UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Pulmozyme

Program	Prior Authorization
Medication	Pulmozyme® (dornase alfa)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island, Washington, New Jersey, Louisiana
Issue Date	3/2014
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

1. Background:

In cystic fibrosis (CF) patients, retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and to exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by degenerating leukocytes that accumulate in response to infection. Pulmozyme (dornase alfa) is a recombinant human deoxyribonuclease I (rhDNase) enzyme indicated. In conjunction with standard therapies, forthe management of cystic fibrosis patients to improve pulmonary function.[1,2] In patients with an FVC $\geq$ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. <u>Authorization</u>

1. **Pulmozyme** will be approved based on the following criteria:

   a. Diagnosis of cystic fibrosis

Authorization of therapy will be issued for 12 months.

3. References:

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; December 2014.
2. Fuchs HJ, Borowitz DS, et al. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in patients with cystic fibrosis. N Engl J Med 1994;331:637–42.
3. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Topic 6372, Version 32.0. Mallory GB and Hoppin AG, Eds. UpToDate, 2014.

Program	Prior Authorization - Pulmozyme® (dornase alfa)
Change Control	
Date	Change
3/2014	New criteria
12/2015	Annual Review, no change
11/2016	Updated background, added reauthorization criteria to align with Employer and Individual's notification policy, updated policy template
2/2017	Annual review with no changes to coverage criteria.
9/2017	Removed requirement for use in conjunction with other CF therapies and reauthorization criteria to allow for Dx to Rx implementation
2/2018	Annual review. No changes to criteria.