Effective Date: 03/13/2026
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Last P&T Approval/Version: 01/28/2026
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Policy Number: C30339-A

Jascayd (nerandomilast)

PRODUCTS AFFECTED

Jascayd (nerandomilast)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Idiopathic Pulmonary Fibrosis (IPF), Progressive pulmonary fibrosis (PPF)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. IDIOPATHIC PULMONARY FIBROSIS:
   1. Documented diagnosis of idiopathic pulmonary fibrosis (IPF)
      AND
   2. Documentation diagnosis was confirmed by one of the following [DOCUMENTATION REQUIRED]:
      a) the presence of usual interstitial pneumonia (UIP) on chest high-resolution computed tomography (HRCT) scan
         OR
      b) probable UIP on HRCT scan and lung biopsy
         [DOCUMENTATION REQUIRED: Submit chest HRCT scan or pathology report if a surgical lung biopsy was performed.]
      AND
   3. Documented baseline Forced Vital Capacity (%FVC) ≥ 45% of predicted and a carbon monoxide diffusing capacity (DLCO) greater than or equal to 25% of predicted for the member [DOCUMENTATION REQUIRED]
      AND
   4. Prescriber attests that member does not have other known causes of interstitial lung disease, including:
      a) No significant environmental exposure known to cause pulmonary fibrosis (e.g., drugs, asbestos, beryllium, radiation, raising birds/livestock, and metal)
         AND
      b) No known explanation for interstitial lung disease (e.g., radiation, sarcoidosis, hypersensitivity pneumonitis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV), viral hepatitis, and cancer),
         AND
      c) No diagnosis of any connective tissue disease known to cause interstitial lung disease (e.g., scleroderma, polymyositis/dermatomyositis, systemic lupus erythematosus, and rheumatoid arthritis)
      AND
   5. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of moderate or strong CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, efavirenz, St. John's wort).
      AND
   6. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).
      MOLINA REVIEWER NOTE: For Illinois Marketplace, please see Appendix

B. PROGRESSIVE PULMONARY FIBROSIS:
   1. Documented diagnosis of progressive pulmonary fibrosis (PPF) (e.g., connective tissue disease-related ILDs (CTD-ILDs) such as those related to rheumatoid arthritis (RA-ILD), and polymyositis/dermatomyositis; ILD related to chronic sarcoidosis; chronic hypersensitivity pneumonitis (HP); idiopathic non-specific interstitial pneumonia (iNSIP); and unclassifiable ILD)
      AND
   2. Documentation member has fibrosing lung disease affecting more than 10% of lung volume on chest high-resolution computed tomography (HRCT) scan [DOCUMENTATION REQUIRED]

AND

3. Documented baseline Forced Vital Capacity (%FVC) ≥ 45% of predicted and a carbon monoxide diffusing capacity (DLCO) greater than or equal to 25% of predicted for the member [DOCUMENTATION REQUIRED]
   AND
4. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of moderate or strong CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, efavirenz, St. John's wort).

CONTINUATION OF THERAPY:

A. IDIOPATHIC PULMONARY FIBROSIS, PROGRESSING PULMONARY FIBROSIS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
      AND
   2. Documentation of positive clinical response or disease stabilization as demonstrated by one of the following [DOCUMENTATION REQUIRED]:
      a) < 10% decline in percent predicted FVC [NOTE: A >10% decline in FVC over a 12-month period indicates disease progression and continuation of treatment will not be authorized]
         OR
      b) < 15% decline in predicted DLCO during a 6-month period

      AND
   3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
      AND
   4. Prescriber attests a recent review of member's current medication has been completed and there is no concomitant use of moderate or strong CYP3A inducers (e.g., carbamazepine, rifampin, phenobarbital, efavirenz, St. John's wort).

