Drug Coverage Policy

Effective Date.....04/15/2026
Coverage Policy Number.....IP0772
Policy Title.....Jascayd

Pulmonary – Antifibrotics - Jascayd

- Jascayd® (nerandomilast tablets – Boehringer Ingelheim)

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Overview

Jascayd, a phosphodiesterase 4 (PDE4) inhibitor is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF) in adults.[1]

Disease Overview

Idiopathic Pulmonary Fibrosis

IPF is a chronic interstitial lung disease characterized by the histologic pattern of usual interstitial pneumonia.[2] The diagnosis is established in patients who present with clinical features and either a usual interstitial pneumonia pattern on histology or a classic high-resolution computed tomography (HRCT) scan. IPF involves cellular proliferation, interstitial inflammation, and fibrosis within the alveolar walls, unrelated to infection or malignancy.[3]

IPF is rare, with U.S. prevalence estimates ranging from 10 to 60 cases per 100,000.[2] However, one study reported a prevalence of 494 cases per 100,000 among adults over 65 years in 2011, suggesting a higher burden in older populations. The disease primarily affects older adults and manifests as progressive dry cough and exertional dyspnea. Patients often experience significant disease burden, including frequent hospitalizations and the need for supplemental oxygen.

The clinical course varies but mean survival after symptom onset is typically 3–5 years.[2] The etiology remains unknown, though environmental and occupational exposures, as well as smoking history, may contribute. Current medical therapies offer only modest benefit, primarily slowing disease progression. FDA-approved agents include Ofev® (nintedanib capsules) and pirfenidone capsules and film-coated tablets (Esbriet®, generic). Lung transplantation remains a therapeutic option for eligible patients.

Progressive Pulmonary Fibrosis

The term PPF is used to describe a progressive disease course in persons with fibrosing interstitial lung disease (ILD) other than IPF.[5,8] It is characterized by gradual and irreversible scarring (fibrosis) of the lungs. The clinical course of PPS is similar to IPF; however, it can be differentiated based on radiologic and physiologic findings, as well as the timeframe of disease progression. Physiologic findings include an absolute decline in forced vital capacity (FVC) of ≥ 5% within one year of follow-up or absolute decline in lung diffusing capacity for carbon monoxide (DL_{CO}), after correction for hemoglobin, of ≥ 10% within one year of follow-up. Radiologic evidence includes at least one of the following: increased extent or degree or fraction bronchiectasis and bronchiolectasis; increased extent or coarseness of reticular abnormality; increased lobar volume loss; new ground-glass opacity with traction bronchiectasis; new fine reticulation; new or increased honeycombing. As of 2022, the term PPF was used to describe what was previously known as chronic fibrosing ILDs with a progressive phenotype. Ofev is approved for this indication.

Clinical Efficacy

Idiopathic Pulmonary Fibrosis

Jascayd was evaluated in two randomized, double-blind, placebo-controlled trials (FIBRONEER-IPF and Trial 2).[1,6,7] A total of 1,177 adults with IPF were enrolled in FIBRONEER-IPF and randomized to receive Jascayd 9 mg twice daily (BID), 18 mg BID, or placebo BID. A total of 147 adults with IPF were enrolled in Trial 2 and randomized to receive Jascayd 18 mg BID or placebo BID. In both trials, patients were required to have a diagnosis of IPF, which was confirmed by chest HRCT and, if available, lung biopsy. Patients were allowed to continue background therapies (Ofev or pirfenidone) but were required to be ≥ 40 years of age with forced vital capacity (FVC) ≥ 45% of predicted value and a carbon monoxide diffusing capacity ≥ 25% of predicted. In FIBRONEER-IPF, treatment with Jascayd resulted in a smaller decline in FVC than placebo over a period of 52 weeks and in Trial 2, Jascayd prevented a decrease in lung function in patients with IPF.

