Kisunla

CareFirst 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 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** 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:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

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

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

Please indicate the place of service for the requested drug:

❑ *Ambulatory Surgical*	❑ *Home*	❑ *Off Campus Outpatient Hospital*
❑ *On Campus Outpatient Hospital*	❑ *Office*	❑ *Pharmacy*

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

Site of Service Questions:

1. Where will this drug be administered?
❑ On-campus outpatient hospital, *Continue to 2*
❑ Off-campus outpatient hospital, *Continue to 2*
❑ Pharmacy, *skip to Clinical Criteria Questions*
❑ Physician office, *skip to Clinical Criteria Questions*
❑ Home infusion, *skip to Clinical Criteria Questions*
❑ Ambulatory surgical, *skip to Clinical Criteria Questions*

2. Is the patient less than 14 years of age?
❑ Yes, *skip to Clinical Criteria Questions*
❑ No, *Continue to 3*

3. Is this request to continue previously established treatment with the requested medication? ***Action Required***: Please attach supporting clinical documentation
❑ Yes, *Continue to 4*
❑ No, *skip to Clinical Criteria Questions*

4. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***Action Required***: If yes, please attach supporting clinical documentation
❑ Yes, *skip to Clinical Criteria Questions*
❑ No, *Continue to 5*

5. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? ***Action Required***: If yes, please attach supporting clinical documentation
❑ Yes, *skip to Clinical Criteria Questions*
❑ No, *Continue to 6*

6. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***Action Required***: If yes, please attach supporting clinical documentation
❑ Yes, *skip to Clinical Criteria Questions*
❑ No, *Continue to 7*

7. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND does not have access to a caregiver? ***Action Required***: If yes, please attach supporting clinical documentation
❑ Yes, *skip to Clinical Criteria Questions*
❑ No, *Continue to 8*

8. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home?
❑ Yes, *continue to Clinical Criteria Questions*
❑ No, *continue to Clinical Criteria Questions*

Criteria Questions:

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

2. Is this request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 32*
❒ No, *Continue to 3*

3. Have other forms of suspected neurodegenerative etiology of cognitive impairment 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 that lack AD biomarkers of a positive amyloid PET or CSF profile)?
❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Has the patient had greater than 4 cerebral microbleeds, cortical superficial siderosis, or a major vascular contribution to cognitive impairment confirmed via MRI?
❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Has the patient had a cerebral contusion, encephalomalacia, brain aneurysm or other vascular malformation, central nervous system infection, or brain tumor?
❒ Yes, *Continue to 6*
❒ No, *Continue to 6*

6. Is the patient concurrently using antiplatelet agents (e.g., aspirin up to 325 mg/day, clopidogrel, prasugrel, ticagrelor)?
❒ Yes, *Continue to 7*
❒ No, *Continue to 8*

7. Will the patient use antiplatelet agent as monotherapy at a standard therapeutic dose (i.e., not using as dual agent anti-platelet therapy)?
❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Does the patient have a history of transient ischemic attacks (TIA), stroke, uncontrolled hypertension, or seizures within the past 12 months?
❒ Yes, *Continue to 9*
❒ No, *Continue to 9*

9. 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 10*
❒ No, *Continue to 10*

10. Does the patient have an immunologic disorder requiring therapy with immunoglobulins, monoclonal antibodies, immunosuppressants, or plasmapheresis?
❒ Yes, *Continue to 11*
❒ No, *Continue to 11*

11. Will the requested drug be used in combination with any other amyloid beta-directed antibodies (e.g., aducanumab, lecanemab)?
❒ Yes, *Continue to 12*
❒ No, *Continue to 12*

12. Is this medication being prescribed by or in consultation with a geriatrician, neurologist, psychiatrist or neuropsychiatrist?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. Is the patient 50 years of age or older?
❒ Yes, *Continue to 17*
❒ No, *Continue to 14*

14. 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 17*
❒ No, *Continue to 15*

15. 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 16*
❒ No, *Continue to 16*

16. Does the patient have objective evidence of cognitive impairment at baseline?
❒ Yes, *Continue to 17*
❒ No, *Continue to 17*

17. Does the patient have Clinical Stage 3 (cognitive impairment with early functional impact) or Clinical Stage 4 (dementia with mild functional impairment) Alzheimer's disease (AD)? ***ACTION REQUIRED***: If Yes, please attach medical records or chart notes documenting diagnosis of Clinical Stage 3 or 4 Alzheimer's disease (AD).
❒ Yes, *Continue to 18*
❒ No, *Continue to 21*

18. Please indicate Clinical Stage:
❒ Clinical Stage 3 (Mild cognitive impairment), *Continue to 19*
❒ Clinical Stage 4 (Dementia with mild functional impairment), *Continue to 20*

19. 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, executive function, attention, language, or visuspatial skills, *Continue to 21*
❒ Cognitive concern reported by the patient, knowledgeable informant, or the physician, *Continue to 21*
❒ Generally preserved activities of daily living (ADL), *Continue to 21*
❒ No dementia, *Continue to 21*
❒ All of the above, *Continue to 21*
❒ None of the above, *Continue to 21*

