UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Name	2025 P 2046-14
Program	Prior Authorization/Medical Necessity
Medications	Esbriet® (pirfenidone)* and Ofev® (nintedanib)
P&T Approval Date	11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 10/2019, 4/2020, 4/2021, 4/2022, 3/2023, 3/2024, 5/2024, 5/2025
Effective Date	8/1/2025

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.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

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

1. **Initial Authorization**

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

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

(a) 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-

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

i. In patients ***not*** 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[5]

-OR-

ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF[5]

-AND-

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

(a) If request is for Esbriet, Esbriet is not being used in combination with Ofev.
(b) If request is for Ofev, 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. **Esbriet** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Esbriet therapy.

-AND-

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

b. **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.

Authorization will be issued for 12 months

B. <u>Systemic sclerosis-associated interstitial lung disease (Ofev only)</u>

1. **Initial Authorization**

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

(1) Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by **<u>all</u>** of the following criteria:[11]

(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) 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.

Authorization will be issued for 12 months

C. <u>Chronic fibrosing interstitial lung disease with a progressive phenotype (Ofev only)</u>

1. **Initial Authorization**

a. **Ofev** will be approved based on **<u>all</u>** 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 **both** of the following criteria:

(1) Documentation of positive clinical response to Ofev therapy

-AND-

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

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

*Brand Esbriet is typically excluded from coverage. Tried/Failed criteria may be in place. Please refer to plan specifics to determine exclusion status.

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 [Prescribing Information]. Genentech USA, Inc. South San Francisco, CA. February 2023.
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® [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2024.
5. 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.
6. 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.
7. Raghu G, Remy-Jardin M, 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;205(9):e18-e47. doi:10.1164/rccm.202202-0399ST

Program	Prior Authorization/Medical Necessity - Esbriet® (pirfenidone) and Ofev® (nintedanib)
Change Control	
11/2014	New Program
11/2015	Annual Review. Updated background info. Administrative changes.
9/2016	Annual Review. Removed ICD-9 codes. Updated background and references.
9/2017	Annual Review. Updated background and references.
9/2018	Annual Review. No change in coverage criteria. Updated references.
9/2019	Annual Review. No change in coverage criteria. Updated references.
10/2019	Added coverage criteria for systemic sclerosis for Ofev. Updated references.
4/2020	Updated background and added Ofev coverage criteria for chronic fibrosing interstitial lung diseases with a progressive phenotype. Updated references.
4/2021	Annual Review. No change in coverage criteria. Updated references.
4/2022	Annual Review. No change in coverage criteria. Updated references.
3/2023	Annual Review. Reformatted criteria for Esbriet and Ofev for

	Idiopathic Pulmonary Fibrosis. Added exclusion footnote for Brand Esbriet and updated references.
3/2024	Annual review. No change in coverage criteria. Updated references.
5/2024	Removed prescriber requirement from reauthorization criteria.
5/2025	Annual review. No changes to coverage criteria.