UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Name	2026 P 2046-15
Program	Prior Authorization/Medical Necessity – Interstitial Lung Disease Agents
Medications	Esbriet® (pirfenidone)*, Jascayd™ (nerandomilast), 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, 2/2026
Effective Date	4/1/2026

1. Background:

Esbriet (pirfenidone) is a pyridone, Jascayd (nerandomilast) is a phosphodiesterase 4 (PDE4) inhibitor, 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. Jascayd is also indicated for the treatment of progressive pulmonary fibrosis in adult patients.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Idiopathic Pulmonary Fibrosis

1. **Initial Authorization**

a. **Esbriet*, Jascayd**, or **Ofev** will be approved based on **all** of the following criteria:

(1) Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by **both** of the following:

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

-AND-

(b) **One** 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

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

-AND-

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

(a) The request is for Esbriet, Esbriet is not used in combination with Ofev

(b) The request is for Ofev, Ofev is not used in combination with Esbriet

(c) The request is for Jascayd, **<u>one</u>** of the following:

i. History of trial and failure, or intolerance, to Esbriet or Ofev

ii. Contraindication to both Esbriet and Ofev

-AND-

(3) Prescribed by a pulmonologist

Authorization will be issued for 12 months

2. **<u>Reauthorization</u>**

a. **Esbriet*, Jascayd**, or **Ofev** will be approved based on **<u>both</u>** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

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

(a) The request is for Esbriet, Esbriet is not used in combination with Ofev

(b) The request is for Ofev, Ofev is not used in combination with Esbriet

(c) The request is for Jascayd

Authorization will be issued for 12 months

B. <u>Progressive Pulmonary Fibrosis (Ofev or Jascayd only)</u>

1. **<u>Initial Authorization</u>**

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

(1) Diagnosis of progressive pulmonary fibrosis

-AND-

(2) At least **two** of the following criteria occurring within the past 12 months with no alternative explanation:

(a) Worsening respiratory symptoms

-OR-

(b) Physiological evidence of disease progression demonstrated by **one** of the following:

i. Absolute decline in forced vital capacity (FVC) ≥ 5% predicted

ii. Absolute decline in diffusing capacity of the lungs for carbon monoxide (DL_{co}) (corrected for Hb) ≥ 10% predicted

-OR-

(c) Radiological evidence of disease progression by at least **one** of the following via HRCT:

i. Increased extent or severity of traction bronchiectasis/bronchiolectasis
ii. Increased extent or increased coarseness of reticular abnormality
iii. Increased lobar volume loss
iv. New ground-glass opacity with traction bronchiectasis
v. New fine reticulation
vi. New or increased honeycombing

-AND-

(3) Prescribed by a pulmonologist

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Ofev or Jascayd** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to therapy

-AND-

(2) Prescribed by a pulmonologist

Authorization will be issued for 12 months

C. Systemic sclerosis-associated interstitial lung disease (Ofev only)

1. **Initial Authorization**

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

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

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

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

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) Prescribed by 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
8. Jascayd [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2024.
   Lee, SJ. Overview of the Management of Adults with Interstitial Lung Disease. In: UpToDate, Dieffenbach P (Ed), UpToDate, Waltham, MN. Accessed on January 5, 2026.

Program	Prior Authorization/Medical Necessity - Interstitial Lung Disease Agents Esbriet® (pirfenidone) Jascayd™ (nerandomilast) 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.
2/2026	Addition of Jascayd to program and addition of coverage criteria for progressive pulmonary fibrosis. Updated coverage criteria for idiopathic pulmonary fibrosis to include Jascayd. Updated Ofev coverage criteria by removing chronic fibrosing interstitial lung disease with progressive phenotype and including Ofev into the section for progressive pulmonary fibrosis. Updated references.