

CONSIDERATIONS FOR COMPOSING SAMPLE LETTERS

This document is intended for the independent consideration and review of healthcare professionals prescribing LEQEMBI® (lecanemab-irmb) injection, for intravenous use to appropriate patients who may be experiencing issues with insurance coverage. These sample letters may be utilized to help justify your patient's need for treatment to an insurance provider.

Below, you'll find instructions and tips for the following letters:

- Medical necessity/prior authorization
- Appeals
- Prescription Coverage Exception Request

We have provided these instructions and sample letters to help request coverage, appeal decisions, or request prescription coverage exception as part of a prior authorization/access process. The sample letters can be found on the HCP reimbursement website by [clicking here](#).

The information contained herein and the sample letters are provided for informational purposes and guidance only. Use of these documents does not guarantee health insurance coverage for you or your patient, and nothing in this document should be construed as a guarantee regarding coverage or payment by any payer at any specific level. We do not advocate or promote the appropriateness of the use of any billing codes referenced in either these instructions or the sample letters.

This information is provided to help meet general prior authorization or other requirements. There is no requirement that any patient or healthcare provider use any EISA product in exchange for this information, and this template letter is not meant to substitute for a prescriber's independent medical decision-making. For information relevant to any prescribing decisions, please see the full Prescribing Information for the FDA-approved label for LEQEMBI, including **Boxed WARNING**.

The treating physician in his or her medical judgment is ultimately responsible for the accuracy, truthfulness, and completeness of all claims and communications submitted to third-party payers.

GENERAL TIPS FOR USE

- To use these letters, please copy the text provided and paste it onto your office letterhead. Be sure to replace all bolded and bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider
- If the fields provided in the sample letters do not accurately reflect your practices, please modify them to represent your circumstances
- Please make all changes to these documents that you believe appropriate, or disregard these suggestions in their entirety if they are not applicable to your patient
- Always include the following information in your communications with insurers:
 - Physician name
 - NPI number
 - Phone number
 - Fax number
 - Practice letterhead
- When communicating by email, select the option to be notified when the email is received and opened and keep a record of this communication
- Remember to keep complete records, including a copy of the materials that you send, and a log of telephone calls made to the patient's health insurance plan

HOW TO DRAFT A LETTER OF MEDICAL NECESSITY/PRIOR AUTHORIZATION

When submitting a prior authorization (PA) request to a patient's health insurance plan, you can include a letter of medical necessity to help explain the rationale and clinical decision-making behind the choice of a specific therapy.

GENERAL TIPS

- To help avoid denials when you submit the PA request to the payer, familiarize yourself with the plan's specific guidelines (ie, obtain any necessary referrals, determine if treatment must be given in a particular setting, etc)
- Be sure to know and meet all deadlines for submitting the PA form and other required documents
- Once you have received the PA, check with the payer to determine the length of the authorization, as this can vary
- Copy the text of the sample letter and paste it onto your office letterhead
- Replace all bolded and bracketed text with the appropriate patient-specific information
- If necessary, please modify the provided fields to more accurately reflect your practice

STANDARD INFORMATION TO INCLUDE:

- Patient information:
 - Full name
 - Date of birth
 - Insurance ID number
 - Insurance group number
 - Case ID number (if available)

COMPLETING THE DISEASE AND MEDICAL HISTORY FIELDS:

- Include specific ICD-10 diagnostic codes where appropriate
- Consider including the following information:
 - The patient's diagnosis and the indication for the medicine being prescribed
 - The severity of the patient's condition
 - A summary of the patient's previous treatments, the duration of each, and the rationale for discontinuation. Include coding information for prior treatments/services to help the health insurance plan conduct their research in a timely manner
 - The clinical rationale for treatment and why it is appropriate for your patient, including trial data supporting the FDA approval, administration and dosing information, etc
 - A summary of your recommendation

COMPLETING THE ENCLOSED MATERIALS FIELD:

- Include appropriate documents with your letter to the patient's insurance provider
- Documents should support your rationale for the recommended therapy, and could include:
 - A summary of the patient's medical records
 - Journal articles and other medical literature
 - Copies of medical correspondence, such as the original prior authorization form or previous denial letter/explanation of benefits (EOB)
 - Specific information about the recommended drug or procedure, such as:
 - Full Prescribing Information
 - FDA approval letter

HOW TO DRAFT A LETTER OF APPEAL

If your patient has been denied coverage, a letter of appeal can help explain the rationale and clinical decision-making behind your choice of a specific therapy. Sending a letter of appeal does not guarantee coverage for the medication for your patient.

