Nerandomilast (JASCAYD) in Idiopathic Pulmonary Fibrosis (IPF) and Non-IPF Interstitial Lung Disease with Progression (PPF) Criteria for Use April 2026

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive nerandomilast.

- ☐ Severe hepatic impairment (Child Pugh C)
- ☐ End stage renal disease (eGFR less than 15 ml/min/1.73 m^2)
- ☐ Recent, active, or uncontrolled vasculitis
- ☐ Patients with severe depression or suicidal ideation or behavior unless a mental health consultant concurs with nerandomilast treatment^1
- ☐ Concurrent use of CYP3A inducer (decreased nerandomilast exposure)

Inclusion Criteria

All of the following criteria must be met.

- ☐ Care provided by VA/VA Community Care pulmonologist experienced in the management of interstitial lung disease (ILD)
- ☐ Confirmed interstitial pulmonary fibrosis (IPF) diagnosis or non-IPF interstitial lung disease with progression, using clinical, radiologic and if applicable, histopathologic information^2^3
- ☐ For monotherapy when there is a contraindication, intolerance, or inadequate response to nintedanib (and pirfenidone in IPF) or for additive therapy to either pirfenidone or nintedanib when further efficacy is desired

Additional Inclusion Criteria

For patients with non-IPF interstitial lung disease with progression, ONE of the following criteria for progression must be met in past 24 months.

- ☐ Relative decline in FVC of 10% or more of predicted
- ☐ Relative decline in FVC of 5% to less than 10% of predicted and: 1) worsening of respiratory symptoms; or 2) increased extent of fibrotic changes on imaging
- ☐ Worsening of respiratory symptoms and increased extent of fibrotic changes on imaging

Additional Inclusion Criteria

Select if applicable.

- ☐ **Patients continuing treatment with pirfenidone and adding nerandomilast**: Prescribed the 18 mg twice daily dose of nerandomilast (nerandomilast dose should not be reduced).
- ☐ **For patients who can become pregnant:** Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy.
- ☐ **For patients who are lactating and providing breastmilk to infant:** Counseling provided on potential risks vs. benefits of treatment.

Footnotes

^1 Other PDE4 inhibitors are associated with psychiatric adverse effects. Patients with severe depression or suicidal behavior or ideation were excluded from the nerandomilast clinical trials. Depression was the most commonly reported psychiatric adverse event in the IPF population, with an excess in the nerandomilast-treated groups relative to placebo. There were few reports of suicidal ideation in all treatment groups.

^2For IPF, confirmation of diagnosis requires exclusion of other identifiable causes of interstitial lung disease (ILD), high resolution CT scan showing usual interstitial pneumonia (UIP) pattern or probable UIP pattern, or indeterminate pattern for UIP with histological confirmation of IPF.

^3 Fornon-IPF interstitial lung disease with progression (also known as “progressive pulmonary fibrosis, or PPF”), in addition to the non-IPF interstitial lung disease diagnosis, patients must have markers for progression (See Additional Inclusion Criteria for non-IPF interstitial lung disease with progression). PPF is not a diagnosis but a pattern of disease progression.

^4 Nerandomilast may be appropriate as monotherapy or add-on therapy in IPF and non-IPF interstitial lung disease with progression. The most common adverse effect with nerandomilast, diarrhea, occurs more frequently when combined with nintedanib and may reduce tolerability.

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Contact: Lisa Longo, PharmD, BCPS, National Program Manager, VA Pharmacy Benefits Management Services – Formulary Management (12PBM)