

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

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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DISCLAIMER

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