Yes, elevated T-Tau/AB42 ratio, *Continue to #22*
❒ No, *Continue to #22*

22. Has the patient had a recent brain magnetic resonance imaging (MRI) within one year, prior to initiating treatment to evaluate for pre-existing Amyloid Related Imaging Abnormalities (ARIA)? ***ACTION REQUIRED****: If Yes, please attach recent (within one year) MRI results*
❒ Yes, *Continue to #23*
❒ No, *Continue to #23*

23. Has genotype testing for apolipoprotein E4 (ApoE) status been performed prior to initiation of treatment to inform patient of the risk of developing ARIA?
❒ Yes, *Continue to #24*
❒ No, *Continue to #25*

24. Please indicate the patient's genotype:
❒ Homozygous, *Continue to #25*
❒ Heterozygous, *Continue to #25*
❒ Non-Carrier, *Continue to #25*
❒ Unknown, *Continue to #25*

25. If genotype testing has not been performed, has the prescriber informed the patient that it cannot be determined if they are apolipoprotein E4 (ApoE) homozygous and may be at higher risk for ARIA?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

26. How many months of therapy on the requested medication has the patient completed?
❒ Therapy completed (in months): _____ months, *Continue to #27*
❒ Unknown, *Continue to #27*

27. Please enter the start date of therapy.
❒ Therapy start date: _____ MM/DD/YYYY, *Continue to #28*
❒ Unknown, *Continue to #28*

28. Which of the following applies to this continuation request?
❒ The patient has completed 7 months of therapy (first reauthorization request after initial 7-month approval period), *Continue to #29*
❒ The patient has completed 19 months of therapy or more, *Continue to #36*

29. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the

5th dose? ***ACTION REQUIRED****: If Yes, please attach brain magnetic resonance imaging results prior to the 5th dose*
❒ Yes, *Continue to #30*
❒ No, *Continue to #30*

30. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the 7th dose? ***ACTION REQUIRED****: If Yes, please attach brain magnetic resonance imaging results prior to the 7th dose*
❒ Yes, *Continue to #31*
❒ No, *Continue to #31*

31. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the 14th dose? ***ACTION REQUIRED****: If Yes, please attach brain magnetic resonance imaging results prior to the 14th dose*
❒ Yes, *Continue to #32*
❒ No, *Continue to #32*

32. Does the patient have evidence of ARIA?
❒ Yes, *Continue to #33*
❒ No, *No Further Questions*

33. Based on the MRI results, which of the following describes the radiographic evidence of ARIA?
❒ The patient has radiographic evidence of ARIA-E, *Continue to #34*
❒ The patient has radiographic evidence of ARIA-H, *Continue to #35*

34. Identify which of the following results pertains to the patient's radiographic evidence of ARIA-E?
❒ The patient has mild ARIA-E on MRI and is asymptomatic or has mild clinical symptoms, *No Further Questions*
❒ The patient has mild ARIA-E on MRI and has moderate or severe clinical symptoms, *No Further Questions*
❒ The patient has moderate ARIA-E on MRI and is asymptomatic or has, mild, moderate, or severe clinical symptoms, *No Further Questions*
❒ The patient has severe ARIA-E on MRI and is asymptomatic or has, mild, moderate, or severe clinical symptoms, *No Further Questions*

35. Identify which of the following results pertains to the patient's radiographic evidence of ARIA-H?
❒ The patient has mild ARIA-H on MRI and is asymptomatic, *No Further Questions*
❒ The patient has mild ARIA-H on MRI and is symptomatic, *No Further Questions*
❒ The patient has moderate ARIA-H on MRI and is asymptomatic or symptomatic, *No Further Questions*
❒ The patient has severe ARIA-H on MRI and is asymptomatic or symptomatic, *No Further Questions*

36. Has the patient had a positive clinical response as evidenced by stabilization or slowing of disease progression as documented by any of the following measures? (Repeat assessment tool(s) must be the same tool that was submitted upon initial request.)
❒ Yes, Clinical Dementia Rating Global Score (CDR-GS), *Continue to #37*
❒ Yes, Mini-Mental Status Examination (MMSE), *Continue to #38*
❒ Yes, Montreal Cognitive Assessment (MoCA), *Continue to #39*
❒ No, None of the above, *No Further Questions*

37. What is the patient's Clinical Dementia Rating Global Score (CDR-GS)? ***ACTION REQUIRED****: Please attach medical records (e.g., chart notes) documenting the most recent (less than 1 month prior to continuation request) result for the Clinical Dementia Rating Global Score (CDR-GS)*
❒ 0, *No Further Questions*
❒ 0.5, *No Further Questions*
❒ 1, *No Further Questions*
❒ 2 or more, *No Further Questions*
❒ Unknown, *No Further Questions*

38. What is the patient's decline on the Mini-Mental Status Examination (MMSE) Score? ***ACTION REQUIRED****: Please attach medical records (e.g., chart notes) documenting the most recent (less than 1 month prior to continuation request) result for the Mini-Mental Status Exam (MMSE)*
❒ Decline of greater than 3 points per year, *No Further Questions*
❒ Decline of 3 points or less per year, *No Further Questions*
❒ Unknown, *No Further Questions*

39. What is the patient's Montreal Cognitive Assessment Score (MoCA)? ***ACTION REQUIRED****: Please attach medical records (e.g., chart notes) of the most recent (less than 1 month prior to continuation request) for the Montreal Cognitive Assessment Score (MoCA)*
❒ Greater than or equal to 16, *No Further Questions*
❒ 15 or less, *No Further Questions*
❒ Unknown, *No Further Questions*

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**