

Applicable Drugs: Esbriet (pirfenidone), Jascayd (nerandomilast), Ofev (nintedanib)

Preferred: generic nintedanib, generic pirfenidone

Non-preferred: Esbriet (pirfenidone), Ofev (nintedanib)

VSI-Excluded Drugs: Jascayd (nerandomilast)

Date of Origin: 8/30/2016

Date Last Reviewed / Revised: 6/1/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following conditions A through C and must meet all criteria under the applicable diagnosis:
 - A. Idiopathic pulmonary fibrosis (IPF)
 - i. Documented exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, and drug toxicity).
 - ii. Documented presence of usual interstitial pneumonia (UIP) confirmed by high resolution computed tomography (HRCT) OR lung biopsy.
 - iii. Documented baseline pulmonary function tests within drug-specific ranges (see Table 1).
 - B. Progressive pulmonary fibrosis (PPF) (ie, chronic fibrosing interstitial lung disease [ILD] with a progressive phenotype)
 - i. Documented diagnosis associated with PPF (not IPF, see above). Examples include, but are not limited to, idiopathic interstitial pneumonia (IIP)-related diseases, autoimmune-ILDs (eg, rheumatoid arthritis, myositis, etc.), hypersensitivity pneumonitis (HP), and occupational exposure-related diseases (eg, asbestosis, silicosis, coal miner, etc.).
 - ii. Documentation of at least TWO of the following three criteria:
 1. Worsening respiratory symptoms (eg, dyspnea or cough).
 2. Physiological evidence of disease progression confirmed by one of the following (a or b):
 - a. Absolute decline in forced vital capacity (FVC) $\geq 5\%$ predicted within 1 year.

- b. Absolute decline in diffusing capacity for carbon monoxide (DLCO) $\geq 10\%$ predicted within 1 year.
 - 3. Radiological evidence of disease progression confirmed by any of the following criteria:
 - a. Increased extent or severity of traction bronchiectasis and bronchiolectasis
 - b. New ground-glass opacity with traction bronchiectasis
 - c. New fine reticulation
 - d. Increased extent or increased coarseness of reticular abnormality
 - e. New or increased honeycombing
 - f. Increased lobar volume loss
 - iii. Documented baseline pulmonary function tests within drug-specific ranges (see Table 1).
- C. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
 - i. Documented skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints, confirming diagnosis of SSc.
 - ii. Documented high resolution computed tomography (HRCT) confirming diagnosis of ILD.
 - iii. Documented treatment failure, intolerance, or contraindication to all the following:
 - 1. Cyclophosphamide
 - 2. Mycophenolate
 - iv. Documented baseline pulmonary function tests within drug-specific ranges (see Table 1).
- II. Minimum age requirement: 18 years old.
- III. Treatment is prescribed by or in consultation with a pulmonologist or rheumatologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Concurrent use of Esbriet and Ofev.

OTHER CRITERIA

- Jascayd may be used alone or in combination with either Esbriet or Ofev.
- Table 1. FDA-labeled indications and drug-specific criteria for pulmonary fibrosis agents

Drug	Indications	Drug-specific criteria
Esbriet (pirfenidone)	IPF	• % FVC $\geq$50% predicted normal • DLCO 30-90% predicted normal
Ofev (nintedanib)	IPF	• % FVC $\geq$50% predicted normal • DLCO between 30-79% predicted normal
	PPF	• % FVC $\geq$45% predicted normal • DLCO between 30-79% predicted normal
	SSc-ILD	• % FVC $\geq$40% predicted normal • DLCO between 30-89% predicted normal
Jascayd (nerandomilast)	IPF	• % FVC greater than or equal to 45% predicted normal
	PPF	• DLCO greater than or equal to 25% predicted normal

IPF: idiopathic pulmonary fibrosis; PPF: progressive pulmonary fibrosis; SSc-ILD: systemic sclerosis-associated interstitial lung disease; FVC: forced vital capacity; DLCO: diffusing capacity for carbon monoxide

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Esbriet (refer to FDA labeling for dosage titration and adjustments):
 - 267 mg: 270 capsules or tablets per 30 days.
 - 801 mg: 90 tablets per 30 days.
- Jascayd: 60 tablets per 30 days.
- Ofev: 60 capsules per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective [eg, reduction in expected decline in FVC percent predicted, increase in six-minute walk distance (6MWD), or decrease in number or severity of acute exacerbations].

APPENDIX

- N/A

REFERENCES

1. Esbriet. Prescribing information. Genentech. 2023. Accessed April 27, 2026.
https://esbriethcp.com/download/pdf/esbriet_prescribing.pdf
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<https://patient.boehringer-ingelheim.com/us/products/jascayd/bipdf/prescribing-information>
3. Ofev. Prescribing information. Boehringer Ingelheim; 2025. Accessed April 27, 2026.
<https://patient.boehringer-ingelheim.com/us/products/ofev/bipdf/ofev-us-pi>
4. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med*. 2011;183(6):788-824. doi:10.1164/rccm.2009-040GL
5. 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
6. Raghu G, Montesi SB, Silver RM, et al. Treatment of Systemic Sclerosis-associated Interstitial Lung Disease: Evidence-based Recommendations. An Official American Thoracic Society Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2024;209(2):137-152. doi:10.1164/rccm.202306-1113ST
7. Galdo FD, Alain Lescoat, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Annals of the Rheumatic Diseases*. 2025;84(1):29-40. doi:10.1136/ard-2024-226430
8. 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. *Arthritis & Rheumatism*. 2013;65(11):2737-2747. doi:10.1002/art.38098

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.