PRIOR AUTHORIZATION POLICY

POLICY: Cystic Fibrosis – Pulmozyme Prior Authorization Policy
- Pulmozyme® (dornase alfa inhalation solution – Genentech/Roche)

REVIEW DATE: 05/04/2022; selected revision 06/22/2022

OVERVIEW

Pulmozyme, a recombinant human deoxyribonuclease I, is indicated in conjunction with standard therapies for the management of patients with **cystic fibrosis** to improve pulmonary function.[1]

Guidelines

According to Patient Registry data compiled by the Cystic Fibrosis Foundation (2020), Pulmozyme is used by the vast majority of patients with cystic fibrosis.[2] Guidelines from the Cystic Fibrosis Foundation (2007, updated in 2013) address the chronic use of medications for management of lung health in cystic fibrosis patients 6 years of age and older.[3,4] These guidelines recommend Pulmozyme use for cystic fibrosis patients regardless of disease severity to improve lung function and reduce exacerbations. Separate guidelines have addressed Pulmozyme use in younger patients.[5,6] Although efficacy data are lacking in patients under 5 years of age, safety and tolerability have been established in patients as young as 3 months.[1,6] Cystic Fibrosis Foundation guidelines for infants under 2 years of age (2009) and children between 2 and 5 years of age (2016) support Pulmozyme use in these populations based on individual circumstances.[5,6]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pulmozyme. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pulmozyme, approval requires Pulmozyme to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 1 year unless otherwise noted below.

Automation: None

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pulmozyme is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Cystic Fibrosis.** Approve for 1 years if Pulmozyme is prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pulmozyme is not recommended in the following situations:

1. **Asthma.** Mucus hypersecretion may be mediated by a variety of causes, including inflammation, irritation, stimulation, or mucus-producing tumors.[7] However, efficacy of Pulmozyme is not established for conditions other than cystic fibrosis. In a pilot study of patients with severe acute asthma (n = 50), there was no significant difference in forced expiratory volume in 1 second (FEV_1) with Pulmozyme use vs. placebo.[8]

2. **Bronchiectasis, Idiopathic.** A multicenter, double-blind, randomized, placebo-controlled 24-week trial (n = 349) examined the effect of Pulmozyme vs. placebo on patients with idiopathic bronchiectasis (i.e., bronchiectasis not related to cystic fibrosis).[9] Patients in the Pulmozyme arm experienced worsened lung function and more frequent pulmonary exacerbations vs. placebo. The authors concluded that Pulmozyme should not be used in this population.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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