dornase alfa (Pulmozyme®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO104

Description

Dornase alfa (Pulmozyme®) inhalation solution is highly purified solution of recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. In vitro, dornase alfa (Pulmozyme) hydrolyzes the DNA in sputum of cystic fibrosis (CF) patients and reduces sputum viscoelasticity.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
dornase alfa (Pulmozyme)	2.5 mg/2.5 mL single-use ampule	Cystic fibrosis	30 single-use ampule/ 30 days

Initial Evaluation

I. Dornase alfa (Pulmozyme) may be considered medically necessary when the following criteria below are met:
   A. Medication is prescribed by or in consultation with a pulmonologist; **AND**
   B. A diagnosis of **cystic fibrosis (CF); AND**
   C. Medication will be used in conjunction with standard CF therapy [e.g. tobramycin (Bethkis®; Kitabis Pak®; Tobi®; Tobi Podhaler®), azithromycin (Zithromax®), aztreonam (Cayston®), ivacaftor (Kalydeco®), lumacaftor/ivacaftor (Orkambi®), inhaled or oral N-acetylcysteine (Acetadote®, Acys-5®, Mucomyst®, Cetylev®)]

II. Dornase alfa (Pulmozyme) is considered investigational when used for all other conditions.

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent; **AND**

II. Member has exhibited improvement or stability of disease symptoms.

Supporting Evidence

I. Dornase alfa (Pulmozyme) has been evaluated in a randomized, placebo-controlled trial of clinically stable CF patients, five years of age and older and receiving standard therapies for CF. Patients were treated with placebo, 2.5 mg of dornase alfa (Pulmozyme) once a day, or 2.5 mg of dornase alfa (Pulmozyme) twice a day for six months.

II. Administration of dornase alfa (Pulmozyme) reduced the risk of all exacerbations of respiratory symptoms requiring parenteral antibiotic therapy and developing any respiratory tract infection by 27% and 29% for the 2.5 mg daily dose and the 2.5 mg twice daily dose. Data suggests that the effects on respiratory tract infections in older patients (> 21 years) may be lower than in younger patients, and that twice daily dosing may be required in the older patients.

III. While clinical trial data is limited in pediatric patients younger than five years of age, the use of dornase alfa (Pulmozyme) should be considered for pediatric CF patients who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

IV. Dornase alfa (Pulmozyme) is used in treatment of CF; however, due to the complexity of the disease it should be prescribed by, or in consultation with, a pulmonologist experienced in the treatment of CF.

V. Several methods of newborn screening may be implemented to detect potential CF, such as the immunoreactivity trypsinogen test (IRT), double IRT testing, and pancreatitis-associated protein testing. A positive or equivocal screening test should be followed by CFTR genetic testing and the sweat chloride test.

VI. Dornase alfa (Pulmozyme) is indicated as an adjunct to standard CF therapies [e.g. tobramycin (Bethkis; Kitabis Pak; Tobi; Tobi Podhaler), azithromycin (Zithromax), aztreonam (Cayston), ivacaftor (Kalydeco), lumacaftor/ivacaftor (Orkambi), inhaled or oral N-acetylcysteine (Acetadote, Acys-5, Mucomyst, Cetylev), ipratropium Bromide (Atrovent HFA)].

VII. The recommended dosage is one 2.5 mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration. Maximum dose upon clinical review is 60 single-use ampule per 30 days.

Investigational or Not Medically Necessary Uses

There is limited or no evidence to support the use of dornase alfa (Pulmozyme) in conditions other than CF.

References

1. Pulmozyme [package insert]. Genetech, Inc. South San Francisco, CA. December 2014.

2. DeSimone, E. (2018, May 18). Cystic Fibrosis: Update on Treatment Guidelines and New Recommendations. Retrieved from https://www.uspharmacist.com/article/cystic-fibrosis-update-on-treatment-guidelines-and-new-recommendations
3. Fuchs, H. J., Borowitz, D. S., Christiansen, D. H., Morris, E. M., Nash, M. L., Ramsey, B. W., Wohl, M. E. (1994). Effect of Aerosolized Recombinant Human DNase on Exacerbations of Respiratory Symptoms and on Pulmonary Function in Patients with Cystic Fibrosis. New England Journal of Medicine, 331(10), 637–642. doi: 0.1056/nejm199409083311003
4. Mccoy, K., Hamilton, S., & Johnson, C. (1996). Effects of 12-Week Administration of Dornase Alfa in Patients with Advanced Cystic Fibrosis Lung Disease. Chest, 110(4), 889–895. doi: 10.1378/chest.110.4.889

Policy Implementation/Update:

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Last Reviewed	11/15/2019

Action and Summary of Changes	Date
Updated criteria to policy format	11/2019