# Pharmacy Drug Policy & Procedure

| Policy Name: | Esbriet (pirfenidone) and Ofev (nintedanib esylate) | Policy #: | 2321P |
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## Purpose of the Policy

The purpose of this policy is to establish prior authorization criteria for Esbriet, pirfenidone, and Ofev (nintedanib esylate).

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Esbriet, pirfenidone, or Ofev under the specialty pharmacy benefit when the following criteria have been met.

## Criteria

**1. 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

**2. 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

**3. 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

**4. 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

**5. Approval Period**

5.1 Initial Approval: 12 months
5.2 Subsequent Approvals: 2 years with documentation of beneficial response (i.e., slowed the rate of decline of lung function, improved symptoms of cough or shortness of breath, improved quality of life, etc.)

## CPT Codes

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## HCPCS Codes

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## References


1. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic Sclerosis-Associated Interstitial Lung Disease. N Engl J Med 2019; 380:2518.
2. Kowal-Bielecka O, Fransen J, Avouac J, et al; EUSTAR Coauthors. Update of EULAR recommendations for the treatment of systemic sclerosis. Ann Rheum Dis. 2017 Aug;76(8):1327-1339.
3. Laurenson S, Sidhu R, Goodall M, Adler AI. NICE guidance on nintedanib for treating idiopathic pulmonary fibrosis. Lancet Respir Med 2016; 4:176.
4. Raghu G, Jardin MR, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2022 May 1;205(9):e18-e47.
5. Wells AU, Flaherty KR, Brown KK, et al; INBUILD trial investigators. Nintedanib in patients with progressive fibrosing interstitial lung diseases-subgroup analyses by interstitial lung disease diagnosis in the INBUILD trial: a randomised, double-blind, placebo-controlled, parallel-group trial. Lancet Respir Med. 2020 May;8(5):453-460.



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