

# 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<sup>1,2</sup>

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 for initial requests:

- Chart notes or medical record documentation of result of a chest high-resolution computed tomography (HRCT) study.
- Chart notes or medical record documentation of pathology report of lung biopsy (if performed).
- Chart notes or medical record documentation of pathology report of transbronchial lung cryobiopsy (if performed).

Reference number(s)
1881-A

## Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or a specialist in the treatment of idiopathic pulmonary fibrosis.

## Coverage Criteria

### Idiopathic Pulmonary Fibrosis (IPF)<sup>1-4</sup>

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, transbronchial lung cryobiopsy (TBLC), or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) or probable UIP pattern and the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.
  - Member has completed an HRCT study of the chest which reveals a result other than the UIP or probable UIP pattern (e.g. indeterminate for UIP) and meets both of the following:
    - The member had a lung biopsy or a TBLC with pathology confirming UIP or probable UIP.
    - 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 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.

Reference number(s)
1881-A

## References

1. Esbriet [package insert]. Scottsdale, AZ: Legacy Pharma USA, Inc.; June 2025.
2. Pirfenidone [package insert] Berkeley Heights, NJ: Laurus Labs Limited; March 2025.
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.
4. Korevaar DA, Colella S, Fally M et al. European Respiratory Society guidelines on transbronchial lung cryobiopsy in the diagnosis of interstitial lung diseases. *Eur Respir J.* 2022; 60: 1-17.