MEDICATION POLICY:
Pulmozyme (dornase alfa)

Applicable Drugs: Pulmozyme (dornase alfa)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/21/2025

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of Cystic Fibrosis.

II. Pulmozyme will be used concurrently with standard therapies for cystic fibrosis (eg, antimicrobials, bronchodilators, chest physiotherapy, other mucolytics).

III. Treatment must be prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- For requests with twice-daily dosing, there must be documented treatment failure on once-daily dosing and age must be $\geq$ 21 years

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Once-daily dosing: One 30-unit carton per 30 days
- Twice-daily dosing: Two 30-unit cartons per 30 days

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** 12 months: An updated letter of medical necessity showing maintenance or improvement on medication.

APPENDIX

- N/A

REFERENCES

1. Pulmozyme. Prescribing information. Genentech Inc; 2024. Accessed May 21, 2025. http://www.gene.com/download/pdf/pulmozyme_prescribing.pdf.
2. Mogayzel PJ Jr, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. *Am J Respir Crit Care Med*. 2013;187(7):680-689. doi:10.1164/rccm.201207-1160oe

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.