UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Name	2025 P 1147-13
Program	Prior Authorization/Notification
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, 3/2025
Effective Date	6/1/2025

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 the following criterion:

      (1) Diagnosis of idiopathic pulmonary fibrosis

   Authorization will be issued for 12 months

2. **Reauthorization**

   a. **Esbriet*** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to Esbriet therapy

   b. **Ofev** will be approved based on the following criterion:

      (1) Documentation of positive clinical response to Ofev therapy

   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 the following criterion:

(1) Diagnosis of systemic sclerosis-associated interstitial lung disease

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

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 the following criterion:

(1) Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype

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

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. Ofev [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2024.

Program	Prior Authorization/Notification - Esbriet® (pirfenidone) and Ofev® (nintedanib)
Change Control	
11/2014	New Program
11/2015	Annual Review. No change to clinical content. Updated background.
9/2016	Annual Review. No change in coverage criteria. Updated references.
9/2017	Annual Review. No change in coverage criteria. Updated 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 reference.
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 reauthorization criteria for Esbriet and Ofev for Idiopathic Pulmonary Fibrosis. Added exclusion footnote for Brand Esbriet. Added state mandate footnote and updated references.
3/2024	Annual review. No change in coverage criteria. Updated references.
3/2025	Annual review. No change in coverage criteria. Updated references.