Pulmozyme

Description

Pulmozyme (dornase alfa)

Background
Cystic fibrosis is caused by defects in the cystic fibrosis gene, which codes for a protein transmembrane conductance regulator (CFTR) that functions as a chloride channel and is regulated by cyclic adenosine monophosphate (cAMP). Mutations in the CFTR gene result in abnormalities of cAMP-regulated chloride transport across epithelial cells on mucosal surfaces (1).

Six classes of defects resulting from CFTR mutations have been described with an autosomal recessive inheritance pattern. Most mutation carriers are asymptomatic and there is some variability in clinical phenotype in persons homozygous for the different mutations (1).

Dornase alfa is a highly purified solution of recombinant human deoxyribonuclease I (rhDNase), an enzyme which selectively cleaves DNA. The enzyme hydrolyzes the DNA present in sputum/mucus of patients with cystic fibrosis and reduces viscosity, thereby improving clearance of secretions (2).

Regulatory Status
FDA-approved indication: Daily administration of Pulmozyme (dornase alfa) Inhalation Solution in conjunction with standard therapies is indicated in the management of cystic fibrosis patients to improve pulmonary function. In 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 (2).

**Related policies**
Kalydeco, Orkambi

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Pulmozyme may be considered **medically necessary** for the treatment of cystic fibrosis. Pulmozyme may be considered **investigational** for any diagnosis other than cystic fibrosis.

**Prior-Approval Requirements**

**Diagnosis**
Patient must have the following:

1. Cystic Fibrosis

**Prior – Approval Renewal Requirements**
Same as above

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Duration** 12 months

**Prior – Approval Renewal Limits**

**Duration** 12 months

**Rationale**

**Summary**
Daily administration of Pulmozyme (dornase alfa) Inhalation Solution in conjunction with standard therapies is indicated in the management of cystic fibrosis patients to improve
pulmonary function. 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 (2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Pulmozyme (dornase alfa) while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>September 2011</td>
<td>Criteria modified to delete requirement for FVC &gt;40%, based on manufacturer’s package labeling: &quot;Pulmozyme (dornase alfa) Inhalation Solution has also been evaluated in a second randomized, placebo-controlled study in clinically stable patients with baseline FVC &lt;40% of predicted. Pulmozyme did not significantly reduce the risk of developing a respiratory tract infection requiring parenteral antibiotics.</td>
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<tr>
<td>September 2012</td>
<td>Annual editorial and reference update</td>
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<tr>
<td>March 2013</td>
<td>Annual editorial review</td>
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<tr>
<td>March 2014</td>
<td>Annual review</td>
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<tr>
<td>March 2015</td>
<td>Annual criteria review and reference update</td>
</tr>
<tr>
<td>December 2015</td>
<td>Annual editorial review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 3, 2015 and is effective on January 1, 2016.

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