VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Pulmonary – Antifibrotics – Jascayd Prior Authorization Policy
- Jascayd® (nerandomilast tablets – Boehringer Ingelheim)

REVIEW DATE: 10/08/2025; selected revision 11/12/2025, 12/30/2025, 01/28/2026

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 ab 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.

POLICY STATEMENT

Prior Authorization is recommended for prescription 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Jascayd is recommended in those who meet the following criteria:

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, and iv):
     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; 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; OR
       - **b)** A surgical lung biopsy demonstrates usual interstitial pneumonia; AND
     - **iv.** The medication is prescribed by or in consultation with a pulmonologist; 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, and v):
     Note: Initial therapy refers to a patient who is not currently receving 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; 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; 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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Jascayd is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. 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.
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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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	10/08/2025
Selected Revision	**Idiopathic Pulmonary Fibrosis**. A Note was added to clarify that initial therapy refers to a patient who is not currently receiving Jascayd. The patient may be taking concomitant Ofev (nintedanib capsules) or pirfenidone capsules and film-coated tablets (Esbriet, generic). The requirement regarding forced vital capacity ≥ 40% was clarified to state at baseline. A Note was added to clarify that baseline is before a patient has started antifibrotic therapies. The examples of antifibrotic therapies were added which include Jascayd, Ofev, and pirfenidone.	11/12/2025
Selected Revision	**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	12/30/2025

	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.	
Selected Revision	The policy name was changed to as listed. Previously, it was Idiopathic Pulmonary Fibrosis and Related Lung Disease – Jascayd Prior Authorization policy. **Progressive Pulmonary Fibrosis.** The specialist requirement was updated to include a rheumatologist. Previously, only a pulmonologist was listed.	01/28/2026