

Specialty Guideline Management

pirfenidone-Esbriet

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Esbriet	pirfenidone

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^{1,2}

Esbriet/pirfenidone is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Result of a chest high-resolution computed tomography (HRCT) study.
- Pathology report of lung biopsy (if performed).

Coverage Criteria

Idiopathic Pulmonary Fibrosis (IPF)¹⁻³

Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes both of the following:

- Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded.
- The member meets either of the following:
 - 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.
 - Member has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP, alternative diagnosis) 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.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy for an indication listed in the coverage criteria section may be granted an authorization of 12 months when the member is currently receiving treatment with the requested medication.

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.

References

1. Esbriet [package insert]. South San Francisco, CA: Genentech USA, Inc.; February 2023.
2. Pirfenidone [package insert] Berkeley Heights, NJ: Laurus Labs Limited; March 2023.
3. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults: An official ATS/ERS/JRS/ALAT clinical practice guideline. Am J Respir Crit Care Med. 2022;205(9):e18-e47.