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| Division: Pharmacy Policy | Subject: State of Florida's Agency for Health Care Administration's 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 ≥ 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 ($<200\text{ml}$ 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.