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 BRONCHITOL® (mannitol) inhalation powder which is prescribed as maintenance therapy for 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 BRONCHITOL® (mannitol) inhalation powder 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 BRONCHITOL Prescribing Information]
[Include other relevant references and publications regarding BRONCHITOL]
[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

BRONCHITOL (mannitol) inhalation powder is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis. Use BRONCHITOL only in adults who have passed the BRONCHITOL Tolerance Test.

Important Safety Information

BRONCHITOL is contraindicated in patients with hypersensitivity to mannitol or to any of the capsule components. BRONCHITOL is contraindicated in patients who fail to pass the BRONCHITOL Tolerance Test (BTT).

BRONCHITOL can cause bronchospasm, which can be severe in susceptible patients. Because of the risk of bronchospasm, prior to prescribing BRONCHITOL, patients must pass the BRONCHITOL Tolerance Test (BTT). The BTT must be administered under the supervision of a healthcare practitioner who can treat severe bronchospasm.

Patients who pass the BRONCHITOL tolerance test (BTT) may experience bronchospasm with add-on maintenance therapy with BRONCHITOL. Patients should premedicate with an inhaled short-acting bronchodilator prior to each administration of BRONCHITOL. If bronchospasm occurs, immediately discontinue BRONCHITOL and treat bronchospasm with an inhaled short-acting bronchodilator.

Hemoptysis can occur with BRONCHITOL use. Monitor patients with history of episodes of hemoptysis. If hemoptysis occurs, discontinue use of BRONCHITOL.

Most common adverse reactions (≥3%) include cough, hemoptysis, oropharyngeal pain, vomiting, bacteria sputum identified, pyrexia, and arthralgia.

Please see **Full Prescribing Information.**