

DRUG POLICY

Jascayd® (nerandomilast)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Jascayd is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis in adult patients.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Chart notes, medical record documentation or claims history supporting diagnosis.
2. Chart notes or medical record documentation of result of a chest high-resolution computed tomography (HRCT) study.
3. Chart notes or medical record documentation of pathology report of lung biopsy (if performed).

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following: Pulmonologist

Criteria for Initial Approval

Idiopathic Pulmonary Fibrosis (IPF)

Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:

1. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded

AND

2. The member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern, OR has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

AND

3. Member has had an inadequate response, intolerance, or contraindication to Ofev or a generic antifibrotic (pirfenidone).

Progressive Pulmonary Fibrosis (PPF)

Authorization of 12 months may be granted for treatment of progressive pulmonary fibrosis when the following criteria are met:

1. The member has completed a high-resolution computed tomography (HRCT) study of the chest which reveals fibrosing lung disease, defined as reticular abnormality with traction bronchiectasis, with or without honeycombing, with fibrosis affecting more than 10% of the lungs.
2. HRCT study does not show widespread consolidation or progressive massive fibrosis
3. The member meets at least one of the following criteria for progression of interstitial lung disease within the last 24 months, despite standard treatment with an agent other than nintedanib (Ofev) or pirfenidone (Esbriet):
 - a. A relative decline in the FVC of at least 10% of the predicted value
 - b. A relative decline in the FVC of 5% to less than 10% of the predicted value combined with at least one of the following:
 - Worsening of respiratory symptoms
 - Increased extent of fibrosis on HRCT
 - c. Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only

Continuation of Therapy

Idiopathic Pulmonary Fibrosis

All members (including new members) requesting authorization for continuation of therapy may be granted an authorization of 12 months when the member is currently receiving treatment with Jascayd (nerandomilast), excluding when Jascayd (nerandomilast) is obtained as samples or via manufacturer's patient assistance programs.

Progressive Pulmonary Fibrosis

All members (including new members) requesting authorization for continuation of therapy may be granted an authorization of 12 months when the member is currently receiving treatment with Jascayd (nerandomilast), excluding when Jascayd (nerandomilast) is obtained as samples or via manufacturer's patient assistance programs.

Jascayd (nerandomilast) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking/vaping cessation options.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Jascayd (nerandomilast) 18 mg tablets	60 tablets per 30 days	18 mg orally twice daily when used concomitantly with pirfenidone
Jascayd (nerandomilast) 9 mg tablets	60 tablets per 30 days	9 mg twice daily for patients who are unable to tolerate 18 mg twice daily, except in patients who concomitantly use Jascayd with pirfenidone

REFERENCES

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3. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for systemic sclerosis-associated interstitial lung disease. N Engl J Med. 2019;380(26):2518-2528.

4. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. *Arthritis Rheum.* 2013;65(11):2737-47.
5. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. *N Engl J Med.* 2019;381(18):1718-1727.
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7. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. *Ann Rheum Dis.* 2024;0:1-12.
8. Richeldi L, Azuma A, Cottin V, et al. Nerandomilast in Patients with Idiopathic Pulmonary Fibrosis. *N Engl J Med.* 2025;392:2193-202.
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POLICY HISTORY

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