

SAMPLE LETTER OF MEDICAL NECESSITY

Some payers may require that the prescriber documents a patient's medical necessity for treatment to get insurance coverage for a pharmaceutical product. The following SAMPLE Letter of Medical Necessity is only intended as a resource outlining the information a payer may request. It is not intended to influence medical decisions for any individual patient. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of this letter does not guarantee coverage for the product.

The prescriber should refer to the Important Safety Information in the full Prescribing Information when determining whether the product is medically appropriate for a patient. The prescriber is responsible for the content of this Letter and should customize all bracketed information in blue with the appropriate payer, office, and patient information.

SAMPLE Letter of Medical Necessity

[Physician's Letterhead]

[Date]

[Name of Pharmacy Director/Payer Contact]

[Contact Title]

[Name of Health Insurance Company]

[Address]

[City, State, ZIP Code]

RE: Coverage for [IMKELDI (imatinib) oral solution]

Patient: [Patient Name]

Date of Birth: [Date]

Diagnosis: [Diagnosis], [ICD-10-CM]

Group/Policy Number: [Number]

Policyholder: [Policyholder Name]

Dear [Pharmacy Director/Payer Contact Name]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity to treat their [Diagnosis] with [IMKELDI]. [Plan Name] has concluded that [Patient Name] plan does not currently cover [IMKELDI]. However, it is my professional opinion as a [Prescriber Specialty] that it is medically necessary for [him/her].

This letter serves to document my patient's medical history and diagnosis and to summarize my treatment rationale. Please review my clinical rationale and the attached [List any Enclosures] to assist with your coverage decision.

Summary of Patient's Medical History and Diagnosis

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

[Provide a discussion of the patient's clinical history, current symptoms and condition, any potential contraindications, and any relevant laboratory test results, highlighting the factors leading you to recommend use of the product]

Rationale for Treatment

[Include your clinical rationale and reasons for prescribing the product]

In summary, based upon the clinical rationale included [IMKELDI] is medically necessary and reasonable to treat [Patient Name's] [Diagnosis], and I am requesting your approval of [IMKELDI] as an appropriate

and medically necessary drug for [Patient Name's] specific case. Please refer to the enclosed supporting documents for further details, and do not hesitate to call me at [Phone Number] if you have any questions or if you require additional information.

Thank you for your attention to this matter.

Sincerely,

[Prescribing Physician Name and Credentials]

[NPI Number]

Enclosures: [List any Enclosures, such as: Prescribing Information, Medication Guide, and Clinical Notes and Records]