Drug Coverage Policy

Effective Date……02/01/2026
Coverage Policy Number……IP0772
Policy Title……Jascayd

Idiopathic Pulmonary Fibrosis and Related Lung Disease – Jascayd for Individual and Family Plans

- Jascayd® (nerandomilast tablets – Boehringer Ingelheim)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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

Disease Overview
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.

Clinical Efficacy
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.

Guidelines
The clinical practice guidelines from the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society, and Latin American Thoracic Association 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.

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.

Individual and Family Plans:

Product	Criteria
Jascayd (nerandomilast)	Patient meets ONE of the following (1, 2, 3, 4, or 5) 1. Patient has tried generic pirfenidone tablets or capsules **[documentation required]** 2. Patient has hepatic impairment. 3. Patient's glomerular filtration rate (eGFR) is < 30 mL/min. 4. Patient cannot swallow tablets or capsules OR has difficulty swallowing tablets or capsules. 5. Patient has already been started on therapy with Jascayd. Note: If the patient has tried Esbriet capsules or pirfenidone 534 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.

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; October 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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	02/01/2026

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