

This template is offered as a sample resource for licensed Healthcare Providers when responding to a request from a patient's insurance company to provide an appeal letter.

Attachments to be included with the sample letter of appeal are the original prior authorization submission, copy of denial or explanation of benefits, and any other additional supporting documents.

If you need additional assistance, please contact Chiesi CareDirect® via phone at 888-865-1222 between 9 am and 6 pm EST or via email at chiesicaredirect@caremetx.com.

Use of this sample letter does not guarantee that the insurance company will provide coverage for Chiesi USA, Inc. medications, and is not intended to be a substitute for, or influence, the independent medical judgment of the Healthcare Provider.

SAMPLE LETTER OF APPEAL

(Printed on Healthcare Provider Letterhead)

Date: [Date]

Attn: Appeals Department

Payer Name: [Payer Name]

Payer Address: [Payer Address]

City, State, ZIP Code: [City, State, ZIP Code]

Payer Phone and Fax Number: [Payer Phone and Fax Number]

Re: Request to Appeal Insurance Denial

Patient Name: [Patient Name]

Patient Date of Birth: [Patient Date of Birth]

Member ID: [Policy Number]

Group Number: [Group Number]

Dear [Name of the Contact Person at the Insurance Company OR Appeals Department]:

I am writing on behalf of my patient, [Name of Patient], to appeal [Name of Health Insurance Company]'s decision to deny coverage for PERTZYE® (pancrelipase) which is prescribed for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis. It is my understanding based on your letter of denial dated, [Date], that coverage has been denied for the following reason(s), [List the Specific Reason(s) for the Denial as Stated in the Denial Letter.]

Patient History and Diagnosis

[Provide a Brief Description of the Patient's Medical Condition Here]

[Include a Short Summary of the Patient's Medical History]

[Explain why you believe it is Medically Necessary for Patient to receive this Medicine. Examples of clinical information to include are as follows and are included at the discretion of the Healthcare Provider:

- Diagnosis and date
- Laboratory results and date
- Previous and current treatments/therapies]

[Describe the Potential Consequences of the Patient if they do not receive this medicine]

Summary

In summary, I am requesting [an appeal/redetermination/reconsideration] of the denial of PERTZYE® (pancrelipase) for [patient name]. I am requesting that you reconsider coverage based on the information provided above. I am available at my office phone [phone number] to address any questions or concerns regarding this appeal. Thank you in advance for your immediate attention to this written appeal.

Sincerely,

[Physician Signature]

[Physician's Name]

[Physician's Practice Name]

Enclosures

[Include Indication and Important Safety Information]

[Include full Prescribing Information, including Patient Information]

Additional References (To be added at the discretion of the Healthcare Provider)

[Include PERTZYE® (pancrelipase) Prescribing Information]

[Include other relevant references and publications regarding PERTZYE]

[Copy of patient denial letter]

[Clinical progress notes]

[Patient's lab results]

[Documentation of Hospitalization/Emergency room visits and/or unscheduled office visits]

[List of sample medications provided including, dosages, dates used, and if samples were given]

Indication

PERTZYE® (pancrelipase) is indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.

Important Safety Information

Fibrosing colonopathy is associated with high-dose use of pancreatic enzyme replacement. Exercise caution when doses of PERTZYE exceed 2,500 lipase units/kg body weight per meal (or greater than 10,000 lipase units/kg body weight per day).

To avoid irritation of oral mucosa, do not chew PERTZYE or retain in the mouth.

Hyperuricemia may develop. Consider monitoring uric acid levels in patients with hyperuricemia, gout, or renal impairment.

There is theoretical risk of viral transmission with all pancreatic enzyme products including PERTZYE.

Exercise caution when administering pancrelipase to a patient with a known allergy to proteins of porcine origin.

Most common adverse reactions (> 10%) are: diarrhea, dyspepsia, and cough.

Please see [Full Prescribing Information](#).

PP-P-0277 V1.0

Chiesi CareDirect® is a registered trademark of Chiesi Farmaceutici, S.p.A

PERTZYE® is a registered trademark of Digestive Care, Inc.

PERTZYE® (pancrelipase) Delayed-Release Capsules are manufactured in the USA by Digestive Care, Inc.

© 2021 Chiesi USA, Inc.