

**POLICY NAME**

Esbriet (pirfenidone) and Ofev (nintedanib esylate)

**POLICY #**

2321P

## Criteria

### Coverage Criteria for Idiopathic Pulmonary Fibrosis (IPF)

- ☐ 1.1 Prescribed by a pulmonologist (lung doctor)
- ☐ 1.2 Documented baseline liver function tests
- ☐ 1.3 Age 18 years or older
- ☐ 1.4 Diagnosis of Idiopathic Pulmonary Fibrosis as defined by The American Thoracic Society:
  - Exclusion of other known causes of interstitial lung disease
  - CT scan of lung shows definite features of usual interstitial pneumonia (UIP)
  - Specific combinations CT scan and lung biopsy patterns showing UIP
- ☐ 1.5 Coverage of brand Esbriet requires a documented allergic reaction to generic pirfenidone

### Coverage Criteria for Systemic Sclerosis-Associated Interstitial Lung Disease (Ofev Only)

- ☐ 2.1 Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease
- ☐ 2.2 Age 18 years or older
- ☐ 2.3 Documented trial, failure, or contraindication to mycophenolate mofetil or cyclophosphamide
- ☐ 2.4 Prescribed by a pulmonologist (lung doctor), or rheumatologist (musculoskeletal doctor)
- ☐ 2.5 Medication will not be used in combination with Actemra

### Coverage Criteria for Chronic Fibrosing Interstitial Lung Disease (Ofev Only)

- ☐ **3.1** Prescribed by a pulmonologist (lung doctor)
- ☐ **3.2** Age 18 years or older
- ☐ **3.3** Documented baseline liver function tests
- ☐ **3.4** Diagnosis of Chronic Fibrosing Interstitial Lung Disease with a progressive phenotype
- ☐ **3.5** Chart notes indicating forced vital capacity (FVC) greater than or equal to 45% of predicted
- ☐ **3.6** Chart notes indicating diffusing lung capacity for oxygen (DLCO) 30 – 79% of predicted

### Quantity Limit

- ☐ **4.1** Esbriet/pirfenidone will have a Managed Dose Limit of #270 capsules per 30 days
- ☐ **4.2** Ofev will have a Managed Dose Limit of #60 capsules per 30 days