

# Esbriet (pirfenidone)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Esbriet (pirfenidone)	May be subject to quantity limit

## APPROVAL CRITERIA

Initial requests for Esbriet (pirfenidone) may be approved if the following criteria are met:

- I. Individual has a diagnosis of idiopathic pulmonary fibrosis as demonstrated by (Raghu 2022):
  - A. Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; **AND**
  - B. High resolution computed tomography (HRCT) with or without lung tissue sampling;

### **AND**

- II. Documentation is provided that individual has had pulmonary function tests within prior 60 days demonstrating forced vital capacity (% FVC) greater than or equal to 45%.

Continuation requests for Esbriet (pirfenidone) may be approved if the following criterion is met:

- I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).

Requests for Esbriet (pirfenidone) may not be approved for the following:

- I. Individual who will be using Esbriet (pirfenidone) in combination with Ofev (nintedanib); **OR**
- II. Individual with end-stage renal disease (ESRD); **OR**
- III. Individual with severe hepatic impairment (Child-Pugh Class C) or end-stage liver disease.

## **Key References:**

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Johnson SR, Bernstein EJ, Bolster MB, et al. 2023 American College of Rheumatology (ACR)/American College of Chest Physicians (CHEST) Guideline for the Treatment of Interstitial Lung Disease in People with Systemic Autoimmune Rheumatic Diseases. *Arthritis & Rheumatology*. 2024;76(8):1182-1200.
4. King TE. Treatment of idiopathic pulmonary fibrosis. Last updated: October 7, 2025. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 16, 2025.
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7. Raghu G, Montesi SB, Silver RM, et al. Treatment of Systemic Sclerosis-associated Interstitial Lung Disease: Evidence-based Recommendations. An Official American Thoracic Society (ATS) Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2023. Online ahead of print.
8. Raghu G, Remy-Jardin M, Richeldi, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in adults. *Am J Respir Crit Care Med*. 2022;205(9):e18-e47.
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13. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: June 25, 2025. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 16, 2025

## **Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma)**

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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