DORNASE ALFA

This drug requires a written request for prior authorization.

GUIDELINES FOR USE

1. Does the patient have a diagnosis of cystic fibrosis?
   - If yes, continue to #2.
   - If no, do not approve.
   **DENIAL TEXT:** Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

2. Is the request for once daily dosing (30 ampules per month)?
   - If yes, **approve for 12 months with a quantity limit of #30 ampules per month.**
   - If no, continue to #3.

3. Has the patient tried once daily dosing (30 ampules per month per MRF or claims history)?
   - If yes, **approve for 12 months with a quantity limit of #60 ampules per month.**
   - If no, do not approve. **Enter a proactive authorization for 12 months with a quantity limit of #30 ampules per month.**
   **DENIAL TEXT:** Approval requires a diagnosis of cystic fibrosis and requests for twice daily dosing require a trial of once daily dosing.

RATIONALE
Promote appropriate utilization of Pulmozyme based on FDA approved indication.

Dosage: The recommended dose for use in most cystic fibrosis patients is one 2.5mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

FDA APPROVED INDICATION
Pulmozyme is indicated in conjunction with standard therapies in the management of cystic fibrosis patients to improve pulmonary function.

REFERENCE

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## DORNASE ALFA

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<th>Library</th>
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<tr>
<td>Yes</td>
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- Created: 05/12
- Effective: 01/01/16
- Client Approval: 11/15