COVERAGE AUTHORIZATION REQUEST AND APPEALS GUIDE

Preparing a Coverage Authorization Appeals Letter

kisunla™ (donanemab-azbt) injection for intravenous use 350 mg/20 mL

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The following information is presented as a guide for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Eli Lilly and Company, with the use of the information contained herein, does not guarantee success in obtaining insurance payments. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Lilly Support Services™ at 1-800-Lilly-Rx (1-800-545-5979).

If the patient's initial claim or Coverage Authorization Request Letter is denied by the patient's health plan, the payer may require a Coverage Authorization Appeals Letter. Depending on the plan, there may be varying levels of appeals. If you are uncertain about a plan's appeal levels or specific procedures, always refer to the plan's appeal guidelines.

This resource, **Preparing a Coverage Authorization Appeals Letter**, provides information to healthcare providers (HCPs) when appealing a coverage authorization decision for a patient's plan. Included on the following page is a list of considerations that can be followed when creating a Coverage Authorization Appeals Letter. In addition, 2 sample letters are attached to this document and feature information that many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting Kisunla, otherwise treatment may be delayed.

A **Coverage Authorization Appeals Letter** originates from the patient and the prescribing HCP.* It should be submitted with 2 additional items: the patient's medical records and a Letter of Medical Necessity. Also see **Composing a Letter of Medical Necessity** for more information.

*For Medicare beneficiaries, specific requirements must be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf.

INDICATION

Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

SELECT IMPORTANT SAFETY INFORMATION for Kisunla™ (donanemab-azbt)

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla, can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla.

ApoE ε4 Homozygotes: Patients who are apolipoprotein E ε4 (ApoE ε4) homozygotes treated with this class of medications, including Kisunla, have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, the risk of ARIA across genotypes and implications of genetic testing results should be discussed with patients.

Consider the benefit for the treatment of Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.

Please see Important Safety Information, including Boxed Warning regarding ARIA, on pages 5-7, and click for full Prescribing Information and Medication Guide for Kisunla.

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Preparing a Coverage Authorization Appeals Letter

Coverage Authorization Requests: Guidance and Recommendations

1. Include the patient's full name, date of birth, and plan identification number.
2. Add the prescribing HCP's National Provider (NPI) number and specialty.
3. Disclose that you are familiar with the plan's policy. Clearly document the basis for the plan's denial within the letter, along with case identification number from the initial denial letter.
4. Provide a copy of the patient's records with the following details: patient's history, diagnosis, and condition. Relevant clinical information may include, but is not limited to:
   - Diagnosis of Alzheimer's disease (mild cognitive impairment (MCI) or mild dementia stage of disease), as well as the date of diagnosis.
     - Consider including the patient's ICD-10 diagnosis code(s) as appropriate.
   - Result and Date of Recent Baseline Magnetic Resonance Imaging (MRI) prior to initiating treatment
   - Confirmation of Amyloid Pathology, including the type of test and date it was performed, for example:
     - Amyloid Positron Emission Tomography (PET) Scan
     - Cerebrospinal Fluid (CSF)
     - Other Amyloid Test
   - Cognitive Assessments with a validated tool (may require more than one), including date, type, and score of test. For example:
     - Clinical Dementia Rating (CDR) Scale
     - Mini-Mental State Exam (MMSE) score
     - Montreal Cognitive Assessment (MoCA)
     - Other Cognitive Test and associated score
   - Functional Assessments with a validated tool (may require more than one), including date, type, and score of test. For example:
     - The Functional Activities Questionnaire (FAQ) score
     - Other Functional Test and associated score
   - Whether the patient has any history of Amyloid-Related Imaging Abnormalities (ARIA), either ARIA-E or ARIA-H. Please note if there is evidence of ARIA and the date of the MRI, if any.
5. Note the severity of the patient's condition. Kisunla is indicated for the treatment of Alzheimer's disease (AD). Treatment with Kisunla should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.
6. Document prior treatment, duration of each, and the rationale for discontinuation.
7. Explain why the plan's preferred formulary agents and/or denial rationale(s) are not appropriate for this patient.
8. Provide the clinical rationale for this treatment; this information may be found in the Kisunla Prescribing Information and/or clinical peer-reviewed literature.
9. Summarize your recommendation at the end of the letter.
10. Include a Letter of Medical Necessity.

Preparing a Coverage Authorization Appeals Letter

HCPs can utilize this format for patients who are **NOT** currently receiving treatment with Kisunla™ (donanemab-azbt).

[Date]
[Prior Authorization/Appeals Department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Kisunla (donanemab-azbt) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Kisunla 350 mg IV for the first infusion, 700 mg IV for the second infusion, 1050 mg IV for the third infusion, then 1400 mg IV every four weeks thereafter is the appropriate treatment for the patient. In support of our recommendation for Kisunla treatment, we have provided an overview of the patient's relevant clinical history below.