Progressive Pulmonary Fibrosis

Jascayd was evaluated in one randomized, double-blind, placebo-controlled trial for PFF (FIBRONEER-ILD).[8] A total of 1,176 adults were randomized to Jascayd vs. placebo; 43.5% of those patients were taking background Ofev at baseline. Patients were randomized to a dose of 18 mg BID, 9 mg BID, or placebo; randomization was stratified by the presence or absence of Ofev background therapy and by HRCT patterns. Patients were required to have ≥ 10% fibrotic features on HRCT, present with clinical signs of progression (defined as FVC decline ≥ 10% or FVC decline ≥ 5% to < 10% with worsening of respiratory symptoms or imaging, or worsening of respiratory symptoms and worsening of imaging in the 24 months prior to screening). Patients were also required to be ≥ 18 years of age, have an FVC ≥ 45% of predicted at baseline and a DL_{CO} ≥ 25%. The primary endpoint was the absolute change in FBC in mL at 52 weeks for Jascayd vs. placebo; treatment with Jascayd led to a statistically significantly smaller decline in FVC compared with placebo.

Guidelines

Idiopathic Pulmonary Fibrosis

The clinical practice guidelines from the American Thoracic Society (ATS), European Respiratory Society (ERS), Japanese Respiratory Society (JRS), and Latin American Thoracic Association (ALAT) on the treatment of IPF was first published in 2015 and later updated in 2022.[4,5] Both Ofev and pirfenidone are conditionally recommended to slow disease progression, alongside other non-pharmacologic strategies (e.g., oxygen therapy, pulmonary rehabilitation, management of comorbidities). Jascayd has not yet been included.

Progressive Pulmonary Fibrosis

In addition to the clinical practice guidelines for IPF, the ATS/ERS/JRS/ALAT updated recommendations for PPF and the ERS made an expert consensus statement (2023) for PPF.[5,9] A conditional recommendation was made for Ofev for the treatment of PPF, but additional research was recommended for the use of pirfenidone in this patient population.

Coverage Policy

Policy Statement

Prior Authorization is required for benefit coverage of Jascayd. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Jascayd as well as the monitoring required for adverse events and long-term efficacy, approval requires Jascayd to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Jascayd is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Idiopathic Pulmonary Fibrosis.** Approve for 1 year if the patient meets the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv and v):
     Note: Initial therapy refers to a patient who is not currently receiving Jascayd. Patient may be taking concomitant Ofev (nintedanib capsules) or pirfenidone capsules and film-coated tablets (Esbriet, generic).

i. Patient is ≥ 18 years of age; AND
ii. Forced vital capacity is ≥ 40% of the predicted value at baseline **[documentation required]**; AND
Note: Baseline is before a patient has started any antifibrotic therapies. Examples of antifibrotic therapies are Jascayd (nerandomilast tablets), Ofev (nintedanib capsules), and pirfenidone capsules and film-coated tablets (Esbriet, generic).
iii. The diagnosis is confirmed by ONE of the following (a or b):
a) Findings on high-resolution computed tomography indicate usual interstitial pneumonia **[documentation required]**; OR
b) A surgical lung biopsy demonstrates usual interstitial pneumonia **[documentation required]**; AND
iv. The medication is prescribed by or in consultation with a pulmonologist; AND
v. Preferred product criteria is met for the product(s) as listed in the below table(s); OR

B) Patient is Currently Receiving Jascayd. Approve if the patient meets ALL of the following (i, ii, and iii):
i. Patient is ≥ 18 years of age; AND
ii. Patient has experienced a beneficial response to therapy over the last year while receiving Jascayd; AND
Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Jascayd. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of idiopathic pulmonary fibrosis exacerbations.
iii. The medication is prescribed by or in consultation with a pulmonologist.

2. Progressive Pulmonary Fibrosis. Approve for 1 year if patient meets ONE of the following (A or B):
Note: Examples of conditions include hypersensitivity pneumonitis; idiopathic non-specific interstitial pneumonitis; idiopathic non-specific interstitial pneumonia; unclassifiable idiopathic interstitial pneumonia; autoimmune interstitial lung disease (e.g., rheumatoid arthritis interstitial lung disease); exposure-related interstitial lung disease; and mixed connective tissue disease interstitial lung disease. This is not associated with idiopathic pulmonary fibrosis (see indication above).

