SPECIALTY GUIDELINE MANAGEMENT

ESBRIET (pirfenidone)

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.

FDA-Approved Indication
Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis.

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

II. CRITERIA FOR INITIAL APPROVAL

Idiopathic Pulmonary Fibrosis (IPF)
Authorization of 24 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:

1. The member does not have a known etiology for interstitial lung disease such as sarcoidosis, scleroderma, polymyositis/dermatomyositis, systemic lupus erythematosus, bronchiolitis obliterans organizing pneumonia, or drug toxicity AND
2. The member has completed a high-resolution computed tomography (HRCT) study of the chest or surgical lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern, OR has completed an HRCT study of the chest which reveals a result consistent with the possible UIP pattern and the diagnosis is supported by surgical lung biopsy (SLB). If SLB has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

III. CONTINUATION OF THERAPY

Idiopathic Pulmonary Fibrosis (IPF)
All members (including new members) requesting authorization for continuation of therapy may be granted an authorization of 24 months when the member is currently receiving treatment with Esbriet, excluding when Esbriet is obtained as samples or via manufacturer's patient assistance programs.

IV. REFERENCES

1. Esbriet [package insert]. South San Francisco, CA: Genentech USA, Inc.; October 2017.
2. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med.* 2011;183:788-824.
3. Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis. An Update of the 2011 Clinical Practice Guideline. *Am J Respir Crit Care Med.* 2015;192:e3-e19.

4. Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with add-on pirfenidone in idiopathic pulmonary fibrosis: results of the Injourney trial. *Am J Respir Crit Care Med.* 2017 Sept 10. doi: 10.1164/rccm.201706-1301OC. [Epub ahead of print].