UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Esbriet, Ofev

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| Program | Prior Authorization |
| Medication | Esbriet (pirfenidone), Ofev (nintedanib) |
| Markets in Scope | Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina |
| Issue Date | 11/2014 |
| Pharmacy and Therapeutics Approval Date | 4/2020 |
| Effective Date | 6/2020 |

## 1. Background:

Esbriet (pirfenidone) is a pyridone and Ofev (nintedanib) is a kinase inhibitor that are indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Ofev is also indicated for slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD) and for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype..

## 2. Coverage Criteria:

**A. <u>Idiopathic pulmonary fibrosis</u>**

**<u>Initial Authorization</u>**

1. **Esbriet or Ofev** will be approved based on **<u>all</u>** of the following criteria:

   a. Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by **<u>all</u>** of the following criteria:

      (1) Exclusion of other known causes of interstitial lung disease (e.g. domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:

         i. ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis)

**-AND-**

      (2) **<u>One</u>** of the following:

         i. In patients **<u>not</u>** subjected to surgical lung biopsy, the presence of a

usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF

**-OR-**

ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF

**-AND-**

b. The agent is not being used in combination with Esbriet or Ofev

**-AND-**

c. The prescriber is a pulmonologist

**Authorization will be issued for 12 months**

**Reauthorization**

2. **Ofev or Esbriet** will be approved based on the following criterion:

a. Documentation of positive clinical response to Esbriet or Ofev therapy

**-AND-**

b. The agent is not being used in combination with Esbriet or Ofev

**-AND-**

c. The prescriber is a pulmonologist

**Authorization will be issued for 12 months**

**B. Systemic sclerosis-associated interstitial lung disease**

**1. Initial Authorization**

a. **Ofev** will be approved based on **all** of the following criteria:

(1) Diagnosis of systemic sclerosis (SSc) - associated interstitial lung disease as documented by **all** of the following criteria:

(a) **One** of the following:

i. Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints

**-OR-**

ii. At least **two** of the following:

- Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
- Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
- Telangiectasia
- Abnormal nailfold capillaries
- Pulmonary arterial hypertension
- Raynaud's phenomenon
- SSc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

**-AND-**

(b) Presence of interstitial lung disease as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs

**-AND-**

(2) The agent is not being used in combination with Esbriet

**-AND-**

(3) The prescriber is a pulmonologist

**Authorization will be issued for 12 months.**

**2. Reauthorization**

a. Ofev will be approved based on the following criterion:

(1) Documentation of positive clinical response to Ofev therapy

**-AND-**

(2) Ofev is not being used in combination with Esbriet

**-AND-**

(3) The prescriber is a pulmonologist

**Authorization will be issued for 12 months.**

**C. Chronic fibrosing interstitial lung disease with a progressive phenotype**

**1. Initial Authorization**

a. **Ofev** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype as documented by **both** of the following criteria

(a) Presence of fibrotic ILD as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs

**-AND-**

(b) Patient is presenting with clinical signs of progression as defined by **one** of the following in the previous 24 months:

i. Forced vital capacity (FVC) decline of greater than 10%

**-OR-**

ii. **Two** of the following:

1. FVC decline of greater than or equal to 5%, but less than 10%
2. Patient is experiencing worsening respiratory symptoms
3. Patient is exhibiting increasing extent of fibrotic changes on chest imaging

**-AND-**

(2) Ofev is not being used in combination with Esbriet

**-AND-**

(3) The prescriber is a pulmonologist

**Authorization will be issued for 12 months**

**2. Reauthorization**

a. Ofev will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Ofev therapy

**-AND-**

(2) Ofev is not being used in combination with Esbriet

**-AND-**

(3) The prescriber is a pulmonologist

**Authorization will be issued for 12 months**

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Esbriet [package insert]. Genentech USA, Inc. South San Francisco, CA. July 2019.
2. King TE, Bradford WZ, Castro-Benardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *N Engl J Med.* 2014;370:2083-92.
3. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomized trials. *Lancet*. 2011;377:1760-69.
4. Ofev [package insert]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2020.
5. Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2018 Sep 1;198(5):e44-e68.
6. Richeldi L, du Boise RM, Raghu G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. *N Engl J Med.* 2014 May 29;370(22):2071-82.
7. Richeldi L, Cottin V, Flaherty KR, et al. Design of the INPULSIS trials: two phase 3 trials of nintedanib in patients with idiopathic pulmonary fibrosis. *Resp Med*. 2014;108:1023-1030.
8. Ryerson CJ, Collard HR. Hot off the breath: a big step forward for idiopathic pulmonary fibrosis. *Thorax.* 2014;69:791-792.

9. Raghu G, Rochwerg B, Zhang Y, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. An update of the 2011 clinical practice guideline. *Am J Respir Crit Care Med*. 2015 Jul 15;192(2):e3-19.
10. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic Sclerosis-Associated Interstitial Lung Disease. N Engl J Med. 2019 Jun 27;380(26):2518-2528.
11. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Ann Rheum Dis 2013;72:1747-1755.

| Program | Prior Authorization - Esbriet (pirfenidone), Ofev (nintedanib) |
|---|---|
| **Change Control** | |
| Date | Change |
| 11/2014 | New policy |
| 12/2015 | Annual review; no change |
| 9/2016 | Removed ICD-9 code. Updated background, references, and policy template. |
| 9/2017 | Annual Review. Updated background and references. |
| 9/2018 | Minor change in reauthorization language. Updated references. |
| 9/2019 | Annual review. Updated references. |
| 10/2019 | Added coverage criteria for systemic sclerosis for Ofev. Changed name of program to Esbriet, Ofev. Updated background and references. |
| 4/2020 | Updated background and added Ofev coverage criteria for chronic fibrosing interstitial lung diseases with a progressive phenotype. Updated references. |