A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
Note: Initial therapy refers to a patient who is not currently receiving Jascayd. Patient may be taking concomitant Ofev (nintedanib capsules).
i. Patient is ≥ 18 years of age; AND
ii. Forced vital capacity is ≥ 40% of the predicted value **[documentation required]**; AND
iii. According to the prescriber, the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography; AND
iv. According to the prescriber, the patient has clinical signs of progression; AND
Note: Examples of clinical signs of progression include a forced vital capacity decline ≥ 10% of the predicted value or forced vital capacity decline ≥ 5% to < 10% with worsening symptoms and/or worsening imaging.
v. The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist; AND
vi. Preferred product criteria is met for the product(s) as listed in the below table(s); OR

B) Patient is Currently Receiving Jascayd. Approve if the patient meets ALL of the following (i, ii, and iii):
i. Patient is ≥ 18 years of age; AND

ii. Patient has experienced a beneficial response to therapy over the last year while receiving Jascayd; AND
Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Jascayd. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of interstitial lung disease-related exacerbations.

iii. The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.

Employer Plans

Product	Criteria
Jascayd (nerandomilast)	Patient meets ONE of the following (1 or 2): **1. Idiopathic Pulmonary Fibrosis**. Patient meets ONE of the following (A, B, C, D, E , F, or G): **A.** Patient has tried or is currently receiving generic pirfenidone tablets or capsules OR Ofev; OR **B.** Patient has hepatic impairment; OR **C.** Patient's glomerular filtration rate (eGFR) is < 30 mL/min; OR **D.** Patient cannot swallow tablets or capsules OR has difficulty swallowing tablets or capsules; OR **E.** Patient is pregnant, approve if the patient tried pirfenidone tablets or capsules; OR **F.** According to the prescriber, the patient has or is at risk of coronary artery disease, bleeding events, or gastrointestinal perforation and the patient tried pirfenidone tablets or capsules; OR **G.** Patient has already been started on therapy with Jascayd. **2. Progressive Pulmonary Fibrosis**. Patient meets ONE of the following (A, B, C, D, E, F, or G): **A.** Patient has tried or is currently receiving Ofev; OR **B.** Patient has hepatic impairment; OR **C.** Patient's glomerular filtration rate (eGFR) is < 30 mL/min; OR **D.** Patient cannot swallow tablets or capsules OR has difficulty swallowing tablets or capsules; OR **E.** Patient is pregnant; OR **F.** According to the prescriber, the patient has or is at risk of coronary artery disease, bleeding events, or gastrointestinal perforation; OR **G.** Patient has already been started on therapy with Jascayd. Note: If the patient has tried Esbriet capsules or pirfenidone 534 mg tablets, this would satisfy the criteria. Note: If the patient tried the brand version of a generic equivalent product, then this trial would count towards the requirement.

Individual and Family Plans:

Product	Criteria
Jascayd (nerandomilast)	Patient meets ONE of the following (1 or 2): **1. Idiopathic Pulmonary Fibrosis.** Patient meets ONE of the following (A, B, C, D, or E)

Product	Criteria
	A. Patient has tried or is currently receiving generic pirfenidone tablets or capsules **[documentation required]**; OR **B.** Patient has hepatic impairment; OR **C.** Patient's glomerular filtration rate (eGFR) is < 30 mL/min; OR **D.** Patient cannot swallow tablets or capsules OR has difficulty swallowing tablets or capsules; OR **E.** Patient has already been started on therapy with Jascayd. Note: If the patient has tried Ofev, this would satisfy the criteria. **[documentation required]** Note: If the patient has tried Esbriet capsules or pirfenidone 534 mg tablets, this would satisfy the criteria. Note: If the patient tried the brand version of a generic equivalent product, then this trial would count towards the requirement. **2. Progressive Pulmonary Fibrosis**. Approve if the patient meets the Progressive Pulmonary Fibrosis criteria above.

