MEDICATION POLICY

Generic Name: Pirfenidone

Therapeutic Class or Brand Name: Esbriet®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 8/30/16 **Date Last Reviewed/Revised:** 11/28/17

GPI Code: 4555006000

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):

I. Documented diagnosis of idiopathic pulmonary fibrosis (IPF).

II. Documentation that patient has a baseline percent predicted forced vital capacity (%FVC) greater than or equal to 50%.

III. Documentation that the patient has a baseline carbon monoxide (%DLCO) greater than or equal to 30%.

IV. Documentation that patient does not smoke and has not smoked for a minimum of six weeks.

V. Minimum age requirement: 18 years old.

VI. The prescriber is a Pulmonologist.

Exclusion Criteria:

- Coadministration of Esbriet® with Ofev® (nintedanib).
- Coadministration of Esbriet® with any of the following:
  - Fluvoxamine or other strong CYP1A2 inhibitors (i.e. enoxacin).
  - Moderate or strong inhibitors of both CYP1A2 and one or more other CYP isoenzymes involved in the metabolism of Esbriet® (i.e. CYP2C9, 2C19, 2D6, and 2E1).
  - Strong CYP1A2 inducers.

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 267 mg strength: Quantities of up to 270 capsules/tablets per 30 days.

- 801 mg strength: Quantities of up to 90 tablets per 30 days.

Approval Length:

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective. Documentation of both a and b are also required:
  a. There is less than a 200 ml decrease in FVC or less than a 10% decline in %FVC.
  b. The patient does not smoke.

Appendix:

N/A

References:

1. http://www.gene.com/download/pdf/esbriet_prescribing.pdf.
2. Medi-Span.
3. http://blue.regence.com/trgmedpol/drugs/dru368.pdf.
4. https://ahca.myflorida.com/medicaid/Prescribed_Drug/drug_criteria_pdf/Esbriet_Criteria.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
11/28/2017	1. **Changed** "Quantities of up to 270 capsules per 30 days" **to** "267 mg strength: Quantities of up to 270 capsules/tablets per 30 days; 801 mg strength: Quantities of up to 90 tablets per 30 days" **under Quantity/Days Supply Restrictions**.