

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 21, 2015 June 2, 2017, March 28, 2018, April 12, 2019, May 19, 2020

### ESBRIET® (pirfenidone)

LENGTH OF AUTHORIZATION: Up to 6 months

CLINICAL NOTES: Esbriet is a pyridone indicated for the treatment of idiopathic pulmonary fibrosis.

REVIEW CRITERIA:

- Patient must be  $\geq 18$  years old.
- Must be prescribed or in consultation with a pulmonologist **AND**
- Confirmation of idiopathic pulmonary fibrosis through exclusions of other known causes of interstitial lung disease: domestic and occupational environmental exposures, drug toxicity or connective tissue disease **AND**
- Documentation submitted that the patient is a nonsmoker or has been abstinent for at least six weeks **AND**
- Confirmation of diagnosis via lung biopsy **OR** high resolution computed tomography **AND**
- Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity(FVC)  $\geq 50\%$  **AND**
- Baseline percent predicted diffusing capacity of the lung for carbon monoxide is  $\geq 30\%$  **AND**
- Patient must obtain a liver function test prior to starting treatment.
- **Trial and failure of Ofev is required.**

CONTINUATION OF THERAPY:

- Documentation of improvement or effectiveness of therapy (<200ml decrease in FVC or <10% decline in percent predicted FVC).
- Clinical documentation that the recipient is tobacco free.

DOSING & ADMINISTRATION:

Dosage form: 267mg and 801mg

Administration: 267mg three times daily with meals on days 1-7, then 534mg three times daily with meals on days 8-14, then 801mg three times daily with meals thereafter.