RXADVANCE
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| **Clinical Policy Title:** | dornase alfa |
| **Policy Number:** | RxA.451 |
| **Drug(s) Applied:** | Pulmozyme® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 09/14/2020 |
| **Line of Business Policy Applies to:** | All lines of Business |

## Background

Dornase alfa (Pulmozyme®) is a recombinant DNase enzyme. It is indicated in conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.

In CF patients with a forced vital capacity ≥ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Dornase Alfa (Pulmozyme®) | CF | One 2.5 mg ampule inhaled QD; some patients may benefit from BID administration | 5 mg/day |

## Dosage Forms

- Inhalation solution in single-use ampules: 2.5 mg/2.5 mL

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

**I. Initial Approval Criteria**

**A. Cystic Fibrosis** (must meet all)**:**

1. Diagnosis of CF;
2. The requested drug is used in conjunction with standard therapies for CF;
3. Dose does not exceed 5 mg per day (2 ampules per day).

**Approval Duration**
**Commercial:** 6 months
**Medicaid:** 6 months

**II. Continued Therapy Approval**

**A. Cystic Fibrosis** (must meet all)**:**

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. The requested drug is used in conjunction with standard therapies for CF;
4. If request is for a dose increase, new dose does not exceed 5 mg per day (2 ampules per day).

**Approval Duration**
**Commercial:** 6 months
**Medicaid:** 6 months

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**
CF: cystic fibrosis
FDA: Food and Drug Administration

**APPENDIX B: Therapeutic Alternatives**
- Not applicable

**APPENDIX C: Contraindications/Boxed Warnings**
- Contraindication(s):
  - known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product

- Boxed Warning(s):
  - None reported

**APPENDIX D: General Information**
- Dornase alfa is recommended for chronic use in both mild and moderate-to-severe disease per the American Thoracic Society 2013 CF guidelines.
- Severity of lung disease is defined by $FEV_1$ predicted as follows: normal, > 90% predicted; mildly impaired, 70-89% predicted; moderately impaired, 40-69% predicted; and severely impaired, < 40% predicted.

**References**
1. Pulmozyme Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2018. Available at https://www.pulmozyme.com. Accessed July 3, 2020.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. April 1, 2013; 187(7): 680-689.

| Review/Revision History | Review/Revised Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Policy title table was updated.<br>2. Line of Business Policy Applies to was update to all lines of business. | 07/03/2020 | 09/14/2020 |

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| 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."<br>4. Initial and Continued Approval<br>Duration was updated to specify Commercial and Medicaid.<br>5. References were updated.<br>6. Added “the requested drug is used in conjunction with standard therapies for CF” to the initial criteria and continued therapy criteria. | | |