Reference number(s)
1886-A

Specialty Guideline Management Pulmozyme

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Pulmozyme	dornase alfa

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

Pulmozyme is indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with an FVC ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

All other indications are considered experimental/investigational and are not medically necessary.

Coverage Criteria

Cystic Fibrosis[1-3]

Authorization of 12 months may be granted for treatment of cystic fibrosis when Pulmozyme will be used

in conjunction with standard therapies for cystic fibrosis.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. chronic medications for maintenance of lung health. *Am J Respir Crit Care Med.* 2013;187:680-689.doi: 10.1164/rccm.201207-1160oe
3. Cohen-Cymberknoh M, Shoseyov D, Kerem E. Managing cystic fibrosis: strategies that increase life expectancy and improve quality of life. *Am J Respir Crit Care Med*. 2011;183:1463-1471. doi: 10.1164/rccm.201009-1478CI