

Clinical Pharmacy Program Guidelines for Pulmozyme

Program	Prior Authorization
Medication	Pulmozyme® (dornase alfa)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York CHIP, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	2/2021
Effective Date	4/2021

1. Background:

Pulmozyme (dornase alfa) is indicated for daily administration in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function. In CF patients with an FVC \geq 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. Pulmozyme will be approved based on the following criteria:</p> <p style="padding-left: 20px;">a. Diagnosis of cystic fibrosis</p> <p>Authorization of therapy will be issued for 12 months.</p>
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3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; January 2018.

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Change Control	
Date	Change
3/2014	New criteria
12/2015	Annual Review, no change
11/2016	Updated background, added reauthorization criteria to align with Employer and Individual's notification policy, updated policy template
2/2017	Annual review with no changes to coverage criteria.
9/2017	Removed requirement for use in conjunction with other CF therapies and reauthorization criteria to allow for Dx to Rx implementation
2/2018	Annual review. No changes to criteria.
2/2019	Annual review. Minor updates to background. Updated references.
2/2020	Annual review. No changes to criteria.
2/2021	Annual review. No changes to coverage criteria.