SPECIALTY GUIDELINE MANAGEMENT

PULMOZYME (dornase alfa)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Pulmozyme is indicated for daily administration in conjunction with standard therapies for the management of cystic fibrosis patients to improve pulmonary function.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. **Cystic Fibrosis**
Authorization of 24 months may be granted for treatment of cystic fibrosis when all of the following criteria are met:
1. Diagnosis was confirmed by appropriate diagnostic or genetic testing.
2. Pulmozyme will be used in conjunction with standard therapies for cystic fibrosis.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Pulmozyme [package insert]. South San Francisco, CA: Genentech, Inc.; December 2014.
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.* 2013;187:680-689.
3. Cohen-Cymberknoh M, Shoseyov D, Kerem E. Managing cystic fibrosis: strategies that increase life expectancy and improve quality of life. *Am J Respir Crit Care Med*. 2011;183:1463-1471.