CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Esbriet (pirfenidone)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 90 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Esbriet (pirfenidone) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IDIOPATHIC PULMONARY FIBROSIS (IPF)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has diagnosis of IPF confirmed by high resolution computed tomography (HRCT) or lung biopsy (results must be submitted for review)[3]; AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 50% predicted;[7,8] 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:** Titrate as follows, to max of 801mg three times per day (2403mg/day total).

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 member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[7,8].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Esbriet (pirfenidone) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/22/2020	New policy for Esbriet created; split off from combined IPF policy with Ofev.
11/17/2021	Annual review, no changes

References:

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3. Raghu G, Collard HR, Egan JJ, et al. An Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management. *American Journal of Respiratory and Critical Care Medicine*. 2011;183(6):788-824. doi:10.1164/rccm.2009-040gl
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. *American Journal of Respiratory and Critical Care Medicine*. 2015;192(2). doi:10.1164/rccm.201506-1063st
5. 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
6. Rogliani P, Calzetta L, Cavalli F, Matera MG, Cazzola M. Pirfenidone, nintedanib and N-acetylcysteine for the treatment of idiopathic pulmonary fibrosis: A systematic review and meta-analysis. *Pulmonary Pharmacology & Therapeutics*. 2016;40:95-103. doi:10.1016/j.pupt.2016.07.009
7. 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
8. 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

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