

SAMPLE LETTER OF MEDICAL NECESSITY

Preparing an effective Letter of Medical Necessity

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 **HEPCLUDEX®**
- 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 chronic HDV 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 as, 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/Medical Exception request for HEPCLUDEX® 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.

[Healthcare Provider's Letter Head]

[Insert Date]

[Medical Director]

[Insurance Company Name]

[Insurance Company Address]

[City, State ZIP]

- RE: [Letter of Medical Necessity or Medical Exception] request for HEPCLUDEX® (bulevirtide-gmod)

Patient Name: [Insert Name]

Date of Birth: [Insert DOB]

Subscriber ID Number: [Insert]

Subscriber Group Number: [Insert]

Dear [Medical Director's Name/Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to [request a medical exception/prior authorization of/document the medical necessity for] HEPCLUDEX® to treat my patient's diagnosed chronic HDV. This letter serves to document my patient's medical history and diagnosis, and to provide evidence for my treatment rationale/recommendation.

HEPCLUDEX® is FDA approved for the treatment of chronic HDV infection in adults without cirrhosis or with compensated cirrhosis. It is my medical opinion that HEPCLUDEX® is the appropriate treatment option for [Patient Name] because [insert reason why appropriate].

Summary of Patient's Medical History and Diagnosis

[Patient's Name] is [Age] years old and was initially diagnosed with [Diagnosis] [ICD-10] on [Date]. [Patient Name] has been under my care since [Date].

[Provide details on the patient's medical history, current symptoms and condition, current medications (if any) for diagnosis, previously used medications and contraindications, any relevant laboratory test results, highlight the factors leading you to recommend use of the product].

In summary, HEPCLUDEX® is medically necessary and reasonable to treat my patient's chronic HDV. Please consider coverage of HEPCLUDEX® based on the included supporting medical documentation and medical history of my patient.

Should you have any questions or require further details, please do not hesitate to call me at [Physician Phone Number].

Thank you for your attention to this matter.

Sincerely,

[Prescribing Physician Name and Credentials]

[Contact Details]

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Enclosures: [List of any enclosure ie: medical notes, Prescribing Information, Denial Letter]

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