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by, or in consultation with, a board-certified pulmonologist or a specialist in the treatment of interstitial lung disease. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

18 mg twice daily
Concomitant use with pirfenidone: 18 mg twice daily (do not reduce to 9 mg twice daily)

Maximum Quantity Limits –

Concomitant use with strong CYP3A inhibitors (e.g., ketoconazole, ritonavir): Reduce nerandomilast to 9 mg twice daily

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Pulmonary Fibrosis Agents - Phosphodiesterase 4 (PDE4) Inhibitor

FDA-APPROVED USES:
Indicated for the treatment of idiopathic pulmonary fibrosis in adult patients and the treatment of progressive pulmonary fibrosis in adult patients.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Illinois (Source: Illinois General Assembly)
"(215 ILCS 134/45.1) Sec. 45.1. Medical exceptions procedures required. (c) An off-formulary exception request shall not be denied if: (1) the formulary prescription drug is contraindicated; (2) the patient has tried the formulary prescription drug while under the patient's current or previous health insurance or health benefit plan and the prescribing provider submits evidence of failure or intolerance; or (3) the patient is stable on a prescription drug selected by his or her health care provider for the medical condition under consideration while on a current or previous health insurance or health benefit plan. (d) Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize the coverage for the drug prescribed by the enrollee's treating health care provider, to the extent the prescribed drug is a covered drug under the policy or contract up to the quantity covered. (e) Any approval of a medical exception request made pursuant to this Section shall be honored for 12 months following the date of the approval or until renewal of the plan."

APPENDIX 1
Diffusing Capacity for Carbon Monoxide (DLCO) is used to measure the ability of the lungs to transfer gas from inhaled air to the red blood cells in pulmonary capillaries. The normal values for CO diffusing capacity vary widely between laboratories, and both absolute values and their reproducibility are largely influenced by the measurement technique. Therefore, this measurement is most useful if the patient's lung function changes are followed consistently by the same laboratory.

Forced vital capacity (FVC) is a widely used measure of disease status and a common endpoint in clinical trials in patients with idiopathic pulmonary fibrosis. FVC is measured via spirometry.

High-resolution computed tomography (HRCT) provides more detail than either chest radiography or conventional CT scanning, with an overall sensitivity of 95 percent and a specificity approaching 100 percent. Compared to chest radiography, HRCT can more accurately assess the pattern and distribution of diffuse lung disease, which may be beneficial when trying to narrow the differential diagnosis or define a target for lung biopsy.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Idiopathic Pulmonary Fibrosis (IPF) is a chronic, progressive fibrosing interstitial lung disease of unknown cause, characterized by scarring of lung tissue and a usual interstitial pneumonia (UIP) pattern. It primarily affects adults over 60 years, with a median survival of 3–5 years from diagnosis without treatment.

Diagnosis follows ATS/ERS/JRS/ALAT guidelines and includes chest high-resolution computed tomography (HRCT) to identify UIP pattern and lung biopsy if HRCT is inconclusive. Other causes such as connective tissue disease, drug toxicity, and environmental exposures must be excluded.

The goals of treatment include: slow disease progression, preserve lung function, and improve quality of life. Current approved pharmacologic options include antifibrotics: Pirfenidone (Esbriet) and Nintedanib (Ofev), which reduce FVC decline but do not reverse fibrosis. Non-pharmacologic measures include pulmonary rehabilitation, supplemental oxygen, and early referral for lung transplantation.

The approval of Jascayd (nerandomilast) for IPF is supported by the results of two randomized, double-blind, placebo-controlled trials (FIBRONEER-IPF [NCT05321069] and Trial 2 [NCT04419506]).

In both the FIBRONEER-IPF trial and Trial 2, patients were required to have a diagnosis of IPF based on ATS/ERS/JRS/ALAT criteria. Diagnosis was confirmed by the investigator based on chest high-resolution computed tomography (HRCT) scan and, if available, lung biopsy, and usual interstitial pneumonia (UIP) or probable UIP HRCT pattern consistent with the clinical diagnosis of IPF. Patients were also required to have an FVC greater than or equal to 45% of predicted and a carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) greater than or equal to 25% of predicted.

The primary endpoint in FIBRONEER-IPF trial was the absolute change from baseline in forced vital capacity (FVC) in milliliters (mL) at 52 weeks for Jascayd (nerandomilast) compared with placebo.

At the conclusion of the FIBRONEER-IPF trial, patients treated with Jascayd (nerandomilast)

experienced a significantly smaller decline in forced vital capacity (FVC) compared to placebo. Adjusted mean decline: Jascayd 18 mg: –106 mL, Jascayd 9 mg: –122 mL, Placebo: –170 mL.

