

Pirfenidone (Esbriet)

Coverage Criteria:

Esbriet is reserved for patients meeting the following criteria:

- 1. Reserved for prescribing by Pulmonary; and
- 2. Patient has been diagnosed with mild-to-moderate idiopathic pulmonary fibrosis (IPF) per ATS/ERS/JRS/ALAT criteria, confirmed by:
 - a. Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity); and either:
 - i. The presence of the high-resolution CT (HRCT) pattern of usual interstitial pneumonia (UIP) as defined by ATS/ERS/JRS/ALAT criteria; or,
 - ii. Combinations of HRCT patterns and histopathology patterns indicative of IPF as defined by ATS/ERS/JRS/ALAT criteria in patients subjected to lung tissue sampling; and,
- 3. Patient has FVC greater than or equal to 50% at baseline; and,
- 4. Patient has a percent predicted diffusing capacity of the lungs for carbon monoxide (%DLCO) greater than or equal to 30%; and,
- 5. Patient does not have underlying liver disease; and,
- 6. Esbriet is prescribed at the FDA approved dosing regimen.

Coverage Duration:

Approvals will be granted for a 12 months duration.

Renewal Criteria:

- 1. Patient continues to meet the criteria above; and,
- 2. Patient has been seen within the past 14 months by the prescribing specialist; and,
- 3. Documentation that the medication continues to be effective has been submitted.