Instructions:

This sample letter of medical necessity is offered as an example that healthcare providers can refer to when a prior authorization for RYTELO™ (imetelstat) is denied. The patient's insurance provider may require that you include certain documents with your letter of medical necessity, such as insurance plan forms, the full Prescribing Information, the FDA approval letter, and clinical trial information.

When determining if treatment with RYTELO is medically appropriate for a patient, please refer to the full <u>Prescribing Information</u>, including <u>Medication Guide</u>.

Use of this sample letter of medical necessity does not guarantee coverage and reimbursement for RYTELO, and this sample letter does not substitute for the independent medical judgment of the treating physician. Text shown below is provided only as an example of the type of information that you may independently determine including in a letter of medical necessity.

Sample	Letter of Medical Necessity
Date:	
Insurance Plan:	
Address:	
City, State, ZIP Code:	
Phone and Fax Number:	_
Re: Coverage of RYTELO™ (imetelstat)	
Patient Name:	
Patient Date of Birth:	
Policy Number:	
Group Number:	
Relationship to Policyholder:	
To whom it may concern:	
I am writing on behalf of my patient,	, to provide information supporting the medical necessity of
RYTELO™ (imetelstat). In this letter, I am providing my par	tient's medical history, diagnosis, prior treatments and medications, and a
clinically based treatment rationale.	

Patient History and Diagnosis

- Consider providing a brief description of the patient's medical condition here, including background on the patient's diagnosis based on clinical diagnostic tests.
- Consider summarizing the patient's clinical status and providing evidence of any diagnostic tests. Consider including a short summary of the patient's medical history and previous treatment regimens, including duration of use and reason for discontinuation.
- Consider providing clinical justification supporting the choice of RYTELO treatment for the patient, citing any relevant literature, and stating any patient-specific reasons for treatment choice.
- Consider describing the potential consequences to the patient if they do not receive RYTELO and providing a medical
 evaluation of potential disease progression if the patient does not receive treatment.
- Consider reviewing the specific insurance plan's medical policy criteria and pointing out the criteria that your patient meets.

 Consider providing clinical rationale on why your patient should be excluded from any criteria they do not meet.
- If applicable, consider obtaining and attaching supporting letters from any other specialist(s) currently providing or previously providing care to the patient.
- Consider supplying clinical trials for RYTELO.
- Consider including the letter of approval from the FDA.
- Consider including the RYTELO indication information.
- Consider including the RYTELO administration information.

To conclude, RYTELO™ (imetelstat) is medically necessary for this patient's medical condition. Please contact me if any additional
information is required to ensure the prompt approval of RYTELO.

Sincerely,		

Consider including the list of references utilized in the letter.

Consider listing supporting documentation/literature.

Attachments

Consider including RYTELO full Prescribing Information and Medication Guide.

Consider including the letter of approval for RYTELO from the FDA.

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