CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Esbriet (pirfenidone)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Esbriet, approved by the FDA in 2014, is a pyridone oral antifibrotic drug indicated for the treatment of idiopathic pulmonary fibrosis (IPF). IPF is an interstitial lung disease characterized by chronic, progressive scarring of the lungs and the pathological hallmark of usual interstitial pneumonia (UIP).

Esbriet (pirfenidone) will be considered for coverage when the following criteria are met:

Idiopathic Pulmonary Fibrosis (IPF)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has a diagnosis of IPF confirmed by a UIP pattern on high resolution computed tomography (HRCT) or by a lung biopsy (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC); AND
5. Member does not have severe hepatic impairment (Child Pugh Class C); AND
6. Member is not a current smoker and provider attests the member will not smoke during treatment; AND
7. Esbriet will not be prescribed in combination with Ofev.
8. **Dosage allowed/Quantity limit:** Titrate as follows, to 801 mg three times per day (2403 mg/day total) QL: 90 tablets per 30 days OR 270 capsules per 30 days

Treatment days	Dosage
Days 1 through 7	267 mg three times daily (801 mg/day)
Days 8 through 14	534 mg three times daily (1602 mg/day)
Days 15 onward	801 mg three times daily (2403 mg/day)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by reduced rate of FVC decline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Esbriet (pirfenidone) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/22/2020	New policy for Esbriet created; split off from combined IPF policy with Ofev.
05/24/2022	Policy transferred to new template. Updated references.
10/17/2024	Updated refs. Specified UIP presence on HRCT. Removed minimum FVC required. Added to not be used with Ofev. Added capsules with QL.

References:

1. Esbriet [package insert]. South San Francisco, CA: Genentech, Inc; 2023.
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3. King TE Jr, Bradford WZ, Castro-Bernardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis [published correction appears in N Engl J Med. 2014 Sep 18;371(12):1172]. N Engl J Med. 2014;370(22):2083-2092. doi:10.1056/NEJMoa1402582
4. Raghu G, Rochwerg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis. An Update of the 2011 Clinical Practice Guideline [published correction appears in Am J Respir Crit Care Med. 2015 Sep 1;192(5):644. doi: 10.1164/rccm.1925erratum. Dosage error in article text]. *Am J Respir Crit Care Med*. 2015;192(2):e3-e19. doi:10.1164/rccm.201506-1063ST
5. 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;198(5):e44-e68. doi:10.1164/rccm.201807-1255ST
6. 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. doi:10.1164/rccm.202202-0399ST

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