



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: _____

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:

- Quantities of up to 270 capsules per 30 days.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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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.

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