Reference number(s)
1881-A

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[1]
Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (where applicable):
A. Result of a chest high-resolution computed tomography (HRCT) study.
B. If a lung biopsy is conducted, submit the associated pathology report.

III. CRITERIA FOR INITIAL APPROVAL

Idiopathic Pulmonary Fibrosis (IPF)
Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:
A. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded AND
B. The member has completed a high-resolution computed tomography (HRCT) study of the chest or a 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 other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

IV. CONTINUATION OF THERAPY

Idiopathic Pulmonary Fibrosis (IPF)
All members (including new members) requesting authorization for continuation of therapy may be granted an authorization of 12 months when the member is currently receiving treatment with Esbriet, excluding when Esbriet is obtained as samples or via manufacturer's patient assistance programs.

V. OTHER

Note: If the member is a current smoker, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking cessation options.

VI. REFERENCES

1. Esbriet [package insert]. South San Francisco, CA: Genentech USA, Inc.; July 2019.
2. Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2018 Sep 1;198(5):e44-e68.
3. 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].