GENERAL TIPS

- Copy the text of the sample letter and paste it onto your office letterhead
- Replace all bolded and bracketed text with the appropriate patient-specific information
- If necessary, please modify the provided fields to more accurately reflect your practice

COMPLETING THE DISEASE AND MEDICAL HISTORY FIELDS:

- Include specific ICD-10 diagnostic codes where appropriate
- Consider including the following information:
 - The patient's diagnosis and the indication for the medicine being prescribed
 - The severity of the patient's condition
 - A summary of the patient's previous treatments, the duration of each, and the rationale for discontinuation. Include coding information for prior treatments/services to help the health insurance plan conduct their research in a timely manner
 - The clinical rationale for treatment and why it is appropriate for your patient, including trial data supporting the FDA approval, administration and dosing information, etc
 - A summary of your recommendation

COMPLETING THE ENCLOSED MATERIALS FIELD:

- Be sure to include appropriate documents with your letter to the patient's insurance provider
- Documents should support your rationale for the recommended therapy, and could include:
 - A summary of the patient's medical records
 - Journal articles and other medical literature
 - Copies of medical correspondence, such as:
 - Original prior authorization form
 - Previous denial letter/explanation of benefits (EOB)
 - Specific information about the recommended drug or procedure, such as:
 - Full Prescribing Information
 - FDA approval letter

HOW TO DRAFT A PRESCRIPTION COVERAGE EXCEPTION REQUEST

If a patient is struggling due to circumstances such as sudden job loss, decrease in income, or increase in out-of-pocket family health care expenses, prescription coverage exception can be requested. Financial hardship assistance requests can be submitted for exemption from future copays or reduction in copay.

Patient hardships may include but are not limited to:

- Homelessness
- Eviction or facing eviction or foreclosure
- Receiving a shut-off notice from a utility company
- Domestic violence
- The death of a family member
- Fire, flood, or other natural or human-caused disaster that caused substantial damage to property
- Filing for bankruptcy

- Substantial debt resulting from medical expenses the patient couldn't pay
- Unexpected increases in necessary expenses due to caring for ill, disabled, or aging family members
- Claiming a child as a tax dependent who's been denied coverage for Medicaid or the Children's Health Insurance Program (CHIP), where another person is required by court order to give medical support to the child
- Being determined ineligible for Medicaid because their state didn't expand eligibility for Medicaid under the Affordable Care Act

GENERAL TIPS

- Copy the text provided and paste it onto your office letterhead
- Replace all bolded and bracketed text with the appropriate patient-specific information
- If necessary, please modify the provided fields to more accurately reflect your practice

COMPLETING THE DISEASE AND MEDICAL HISTORY FIELDS:

- Include specific ICD-10 diagnostic codes where appropriate
- Consider including the following information:
 - The patient's diagnosis and the indication for the medicine being prescribed
 - The severity of the patient's condition
 - A summary of the patient's previous treatments, the duration of each treatment, and the rationale for discontinuation. Include coding information for prior treatments/services to help the patient's health insurance plan conduct their research in a timely manner
 - The clinical rationale for treatment and why it is appropriate for your patient, including trial data supporting the FDA approval, administration and dosing information, etc
 - A summary of your recommendation
- Include specific rationale for financial hardship

COMPLETING THE ENCLOSED MATERIALS FIELD:

- Include documentation of patient's financial hardship, such as:
 - Documentation of financial hardship from the patient's medical record
 - Supporting notes in the patient's financial account
 - If available, documented proof of a patient's income and percentage at or below the [federal poverty guidelines](#) (updated annually by the US Department of Health and Human Services)
 - If available, include:
 - W-2 withholding statements
 - Unemployment check stubs
 - Paycheck stubs
 - Income tax return (1040)
 - Forms from Medicaid or other State-funded medical assistance
 - Forms from employers
 - Forms from welfare or community agencies
 - Documentation that a patient has other circumstances that indicate financial hardship, which may include, but may not be limited to:
 - Proof of bankruptcy settlement
 - Catastrophic situations (eg, death or disability in family)
 - Any another documentation that shows the patient would be unable to pay their medical bill and still be able to pay for other financial hardship

Eisai Inc. 200 Metro Blvd, Nutley, NJ 07110 © 2023 Eisai Inc.
LEQE-US2676 08/23