20. Based on clinical and cognitive evaluation of the patient, which of the following characteristics does the patient exhibit as objective evidence of dementia with mild functional impairment at baseline?
❒ Cognitive concern reported by the patient, knowledgeable informant, or the physician, *Continue to 21*

❒ Performance in the impaired/abnormal range on objective cognitive tests, *Continue to 21*
❒ Evidence of decline from baseline, documented by the individual's report or by observer (e.g., study partner) report or by change on longitudinal cognitive testing or neurobehavioral assessments, *Continue to 21*
❒ Progressive cognitive and mild functional impairment on instrumental ADL with independence in basic ADL, *Continue to 21*
❒ All of the above, *Continue to 21*
❒ None of the above, *Continue to 21*

21. Which of the following assessment tools have been completed at baseline?
❒ Clinical Dementia Rating Global Score (CDR-GS), *Continue to 22*
❒ Mini-Mental Status Examination (MMSE), *Continue to 23*
❒ Montreal Cognitive Assessment (MoCA), *Continue to 24*
❒ None of the above, *Continue to 25*

22. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ 0.5 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ 1 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ 2 or more ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ Unknown ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*

23. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ 21 - 30 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ Unknown ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*

24. 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 ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ 15 or less ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*
❒ Unknown ***ACTION REQUIRED****: Submit supporting documentation, Continue to 25*

25. 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 27*
❒ No, *Continue to 26*

26. 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, low AB42/AB40 ratio ***ACTION REQUIRED****: Submit supporting documentation, Continue to 27*
❒ Yes, elevated P-Tau/AB42 ratio ***ACTION REQUIRED****: Submit supporting documentation, Continue to 27*
❒ Yes, elevated T-Tau/AB42 ratio ***ACTION REQUIRED****: Submit supporting documentation, Continue to 27*
❒ No *Continue to 27*

27. 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 28*
❒ No, *Continue to 28*

28. Has the patient undergone genotype testing to determine apolipoprotein E4 (ApoE) status prior to initiation of treatment to inform patient of the risk of developing ARIA?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. Will the patient use the requested medication in combination with anticoagulants including warfarin, heparin, and direct oral anticoagulants (e.g., dabigatran, rivaroxaban, edoxaban, apiximab, betrixaban)?
❒ Yes, *Continue to 30*
❒ No, *Continue to 30*

30. Is the patient or provider currently participating in a provider-enrolled patient registry that collects information on treatments for Alzheimer's disease (e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET))?
❒ Yes, *Continue to 31*
❒ No, *Continue to 31*

31. Please indicate name of provider-enrolled patient registry:
❒ Patient registry name, please specify. _____, *No Further Questions*
❒ Unknown, *No Further Questions*

32. Does the patient or provider continue to participate in a provider-enrolled patient registry that collects information on treatments for Alzheimer's disease (e.g., Alzheimer's Network for Treatment and Diagnostics (ALZ-NET))?
❒ Yes, *Continue to 33*
❒ No, *Continue to 33*

33. How many months of therapy on the requested medication has the patient completed?
❒ Therapy completed (in months), please specify. _____months, *Continue to 34*
❒ Unknown, *Continue to 34*

34. Please enter the start date of therapy.
❒ Therapy start date, please specify. _____ MM/DD/YYYY, *Continue to 35*
❒ Unknown, *Continue to 35*

35. Which of the following applies to this continuation request?
❒ The patient has completed 6 months of therapy (first reauthorization request after initial 6-month approval period), *Continue to 36*
❒ The patient has completed 18 months of therapy or more, *Continue to 44*

36. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the 2nd dose? ***ACTION REQUIRED***: If Yes, please attach brain magnetic resonance imaging results prior to the 2nd dose.
❒ Yes, *Continue to 37*
❒ No, *Continue to 37*

37. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the 3rd dose? ***ACTION REQUIRED***: If Yes, please attach brain magnetic resonance imaging results prior to the 3rd dose.
❒ Yes, *Continue to 38*
❒ No, *Continue to 38*

38. Has the patient been evaluated for evidence of amyloid-related imaging abnormalities (ARIA) on MRI prior to the 4th dose? ***ACTION REQUIRED***: Is Yes, please attach brain magnetic resonance imaging results prior to the 4th dose.
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

39. 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 40*
❒ No, *Continue to 40*

40. Does the patient have evidence of ARIA?
❒ Yes, *Continue to 41*
❒ No, *No Further Questions*

41. 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 42*
❒ The patient has radiographic evidence of ARIA-H, *Continue to 43*

42. Identity 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*

43. Identity 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*

44. 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 45*
❒ Yes, Mini-Mental Status Examination (MMSE), *Continue to 46*
❒ Yes, Montreal Cognitive Assessment (MoCA), *Continue to 47*
❒ No, None of the above, *No Further Questions*

45. 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 ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ 0.5 ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ 1 ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ 2 or more ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ Unknown, *No Further Questions*

46. 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 ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ Decline of 3 points or less per year ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ Unknown, *No Further Questions*

47. 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 ***ACTION REQUIRED****: Submit supporting documentation*, *No Further Questions*
❒ 15 or less ***ACTION REQUIRED****: Submit supporting documentation*, *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)**

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720