Clinical Policy: Nerandomilast (Jascayd)

Reference Number: NH.PHAR.759
Effective Date: 04.26
Last Review Date: 04.26
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Nerandomilast (Jascayd®) is a phosphodiesterase 4 (PDE4) inhibitor.

FDA Approved Indication(s)
Jascayd is indicated in adult patients for the treatment of:
- Idiopathic pulmonary fibrosis (IPF)
- Progressive pulmonary fibrosis (PPF)

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Jascayd is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets both of the following (a and b):
   a. Pulmonary fibrosis on high resolution computed tomography (HRCT) with one of the following (i or ii):
      i. Usual interstitial pneumonia (UIP) pattern;
      ii. Probable or indeterminate UIP pattern, and surgical lung biopsy, cellular analysis of bronchoalveolar lavage fluid, or transbronchial lung cryobiopsy confirms the diagnosis of IPF;
   b. Known causes of pulmonary fibrosis have been ruled out (*see Appendix D*);
5. Baseline forced vital capacity (FVC) ≥ 45% of predicted;
6. Baseline carbon monoxide diffusing capacity (DLCO) ≥ 25% of predicted;
7. If baseline FVC ≥ 50% and DLCO ≥ 30%, failure of ONE of the following (a or b) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated:
   a. Generic pirfenidone;
   b. Ofev®;
8. Request does not exceed health plan-approved quantity limit, if applicable;

9. Dose does not exceed both of the following (a and b):
    a. 36 mg per day;
    b. 2 tablets per day.

Approval duration: 12 months

B. Progressive Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of one of the following interstitial lung diseases (ILD) manifesting PPF (a, b, c, or d):
    a. Idiopathic interstitial pneumonia;
    b. Autoimmune ILD (e.g., rheumatoid arthritis-related ILD, mixed connective tissue disease-associated ILD, systemic sclerosis-associated ILD);
    c. Environmental/occupational exposure-related ILD (e.g. hypersensitivity pneumonitis);
    d. Sarcoidosis;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. For new starts only: Member meets both of the following within the past 24 months (a and b):
    a. Pulmonary fibrosis affecting > 10% of lung volume on HRCT;
    b. Documentation of one of the following (i or ii):
        i. A relative decline in the FVC of ≥ 10% of the predicted value;
        ii. A relative decline in the FVC of 5% to < 10% of the predicted value plus either worsening of respiratory symptoms or an increased extent of fibrosis on HRCT;
5. Baseline FVC ≥ 45% of predicted;
6. Baseline DLCO ≥ 25% of predicted;
7. If baseline DLCO ≥ 30%, failure of Ofev at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
8. Request does not exceed health plan-approved quantity limit, if applicable;
9. Dose does not exceed both of the following (a and b):
    a. 36 mg per day;
    b. 2 tablets per day.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
    a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
    b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy;
3. Request does not exceed health plan-approved quantity limit, if applicable;
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 36 mg per day;
   b. 2 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ATS: American Thoracic Society
DLCO: carbon monoxide diffusing capacity
FDA: Food and Drug Administration
FVC: forced vital capacity
HRCT: high resolution computed tomography
ILD: interstitial lung disease
IPF: idiopathic pulmonary fibrosis
PDE4: phosphodiesterase 4
PPF: progressive pulmonary fibrosis
UIP: usual interstitial pneumonia

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
pirfenidone (Esbriet®)	**IPF** 801 mg PO TID	2,403 mg/day
Ofev (nintedanib)	**IPF and ILD** 150 mg PO BID	300 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: American Thoracic Society (ATS) 2022 IPF Guidelines

- ATS diagnostic criteria for IPF are built around pulmonary fibrosis findings on HRCT and exclusion of known causes of interstitial lung disease (e.g., domestic, and occupational environmental exposures, connective tissue disease, drug toxicity)
- UIP is the hallmark radiologic pattern of IPF. Honeycombing is a distinguishing feature of UIP and must be present for a definite HRCT diagnosis of UIP to be made.
- In patients with a probable or indeterminate UIP pattern, surgical lung biopsy, transbronchial lung cryobiopsy, or cellular analysis of bronchoalveolar lavage fluid is recommended to confirm the diagnosis of IPF. Patients with a probable UIP pattern can receive a diagnosis of IPF without confirmation by lung biopsy after multidisciplinary discussion in the appropriate clinical setting (e.g., 60 years old, male, smoker).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IPF, PPF	18 mg PO BID Reduce to 9 mg PO BID for patients who are unable to tolerate 18 mg PO BID, except in patients taking concomitant pirfenidone	36 mg/day

VI. Product Availability

Tablets: 9 mg, 18 mg

VII. References

1. Jascayd Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; December 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/220449s000lbl.pdf. Accessed December 26, 2025.
2. Richeldi L, Azuma A, Cottin V, et al; FIBRONEER-IPF Trial Investigators. Nerandomilast in patients with idiopathic pulmonary fibrosis. N Engl J Med. 2025 Jun 12;392(22):2193-2202. doi: 10.1056/NEJMoa2414108.
3. Maher TM, Assassi S, Azuma A, et al; FIBRONEER-ILD Trial Investigators. Nerandomilast in patients with progressive pulmonary fibrosis. N Engl J Med. 2025 Jun 12;392(22):2203-2214. doi: 10.1056/NEJMoa2503643.
4. Raghu G, Rochwerg B, Yuang Z, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015; 192(2): e3-e19.
5. 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: 788-824.
6. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT clinical Practice guideline: Diagnosis of idiopathic pulmonary fibrosis. Am J Respir Crit Care Med. 2018 September; 198(5): e44-68.
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): e18-47.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.26	04.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2025 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise

published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.