

SAMPLE LETTER OF MEDICAL NECESSITY or APPEAL- Comorbidities

Preparing an effective Letter of Medical Necessity or Appeal

1. Obtain a copy of the denial letter to include as an attachment with your letter
2. If available, get a copy of the health plan coverage policy by
 - a. Requesting a copy directly from the health plan
 - b. Accessing a copy from the health plan's website
 - c. Contacting Support Path® to request a copy, if available
3. Compare the patient's medical history with the health plan's medical coverage criteria, if one is available

Determine if a letter is needed (reasons why a letter would be needed)

- This letter will be used in support of an initial submission to request approval of a PBC product
 - Treatment was denied because of missing information
- Note: The payer's denial letter may be referenced in the appeal letter to the payer and added as an enclosure

Note: If you have the missing information available for submission, you may have the option to resubmit the authorization request with the missing information and request a redetermination instead of an appeal, thus saving an appeal option that may be needed later.

Key Considerations

- 1. Be direct and precise:**
 - a. Lead with the headline
 - b. State your request from the onset and provide the diagnosis history for the treatment of Primary Biliary Cholangitis (PBC) and the relevant disease state up front
 - c. If other diagnostic histories are contributing factors, list those in appropriate sections of the letter
- 2. Make it organized and explain why you disagree with the denial:**
 - a. Explain the medical criteria used to make the decision to treat
 - b. If the criteria doesn't match the criteria required in the health plan's medical coverage policy, explain why the decision was made to treat the patient with the requested product
 - c. As the treating healthcare provider, this is an opportunity to educate
- 3. Support your request with evidence:**
 - a. Include documentation of the patient's treatment history and illness
 - b. Include all appropriate information to support treatment
 - c. Include prior therapies and treatment outcomes
 - d. Include test results and diagnostic studies to support the appropriateness of the prescribed therapy and attach all test results as enclosures
 - e. Your letter may be better understood with copies of peer-reviewed literature and/or copies of clinical trial outcomes
- 4. Exercise independent clinical judgment and provide accurate information:** Accurate completion of applicable documentation is the responsibility of the provider and the patient. The healthcare provider should exercise independent clinical judgment at all times

Note: Keep a copy of all information you submit.

This sample letter is for general information purposes only and is not intended, and does not constitute, legal reimbursement, business, clinical or other advice. Use of this template or the information in this template does not guarantee reimbursement for coverage. Coverage and reimbursement may vary significantly by payer plan, patient, and other factors. The information provided is not intended to be a substitute for or to influence the independent clinical decision of the prescribing healthcare professional. Responsibility for ensuring the accuracy of information included in any communication between the healthcare provider and the payer remains solely with the healthcare provider.

SAMPLE

This letter is only intended as a TEMPLATE Letter of Medical Necessity or Appeal for LIVDELZI® (seladelpar) with comorbidities and may be used or referred to at the discretion of the healthcare provider.

INSTRUCTIONS: MUST BE ON HEALTHCARE PROVIDER'S LETTERHEAD AND MUST BE COMPLETED AND SUBMITTED BY THE HEALTHCARE PROVIDER WHEN USED.

Date: [Insert Date]

MD Name

Title

Organization

Address

City, State ZIP Code

Phone Number

Email Address

Medical Director / Appeals Department

Insurance Company Name

Address

City, State ZIP Code

Re: Appeal for Coverage – [Patient Name], DOB: [MM/DD/YYYY], Member ID: [Insurance ID]

Dear Medical Director / Appeals Reviewer,

I am writing to formally appeal the denial of coverage for **LIVDELZI® 10mg** for my patient, [Patient Name], who has been diagnosed with Primary Biliary Cholangitis (PBC). I have reviewed your denial letter and understand that coverage was denied based on **[insert denial reason]**.

[Indicate whether based on the patient's medical history, current condition, and your clinical experience in treating individuals with PBC and related comorbidities and/or concurrent therapies, whether you believe that Livdelzi (seladelpar) is both appropriate and medically necessary for this patient's ongoing management.]

PBC is a chronic, progressive autoimmune liver disease that, if not properly treated, can result in cirrhosis, hepatic decompensation, and liver failure.

Concurrent Therapy Considerations (as applicable):

[Include clinical rationale supporting the use of Livdelzi in this case, including prior or concurrent therapies, response to previous treatments, and relevant safety considerations].

[Describe whether the patient has demonstrated clinical stability on current treatment for his/her prescribed **(name of additional medication)**]. [As applicable, consider providing support for clinical stability (eg, results of liver function tests)].

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[Discuss rationale for why **Livdelzi 10mg** is medically necessary for the treatment of PBC given the patient's risk profile].

Comorbidity Considerations (as applicable):

In addition to PBC, this patient has been diagnosed with [insert comorbidity]. [Indicate whether this comorbidity may further impact liver function and overall disease management].

[Indicate whether, given this patient's clinical profile, disease trajectory, and response to prior therapy, Livdelzi 10 mg represents the most appropriate next step in their treatment plan.] [If applicable, explain whether denying access to treatment poses a risk to the patient]

I respectfully request that you reconsider your decision and approve coverage for Livdelzi 10mg, which is [indicate whether supported by the patient's clinical history and/or evidence-based medicine]. [Indicate whether denial of access to this therapy may place the patient at increased risk for disease progression and hepatic complications].

Please find attached supporting documentation, including clinical notes, laboratory results, and relevant literature for your review.

Thank you for your time and consideration. Should you require any additional information, I am available to discuss this case further.

Sincerely,

MD Full Name

MD Credentials

MD Contact Information

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