MEDICAL MUTUAL®

Drug Policy

Policy:	Jascayd (nerandomilast tablets)	Annual Review Date: 6/18/2026 Last Revised Date: 6/18/2026

OVERVIEW

Jascayd is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) and for treatment of progressive pulmonary fibrosis (PPF) in adults.[1] Ofev has two additional indications: slowing the rate of decline in pulmonary function in adults with systemic sclerosis-associated interstitial lung disease (ILD) and treatment of chronic fibrosing ILDs with a progressive phenotype in adults.[2] Of note, the terms PPF and chronic fibrosing ILDs with a progressive phenotype are used interchangeably.

POLICY STATEMENT

This policy involves the use of Jascayd. Prior authorization is recommended for pharmacy benefit coverage of Jascayd. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Jascayd be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

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; 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; AND

v. Patient meets ONE of the following (a, b, or c):
- **a)** Patient has tried pirfenidone and nintedanib for 90 days*; OR
- **b)** According to the prescriber, patient has tried but could not complete a 90-day trial of pirfenidone and nintedanib due to an intolerance*; OR
- **c)** According to the prescriber, patient cannot use pirfenidone and nintedanib due to a clinical contraindication*; OR

  Note: Examples of clinical contraindications include hepatic impairment, estimated glomerular filtration rate (eGFR) < 30mL/min, pregnancy, or being at high risk of coronary artery disease, bleeding events or gastrointestinal perforation.

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; 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. Patient meets ONE of the following (i, ii, or iii):

i. Patient has tried nintedanib for 90 days*; OR

ii. According to the prescriber, patient has tried but could not complete a 90-day trial of nintedanib due to an intolerance*; OR

iii. According to the prescriber, patient cannot use pirfenidone or nintedanib due to a clinical contraindication*;
Note: Examples of clinical contraindications include hepatic impairment, estimated glomerular filtration rate (eGFR) < 30mL/min, pregnancy, or being at high risk of coronary artery disease, bleeding events or gastrointestinal perforation. 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.

Initial Approval/ Extended Approval.
A) *Initial Approval: 12 months*
B) *Extended Approval: 12 months*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Jascayd has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Jascayd® tablets [prescribing information]. Ridgefield, CT: Boehringer Ingelheim; October 2025.
2. 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.