Conditions Not Covered

Jascayd for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

References

1. Jascayd® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; December 2025.
2. Lederer DJ, Martinez FJ. Idiopathic pulmonary fibrosis. *N Engl J Med*. 2018;378(19):1811-1823.
3. Lynch JP, Huynh RH, Fishbein MC, et al. Idiopathic pulmonary fibrosis: epidemiology, clinical features, prognosis, and management. *Semin Respir Crit Care Med*. 2016;37:331-357.
4. Raghu G, Rochwerg B, Zhang Y, et al, on behalf of the ATS, ERS, JRS, and ALAT. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. Executive summary. An update of the 2011 clinical practice guideline. *Am J Respir Crit Care Med*. 2015;192(2):238-248.
5. Raghu G, Remy-Jardin M, Richeldi L, et al, on behalf of the ATS, ERS, JRS, and ALAT. 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.
6. Richeldi L, Azuma A, Cottin V, et al. Nerandomilast in patients with idiopathic pulmonary fibrosis. *NEJM*. 2025;392(22):2193-2202.
7. Richeldi L, Azuma A, Cottin V, et al. Trial of a preferential phosphodiesterase 4B inhibitor for idiopathic pulmonary fibrosis. *NEJM*. 2022;386:2178-2187.
8. Maher TM, Assassi S, Azuma A, et al. Nerandomilast in patients with progressive pulmonary fibrosis. *NEJM.* 2025;392(22):2203-2214.
9. Rajan SJ, Cottin V, Dhar R, et al. Progressive pulmonary fibrosis: an expert group consensus statement. *Eur Respir J*. 2023;61:1-19.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	02/01/2026
Selected Revision	The policy name was changed to Pulmonary – Antifibrotics – Jascayd. Previously, it was Idiopathic Pulmonary Fibrosis and Related Lung Disease – Jascayd PA policy. **Progressive Pulmonary Fibrosis**. This condition of approval was added to the policy. A Note of examples of conditions was provided and includes hypersensitivity pneumonitis; idiopathic non-specific interstitial pneumonitis; unclassifiable idiopathic interstitial pneumonia; autoimmune interstitial lung disease (e.g., rheumatoid arthritis interstitial lung disease); exposure-related interstitial lung disease; and mixed connective tissue disease interstitial lung disease. This condition for approval includes both Initial therapy and patients currently receiving Jascayd. A Note was added to clarify that patients initiating therapy with Jascayd could be on concomitant Ofev (nerandomilast tablets). The requirements for initial therapy are as follows: patient is ≥ 18 years of age; forced vital capacity is ≥ 40% of the predicted value; according to the prescriber, patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography; according to the prescriber, patient has clinical signs of progression; and the medication was prescribed by or in consultation with a pulmonologist. A Note of examples of clinical signs of progression was included and lists a forced vital capacity decline ≥ 10% of the predicted value or forced vital capacity ≥5% to <10% with worsening symptoms and/or worsening imaging. The requirements for patients currently receiving Jascayd are as follows: patient is ≥ 18 years of age; patient has experienced a beneficial response to therapy over the last year while receiving Jascayd; and the medication is prescribed by or in consultation with a pulmonologist. A Note of examples of a beneficial response to therapy includes a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of interstitial lung disease-related exacerbations.	04/01/2026

Selected Revision	**Updated** the policy title from "Pulmonary - Antifibrotics Jascayd for Individual and Family Plans" to "Pulmonary - Antifibrotics Jascayd" **Added** Employer Plans preferred product requirements requiring a step through either pirfenidone or Ofev for a diagnosis of Idiopathic Pulmonary Fibrosis and a step through Ofev for a diagnosis of Progressive Pulmonary Fibrosis. **Clarified** the Individual and Family Plans preferred product requirements only apply to a diagnosis of Idiopathic Pulmonary Fibrosis.	04/15/2026

The policy effective date is in force until updated or retired.