[Patient's history, diagnosis, condition, and symptoms*:
Patient must have a diagnosis for an indication of Kisunla. Kisunla is indicated for the treatment of Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia stage of disease. Please reference the guidance on page 2 and include any co-morbidities, confirmation of amyloid positivity, concomitant medications, and all relevant information pertaining to the patient's diagnosis, condition, and symptoms.]

Past Treatments†	Start/Stop Dates	Reason(s) for Discontinuation

[Please detail all that apply and add additional lines as needed.]

[Provide clinical rationale for this treatment; this information may be found in the full Prescribing Information for Kisunla and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Kisunla.]

Please feel free to contact me, **[HCP's name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]

Encl: Medical records
Clinical trial information
Letter of Medical Necessity

When appealing a plan's step edit therapy requirement, consider providing statements indicating why these requirements are inappropriate for the patient, including contraindications and examples of previous therapy trials/failures due to lack of response or drug intolerance.

*Include patient's medical records and supporting documentation.
†Identify drug name, strength, dosage form, and therapeutic outcome.

Preparing a Coverage Authorization Appeals Letter

HCPs can utilize this format for patients who **HAVE** been treated with Kisunla™ (donanemab-azbt) and may have experienced a treatment interruption.

[Date]
[Prior authorization/appeals department]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]

To whom it may concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Kisunla (donanemab-azbt) coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe the patient should resume administration every 4 weeks at the same dose as soon as possible. We have provided an overview of the patient's relevant clinical history below.

[In this section, describe the clinical presentation of the disease at the time when the patient was first prescribed Kisunla. In addition, include the results of any safety monitoring MRIs. It may be necessary to review past medical records to gather this information].

[Patient's history, diagnosis, condition, and symptoms*:
Patient must have a diagnosis for an indication of Kisunla. Kisunla is indicated for the treatment of Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia stage of disease. Please reference the guidance on page 2 and include any co-morbidities, confirmation of amyloid positivity, concomitant medications, and all relevant information pertaining to the patient's diagnosis, condition, and symptoms.]

Past Treatments†	Start/Stop Dates	Reason(s) for Discontinuation

[Provide clinical rationale for this treatment; this information may be found in the Kisunla Prescribing Information and/or clinical peer-reviewed literature.]

[Please detail all that apply and add additional lines as needed.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Kisunla.]

Please feel free to contact me, **[HCP's name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]

Encl: Medical Records
Clinical trial information
Letter of Medical Necessity

When appealing a plan's step edit therapy requirement, consider providing statements indicating why these requirements are inappropriate for the patient, including contraindications and examples of previous therapy trials/failures due to lack of response or drug intolerance.

*Include patient's medical records and supporting documentation.
†Identify drug name, strength, dosage form, and therapeutic outcome.

IMPORTANT SAFETY INFORMATION FOR Kisunla™ (donanemab-azbt)

WARNING: AMYLOID-RELATED IMAGING ABNORMALITIES

Monoclonal antibodies directed against aggregated forms of beta amyloid, including Kisunla, can cause amyloid-related imaging abnormalities (ARIA), characterized as ARIA with edema (ARIA-E) and ARIA with hemosiderin deposition (ARIA-H). ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events can occur. ARIA can be fatal. Serious intracerebral hemorrhages >1 cm, some of which have been fatal, have been observed in patients treated with this class of medications. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with Kisunla.

ApoE ε4 Homozygotes: Patients treated with this class of medications, including Kisunla, who are apolipoprotein E ε4 (ApoE ε4) homozygotes (approximately 15% of Alzheimer's disease patients) have a higher incidence of ARIA, including symptomatic, serious, and severe radiographic ARIA, compared to heterozygotes and noncarriers. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. Prior to testing, the risk of ARIA across genotypes and the implications of genetic testing results should be discussed with patients.

Consider the benefit for treating Alzheimer's disease and risk of ARIA when deciding to treat with Kisunla.

Kisunla is **contraindicated** in patients with known serious hypersensitivity to donanemab-azbt or to any of the excipients. Reactions have included anaphylaxis.

Amyloid-Related Imaging Abnormalities (ARIA)

ARIA usually occurs early in treatment and is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, can occur. ARIA can be fatal. When present, reported symptoms associated with ARIA may include, but are not limited to, headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

In Study 1, safety was assessed in patients who received Kisunla Dosing Regimen 1 (n=853) compared to those who received placebo (n=874). In Study 2, the effect of different dosing regimens of Kisunla on ARIA was assessed, including in patients who received Kisunla Dosing Regimen 2 (n=212).

Incidence of ARIA

A lower incidence of ARIA was observed with Dosing Regimen 2 as compared to Dosing Regimen 1. Therefore, Dosing Regimen 2 is the recommended dosage for Kisunla.

In Study 1, symptomatic ARIA-E occurred in 6% of patients through 18 months of treatment with Kisunla.

Clinical symptoms associated with ARIA resolved in approximately 85% of those patients.

Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed with Kisunla: 36%, 24%, and 31% of patients treated with Kisunla, respectively compared to 14%, 2%, and 13% of patients on placebo. There was no increase in isolated ARIA-H for Kisunla vs placebo.

In Study 2, symptomatic ARIA-E occurred in 3% of patients and symptomatic ARIA-H occurred in less than 1% of patients through 12 months of treatment with Kisunla. Clinical symptoms associated with ARIA-E resolved in approximately 67% of patients at 12 months. Including asymptomatic radiographic events, ARIA, ARIA-E, and ARIA-H were observed in 29%, 16%, and 25% of patients treated with Kisunla.

Please see Important Safety Information, including Boxed Warning regarding ARIA, on pages 5-7, and click for full Prescribing Information and Medication Guide for Kisunla.

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IMPORTANT SAFETY INFORMATION FOR Kisunla™ (donanemab-azbt) (continued)

Incidence of Intracerebral Hemorrhage (ICH)

ICH >1 cm in diameter was reported in 0.5% of patients treated with Kisunla vs 0.2% on placebo in Study 1 and in 1% of patients treated with Kisunla in Study 2. Fatal events of ICH have been observed in patients taking Kisunla.

Risk Factors for ARIA and ICH

ApoE ε4 Carrier Status

The risk of ARIA, including symptomatic and serious ARIA, is increased in ApoE ε4 homozygotes.

Recommendations for management of ARIA do not differ based on ApoE ε4 carrier status. Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA. An FDA-authorized test for detection of ApoE ε4 alleles is not currently available. Currently available tests may vary in accuracy and design.

Radiographic Findings of Cerebral Amyloid Angiopathy (CAA)

Neuroimaging findings that may indicate CAA include evidence of prior ICH, cerebral microhemorrhage, and cortical superficial siderosis. CAA has an increased risk for ICH. The presence of an ApoE ε4 allele is also associated with CAA.

The baseline presence of at least 2 microhemorrhages or the presence of at least 1 area of superficial siderosis on magnetic resonance imaging (MRI), which may be suggestive of CAA, were identified as risk factors for ARIA. Patients were excluded from enrollment in Study 1 and Study 2 for findings on neuroimaging of prior ICH >1 cm in diameter, >4 microhemorrhages, >1 area of superficial siderosis, severe white matter disease, and vasogenic edema.

Concomitant Antithrombotic or Thrombolytic Medication

In Study 1, baseline use of antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) was allowed. The majority of exposures to antithrombotic medications were to aspirin. The number of events and the limited exposure to non-aspirin antithrombotic medications limit definitive conclusions about the risk of ARIA or ICH in patients taking antithrombotic medications.

One fatal ICH occurred in a patient taking Kisunla in the setting of focal neurologic symptoms of ARIA and the use of a thrombolytic agent in Study 1, and one fatal intracerebral hemorrhage occurred in the setting of ARIA and the use of a thrombolytic agent in Study 2. Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E, and additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (eg, tissue plasminogen activator) to a patient being treated with Kisunla. Advise patients to carry information that they are being treated with Kisunla.

Caution should be exercised when considering the use of Kisunla in patients with factors that indicate an increased risk for ICH and in particular for patients who need to be on anticoagulant therapy or patients with findings on MRI that are suggestive of CAA.

Monitoring and Dose Management Guidelines

Obtain a recent baseline brain MRI prior to initiating treatment and prior to the 2nd, 3rd, 4th, and 7th infusions. Enhanced clinical vigilance for ARIA is recommended during the first 24 weeks of treatment with Kisunla. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.

Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, interrupt treatment, or permanently discontinue Kisunla. See Prescribing Information for additional dosing considerations.

IMPORTANT SAFETY INFORMATION FOR Kisunla™ (donanemab-azbt) (continued)

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis and angioedema, have occurred in patients who were treated with Kisunla. Promptly discontinue the infusion upon the first observation of any signs or symptoms consistent with a hypersensitivity reaction and initiate appropriate therapy.

Infusion-Related Reactions (IRR)

IRRs were observed with Kisunla with the majority occurring within the first 4 infusions. Most IRRs occurred during the infusion or within 30 minutes after completion of the infusion, however some have occurred hours after an infusion. Signs and symptoms of IRRs include chills, erythema, nausea/vomiting, flushing, difficulty breathing/dyspnea, sweating, elevated blood pressure, headache, chest pain, and low blood pressure.

In the event of an IRR, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Consider pre-treatment with antihistamines, acetaminophen, or corticosteroids prior to subsequent dosing.

Adverse Reactions: The most common adverse reactions reported in ≥5% of patients treated with Kisunla and ≥2% higher than placebo were ARIA-H microhemorrhage, ARIA-E, ARIA-H superficial siderosis, headache, and IRRs.

Kisunla (donanemab-azbt) injection for intravenous use is available as a 350 mg/20 mL single-dose vial.

Please see full Prescribing Information for Kisunla, Including Boxed Warning regarding ARIA, and Medication Guide.

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