AFTNA BE	TTER HEALTH®		* ae	etna [®]		
Coverage Policy/Guideline						
Name:	Pulmozyme		Page:	1 of 2		
Effective Date: 8/17/2023			Last Review Date:	6/2/2023		
Applica	□Illinois	□Florida	□Florida Kids			
Applies to:	⊠New Jersey	⊠Maryland	□Michigan			
	⊠Pennsylvania Kids	⊠Virginia	□Arizona			

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Pulmozyme under the patient's prescription drug benefit.

Description:

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

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.

Applicable Drug List:

Pulmozyme

Policy/Guideline:

Criteria for Initial Approval:

Cystic Fibrosis

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 criteria for initial approval who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

Approval Duration and Quantity Restrictions:

Approval: 12 months

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Quantity Level Limit:

Pulmozyme: 150 mL per 30 days (60 ampules per 30 days)

References:

- 1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.
- 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.
- 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.