The FIBRONEER-ILD trial was a large Phase 3 randomized, double-blind, placebo-controlled study evaluating nerandomilast (Jascayd) for the treatment of progressive pulmonary fibrosis (PPF), a serious interstitial lung disease characterized by gradually worsening lung scarring. The trial enrolled approximately 1,100–1,178 adults with PPF, many of whom were already receiving background therapy with nintedanib. Participants were required to have a forced vital capacity (FVC) of at least 45% and DLCO of at least 25% of predicted values, ensuring enrollment of patients with measurable functional decline. Participants were evenly randomized to receive either nerandomilast 18 mg, nerandomilast 9 mg, or placebo, all taken twice daily for at least 52 weeks.

The primary endpoint was the change in FVC at week 52. Nerandomilast demonstrated clear, clinically meaningful benefits by slowing lung function decline compared with placebo. Patients receiving 18 mg experienced a decline of −86 mL, while those receiving 9 mg declined by −69 mL, compared with −152 mL in the placebo group. These differences corresponded to treatment benefits of 65 mL and 83 mL, respectively. An independent set of results later published in the New England Journal of Medicine reported similar findings, further reinforcing the robustness of the study outcomes.

In terms of secondary outcomes, nerandomilast did not show a statistically significant difference when compared with placebo for the composite endpoint of first acute ILD exacerbation, respiratory hospitalization, or death over the 52-week period. However, long-term follow-up extending to 114 weeks revealed an important survival signal: both nerandomilast doses were associated with a hazard ratio of 0.51 for all-cause mortality compared with placebo, suggesting a potential reduction in mortality risk that may emerge over time. Additional analyses also suggested trends toward fewer acute disease flares and respiratory hospitalizations, though these did not consistently reach statistical significance.

The safety profile of Jascayd in the FIBRONEER-ILD trial was consistent with observations from earlier idiopathic pulmonary fibrosis studies. Diarrhea was the most frequently reported adverse event and occurred more often in patients on concurrent nintedanib therapy. Rates of treatment discontinuation due to adverse effects were comparable across study arms—10.0% for the 18 mg dose, 8.1% for the 9 mg dose, and 10.2% for placebo—indicating overall good tolerability. Other adverse effects included weight loss, decreased appetite, nausea, and upper respiratory infections, but no new safety concerns were identified.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Jascayd (nerandomilast) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Jascayd (nerandomilast) include: No labeled contraindications. Avoid use of Jascayd (nerandomilast) with strong or moderate CYP3A inducers.

Exclusions/Discontinuation:

Use of Jascayd (nerandomilast) is not recommended in patients with end stage renal disease (eGFR <15 mL/min/1.73 m2).

Use of Jascayd (nerandomilast) is not recommended in patients with severe (Child-Pugh Class C) hepatic impairment.

OTHER SPECIAL CONSIDERATIONS:

Jascayd (nerandomilast) should be swallowed whole or dispersed in water for patients with swallowing difficulty.

Reduce Jascayd (nerandomilast) to 9 mg twice daily for patients who are unable to tolerate 18 mg twice daily, except in patients who concomitantly use Jascayd (nerandomilast) with pirfenidone.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Jascayd TABS 9MG

Jascayd TABS 18MG

REFERENCES

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patients with idiopathic pulmonary fibrosis. Chest. Published online February 18, 2025. doi:10.1016/j.chest.2025.02.018
5. Wuyts WA, Wijsenbeek M, Bondue B, et al. Idiopathic pulmonary fibrosis: Best practice in monitoring and managing a relentless fibrotic disease. Respiration. 2020;99(1):73-82. doi:10.1159/000504763
6. AJMC Contributor. (2025, May 22). Real-world findings suggest new look at thresholds for IPF progression. The American Journal of Managed Care. Retrieved from https://www.ajmc.com/view/real-world-findings-suggest-new-look-at-thresholds-for-ipf-progression
7. Boehringer Ingelheim. (n.d.). A study to test different doses of BI 1015550 in people with progressive fibrosing interstitial lung diseases (FIBRONEER-ILD) (ClinicalTrials.gov Identifier: NCT05321082). ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT05321082

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q1 2026