

Pulmozyme® (dornase alfa)



When requesting Pulmozyme® (dornase alfa), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications

- Used in conjunction with standard therapies for the management of cystic fibrosis to improve pulmonary function¹
- In patients with cystic fibrosis and a forced vital capacity (FVC) $\geq$ 40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics¹

Approved Off-label Compendial uses²

- No off-label uses meet evidence standards

Coverage Guidelines

Cystic Fibrosis¹

- Diagnosis of cystic fibrosis¹ confirmed by appropriate diagnostic or genetic testing⁵
- The individual is receiving standard therapy for cystic fibrosis including any of the following (alone or in combination):^{1,3,4,6}
 - Beta₂-adrenergic receptor agonists
 - Corticosteroids
 - Ivacaftor (Kalydeco®)
 - Lumacaftor/Ivacaftor (Orkambi®)
 - Aerosolized antibiotics
 - Nonsteroidal anti-inflammatory drugs

Approval duration: 12 months

Additional Information for Prescribers

- None

References

1. Pulmozyme® prescribing information. South San Francisco, CA: Genentech, Inc: Revised December 2014. https://www.gene.com/download/pdf/pulmozyme_prescribing.pdf. Accessed January 28, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed January 28, 2017. <https://www.micromedexsolutions.com>.
3. 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*. 2013;187:680-689. <http://www.atsjournals.org/doi/abs/10.1164/rccm.201207-1160OE>. Accessed January 27, 2017.
4. Flume PA, Mogayzel PJ, Robinson KA, et al. Cystic Fibrosis Pulmonary Guidelines Treatment of Pulmonary Exacerbations. *Am J Respir Crit Care Med*; 2009;180:802-808. <https://www.cff.org/For-Caregivers/Clinical-Care-Guidelines/CF-Care-Guidelines-Pulmonary-Exacerbations.pdf>. Accessed January 27, 2017.
5. Farrell PM, Rosenstein BJ, White TB, et al. Guidelines for diagnosis of cystic fibrosis in newborns through older adults: Cystic Fibrosis Foundation consensus report. *J Pediatr*. 2008;153(2):S4.
6. Orkambi® prescribing information. Boston, MA: Vertex Pharmaceuticals, Inc: Revised July 2015. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206038Orig1s000lbl.pdf. Accessed April 3, 2017.