Esbriet (pirfenidone)

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

Medications	Quantity Limit
Esbriet (pirfenidone) – Brand and Generic	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. Individual has had pulmonary function tests within prior 60 days demonstrating forced vital capacity (% FVC) greater than or equal to 50%, and documentation is provided.

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 **brand** Esbriet must meet the following, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial of one chemically equivalent generic pirfenidone agent. Medication samples/coupons/discount cards are excluded from consideration as a trial.;
   AND
   A. Generic pirfenidone had inadequate response; **OR**
   B. Generic pirfenidone caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

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

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

Key References:

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3. King TE. Treatment of idiopathic pulmonary fibrosis. Last updated: September 6, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 8, 2023.
4. Lederer DJ, Martinez FJ. Idiopathic Pulmonary Fibrosis. *NEJM.* 2018;379(8): 797-798.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
6. 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.
7. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Diagnosis of idiopathic pulmonary fibrosis. *Am J Respir Crit Care Med.* 2018;198(5):e44-e68.
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10. Varga J. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: April 12, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 8, 2023.
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