09-J5000-48

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Subject: Interstitial Lung Disease (ILD)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Idiopathic pulmonary fibrosis is defined as a specific form of chronic, progressive fibrosing interstitial pneumonia of unknown cause, occurring primarily in older adults, limited to the lungs, and associated with the histopathologic and/or radiologic pattern of usual interstitial pneumonia (UIP). It is characterized by progressive worsening of dyspnea and lung function and is associated with a poor prognosis.

The American Thoracic Society published guidelines for the diagnosis and management of IPF in 2011, with an update to treatment recommendations in 2015. According to those guidelines, the diagnosis of IPF requires exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), the presence of a UIP pattern on high-resolution computed tomography (HRCT) in patients not subjected to surgical lung biopsy, and specific combinations of HRCT and surgical lung biopsy pattern in patients subjected to surgical lung biopsy.

Nerandomilast (Jascayd)

Nerandomilast (Jascayd) was approved by the U.S. Food and Drug Administration (FDA) in October 2025 as a breakthrough therapy for the treatment of idiopathic pulmonary fibrosis (IPF) in adults. Prior to FDA approval, nerandomilast was designated as an orphan drug for this same indication. In December 2025, nerandomilast was approved for progressive pulmonary fibrosis (PPF) in adults.

Nerandomilast is a preferential inhibitor of phosphodiesterase (PDE) 4 that reduces pro-inflammatory cytokine release and fibroblast release. This mechanism of action differs from that of antifibrotic treatments (nintedanib and pirfenidone).

Idiopathic Pulmonary Fibrosis (IPF)

The safety and efficacy of nerandomilast were evaluated in a double-blind, randomized, placebo controlled clinical trial (FIBRONEER-IPF, NCT05321069) in adults with IPF with or without background antifibrotic treatments (n=1,177). Patients were required to have a diagnosis of IPF confirmed by investigator with chest HRCT scan (UIP or probable UIP HRCT pattern) or lung biopsy, FVC greater than or equal to 45% of predicted normal, naïve to antifibrotics or stable on either nintedanib or pirfenidone. Patients were randomized 1:1:1 to receive nerandomilast 18 mg twice daily, nerandomilast 9 mg twice daily, or placebo.

The primary outcome of adjusted mean change in FVC from baseline was significantly lower in those receiving nerandomilast compared to placebo at 52 weeks:

- Nerandomilast 18 mg: FVC change of -114.7 mL (95% CI, -141.8 to -87.5), [adjusted difference vs placebo, 68.8 mL (95% CI, 30.3 to 107.4)]
- Nerandomilast 9 mg: FVC change of -138.6 mL (95% CI, -165.6 to -111.6) [adjusted difference vs placebo, 44.9 mL (95% CI, 6.4 to 83.3)]
- Placebo: FVC change of -183.5 mL (95% CI, -210.9 to -156.1)

Among subgroups, there was a significant difference from placebo with nerandomilast in combination with background nintedanib. Results from patients receiving background pirfenidone or no background antifibrotic therapy were not significantly different than placebo for both dosage groups; however, numbers were consistent with the overall population (except for nerandomilast 9 mg in combination with pirfenidone). The study was not powered to measure differences from placebo in the individual subgroups. Composite secondary endpoint of first acute exacerbation, respiratory-related hospitalization, or death was not different between groups (18 mg: 21.7%, 9 mg: 20.2%, Placebo: 20.4%).

Diarrhea was the most common adverse event overall and the most common event leading to treatment discontinuation:

- Nerandomilast 18 mg: 41.3% (6% severe)
- Nerandomilast 9 mg: 31.1% (4% severe)
- Placebo: 16% (2% severe)
- Led to discontinuation: 6.1% (18 mg), 1.8% (9 mg), 0.5% (placebo)

Progressive Pulmonary Fibrosis

The safety and efficacy of nerandomilast were evaluated in a double-blind, randomized, placebo controlled clinical trial (FIBRONEER-ILD, NCT05321082) in adults with progressive pulmonary fibrosis with or without background treatment with nintedanib. Patients were required to have a diagnosis of progressive fibrosing interstitial lung disease (ILD) other than IPF confirmed by investigator with chest HRCT scan (UIP or probable UIP HRCT pattern) or lung biopsy, FVC greater than or equal to 45% of predicted normal, naïve to nintedanib or stable on nintedanib. Patients were randomized 1:1:1 to receive nerandomilast 18 mg twice daily, nerandomilast 9 mg twice daily, or placebo.

The primary outcome of adjusted mean change in FVC from baseline was significantly lower in those receiving nerandomilast compared to placebo at 52 weeks:

- Nerandomilast 18 mg: FVC change of -98.6 mL (95% CI, -123.7 to -73.4), [adjusted difference vs placebo, 67.2 mL (95% CI, 31.9 to 102.5)]
- Nerandomilast 9 mg: FVC change of -94.6 mL (95% CI, -109.6 to -59.7) [adjusted difference vs placebo, 81.1 mL (95% CI, 46.0 to 116.3)]
- Placebo: FVC change of -165.8 mL (95% CI, -190.5 to -141.0)

Among subgroups, there was a significant difference from placebo with nerandomilast in combination with background nintedanib. The study was not powered to measure differences from placebo in the individual subgroups. Composite secondary endpoint of first acute exacerbation, respiratory-related hospitalization, or death was not different between groups.

