CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Esbriet (pirfenidone)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Esbriet is a pyridone oral antifibrotic drug approved by the FDA in 2014. Idiopathic pulmonary fibrosis (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 high resolution computed tomography (HRCT) or lung biopsy (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 50% predicted; 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.
7. **Dosage allowed/Quantity limit:** Titrate as follows, to 801 mg three times per day (2403 mg/day total) (90 tablets 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.

References:

1. Esbriet [package insert]. South San Francisco, CA: Genentech, Inc; 2022.
2. 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. American Journal of Respiratory and Critical Care Medicine. 2015;192(2). doi:10.1164/rccm.201506-1063st
3. Canestaro WJ, Forrester SH, Raghu G, Ho L, Devine BE. Drug Treatment of Idiopathic Pulmonary Fibrosis. Chest. 2016;149(3):756-766. doi:10.1016/j.chest.2015.11.013
4. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomised trials. Lancet. 2011;377(9779):1760-1769. doi:10.1016/S0140-6736(11)60405-4
5. 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
6. Sharif R. Overview of idiopathic pulmonary fibrosis (IPF) and evidence-based guidelines. *Am J Manag Care*. 2017;23(11 Suppl):S176-S182.
7. Belhassen M, Dalon F, Nolin M, Van Ganse E. Comparative outcomes in patients receiving pirfenidone or nintedanib for idiopathic pulmonary fibrosis. *Respir Res*. 2021;22(1):135. Published 2021 May 4. doi:10.1186/s12931-021-01714-y
8. Fleetwood K, McCool R, Glanville J, et al. Systematic Review and Network Meta-analysis of Idiopathic Pulmonary Fibrosis Treatments. *J Manag Care Spec Pharm*. 2017;23(3-b Suppl):S5-S16. doi:10.18553/jmcp.2017.23.3-b.s5

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