

Generic Name: Dornase alfa

Preferred: N/A

Therapeutic Class or Brand Name: Pulmozyme

Non-preferred: N/A

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 2/1/2013

GPI Code: 4530402000

Date Last Reviewed / Revised: 5/30/2019

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of Cystic Fibrosis.
- II. The prescriber is a Pulmonologist or a physician with expertise in the care of patients with Cystic Fibrosis.
- III. For a request for twice daily (BID) Pulmozyme, documentation must be submitted of an adequate trial of once daily (QD) dosing.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- The recommended dose for use in most cystic fibrosis patients is one 2.5 mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- One 30 unit carton per 30 days (unless BID dosing is approved, then two 30 unit cartons per 30 days).

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity showing maintenance or improvement on medication.

APPENDIX

N/A

REFERENCES

1. Cystic Fibrosis Foundation. Chronic Medications to Maintain Lung Health Clinical Care Guidelines. Available at: <https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/Chronic-Medications-to-Maintain-Lung-Health-Clinical-Care-Guidelines/>
2. Medi-Span.
3. Pulmozyme® [Package insert] South San Francisco, CA: Genentech, Inc.; January 2018. Available at: http://www.gene.com/download/pdf/pulmozyme_prescribing.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
5/30/2019	1. Removed outdated references. Added "https://www.cff.org/Care/Clinical-Care-Guidelines/Respiratory-Clinical-Care-Guidelines/Chronic-Medications-to-Maintain-Lung-Health-Clinical-Care-Guidelines/" under References .
9/25/2018	1. Policy reviewed: No changes made.
12/7/2017	1. Removed "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7289.pdf" from References (link no longer valid).
9/26/2016	1. Policy reviewed: no changes made.
4/7/2015	1. Updated "https://www.mdwise.org/docs/providerpharmacy/specialtydrugs/CysticFibrosisPA.pdf" to "http://www.mdwise.org/MediaLibraries/MDwise/Files/For%20Providers/Tools%20and%20Resources/Pharmacy%20Resources/Specialty%20Drug/CysticFibrosisPA.pdf" under References .
2/13/2014	1. Adapted policy to new format. 2. Added GPI Code. 3. Updated references to include Medi-Span.