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PHARMACY POLICY STATEMENT Kentucky Medicaid		
DRUG NAME	Pulmozyme (dornase alfa inhalation solution)	
BILLING CODE	Must use valid NDC code	
BENEFIT TYPE	Pharmacy	
SITE OF SERVICE ALLOWED	Home	
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product)	
	QUANTITY LIMIT – 75 per 30 days	
LIST OF DIAGNOSES CONSIDERED NOT	Click Here	
MEDICALLY NECESSARY		

Pulmozyme (dornase alfa inhalation solution) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For initial authorization:

- 1. Member must be 5 years of age or older; AND
- 2. Medication must be prescribed by a pulmonologist or an infectious disease specialist; AND
- 3. Member has forced vital capacity (FVC) predicted > 40% documented in chart note.
- 4. **Dosage allowed:** 2.5 mg daily through selected jet nebulizers in conjunction with a Pulmo-Aide, Pari-Proneb, Mobilaire, Porta-Neb compressor system, or eRapid Nebulizer System. Some patients may benefit from twice daily administration.

If member meets all the requirements listed above, the medication will be approved for 12 months. For <u>reauthorization</u>:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Pulmozyme (dornase alfa inhalation solution) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Atelectasis
- Parapneumonic pleural effusions and empyemas (adults)

DATE	ACTION/DESCRIPTION
05/25/2017	New policy for Pulmozyme created. Not covered diagnosis added.

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- National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. [cited 2016 Dec 19]. Available: https://www.guideline.gov. Accesses February 9, 2017.
- 2. Pulmozyme [package insert]. South San Francisco, CA: Genentech Inc; 2014. Accessed March 10, 2017.
- 3. Pulmozyme. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed March 10, 2017.
- 4. Pulmozime. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 10, 2017.

Effective date: 08/09/2017 Revised date: 05/25/2017