

ALASKA MEDICAID
Prior Authorization Criteria

**Esbriet®
(pirfenidone)**

FDA INDICATIONS AND USAGE¹

Esbriet® is a pyridone indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

APPROVAL CRITERIA^{1,2,3,4}

1. Patient is 18 years of age or older **AND;**
2. Patient has the diagnosis of Idiopathic Pulmonary Fibrosis confirmed by lung biopsy for idiopathic pulmonary fibrosis diagnosis OR high-resolution computed tomography **AND;**
3. Other known causes of interstitial lung disease such as, domestic and occupational environmental exposures, drug toxicity or connective tissue disease have been ruled out **AND;**
4. The medication is being prescribed by or in consultation with a pulmonologist **AND;**
5. Documentation submitted shows that the patient is a nonsmoker or has been abstinent from smoking for at least six weeks **AND;**
6. A liver function test has been obtained prior to starting treatment **AND;**
7. Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity (FVC) $\geq 50\%$ of predicted **AND;**
8. Baseline percent predicted diffusing capacity of the lung for carbon monoxide is $\geq 30\%$ for idiopathic pulmonary fibrosis.

DENIAL CRITERIA¹

1. Failure to meet approval criteria **OR;**
2. Patient has end stage renal disease requiring dialysis **OR;**
3. Esbriet is being used in combination with Ofev.

CAUTIONS¹

- Monitor for elevated ALT, AST, and bilirubin and drug -induced liver injury.
- Gastrointestinal disorders have been observed.
- Photosensitivity and rash have been noted with ESBRIET. Avoid exposure to sunlight and sunlamps. Wear sunscreen and protective clothing daily.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months with documentation showing improvement and effectiveness of therapy.

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QUANTITY LIMIT

- 180– 267mg capsules per 30 days
- 90 – 801mg capsules per 30 days

REFERENCES / FOOTNOTES:

1. Esbriet® [Prescribing Information]. Genentech USA, Inc. South San Francisco, CA. July 2019.
2. 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 Sep 1;198(5):e44-e68.
3. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomized trials. Lancet. 2011;377:1760-69.
4. King TE, Bradford WZ, Castro-Benardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. N Engl J Med. 2014;370:2083-92.