Diarrhea was the most common adverse event overall and the most common event leading to treatment discontinuation:

- Nerandomilast 18 mg: 36.6% (2.1% severe)
- Nerandomilast 9 mg: 29.5% (1.7% severe)
- Placebo: 24.7% (1% severe)

Adverse events that led to discontinuation occurred in 10%, 8.1%, 10% of nerandomilast 18 mg, 9 mg, and placebo groups, respectively.

Nintedanib (Ofev)

Nintedanib (Ofev®) was approved by the U.S. Food and Drug Administration (FDA) in October 2014 as a breakthrough therapy for the treatment of idiopathic pulmonary fibrosis (IPF). Prior to FDA approval, nintedanib was designated as an orphan drug for this same indication. In 2019, nintedanib was FDA approved for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD). Nintedanib inhibits multiple receptor tyrosine kinases.

INPULSIS-1 (Safety and Efficacy of BIBF 1120 at High Dose in Idiopathic Pulmonary Fibrosis Patients) and INPULSIS-2 (Safety and Efficacy of BIBF 1120 at High Dose in Idiopathic Pulmonary Fibrosis Patients II) were replicate phase 3 RCTs that enrolled a total of 1,066 patients in a 3:2 ratio to receive 150 mg of nintedanib twice daily versus placebo. Patients were required to have a diagnosis of IPF for less than five years and with an FVC greater than or equal to 50%. Nintedanib significantly reduced the annual rate of FVC decline compared with placebo in the INPULSIS-1 (-114.7 vs -239.9 mL) and the INPULSIS-2 (-113.6 vs -207.3 mL) randomized trials.

Nintedanib significantly reduced acute exacerbations (3.6% vs 9.6%), time to first acute exacerbation, and quality of life in INPULSIS-2 but not in INPULSIS-1. Considering these trials as one, there was no significant benefit of nintedanib on mortality (RR, 0.70; 95% CI, 0.44–1.11) or acute exacerbation of IPF (HR, 0.64; 95% CI, 0.39–1.05). However, fewer patients treated with nintedanib had a more than 10% absolute decline in FVC during the study period (RR, 1.16; 95% CI, 1.06–1.27).

Pirfenidone (Esbriet)

Pirfenidone (Esbriet®) was approved by the U.S. Food and Drug Administration (FDA) in October 2014 as a breakthrough therapy for the treatment of idiopathic pulmonary fibrosis (IPF). Prior to FDA approval, pirfenidone was designated as an orphan drug for this same indication.

The CAPACITY trial reported on two independent study protocols: study 004 included 435 patients randomized to one of three treatment groups (high-dose pirfenidone [2,403 mg/d], low-dose pirfenidone [1,197 mg/d], and placebo), whereas study 006 had 344 patients randomized to only two treatment groups (high-dose pirfenidone [2,403 mg/d] and placebo). Patients were eligible if they were diagnosed with IPF and had a FVC greater than or equal to 50%. The results of the low-dose pirfenidone group were intermediate to the higher dose, and to avoid heterogeneity of intervention, we chose to focus on the results of the high-dose pirfenidone group versus those of the placebo group across both studies. In study 004, pirfenidone showed a reduction in decline of FVC during the 72-week treatment period. Study 006 did not show a benefit in the same outcome during the same period. Importantly, patients from both studies who were assigned to receive high-dose pirfenidone reported increased rates of nausea, dyspepsia, vomiting, anorexia, photosensitivity, and rash compared with placebo.

The ASCEND trial (A Randomized, Double-Blind, Placebo Controlled Trial of Pirfenidone in Patients with Idiopathic Pulmonary Fibrosis) randomized 555 patients with IPF to either high-dose pirfenidone (2,403 mg/d) or placebo (38). As opposed to the CAPACITY trials, the ASCEND trial had stricter patient selection criteria, such as a FEV1/FVC ratio below 0.8 (FVC required to be greater than 50%). Of 1,562 screened patients, 1,007 were excluded because of these predefined exclusion criteria. Pirfenidone significantly reduced the proportion of patients who had a more than 10% decline in their FVC during the 52-week follow-up period (47% reduction in pirfenidone group vs placebo). Pirfenidone treatment increased 6-minute-walk distance and progression-free survival when compared with placebo. Mortality or dyspnea scores did not differ. Consistent with previous studies, patients randomized to pirfenidone reported more treatment-related adverse effects.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Nerandomilast (Jascayd)

Initiation of nerandomilast (Jascayd) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member is diagnosed with any of the following:
    a. Idiopathic pulmonary fibrosis (IPF) confirmed by **ONE** of the following:
        i. Presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) – imaging documentation must be provided
        ii. Surgical lung biopsy – lung biopsy documentation must be provided

b. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype confirmed by **BOTH** of the following:

i. Presence of fibrosis affecting at least 10% of the lungs on high-resolution computed tomography (HRCT) – imaging documentation must be provided

ii. Clinical signs of disease progression resulting in declining FVC, worsening symptoms, or worsening imaging – documentation from the medical record must be provided

2. Member's forced vital capacity (FVC) is equal to or greater than 45% of the predicted FVC – documentation of assessment within the most recent 6 months must be provided
3. Nerandomilast is prescribed by a pulmonologist or rheumatologist
4. Dose does not exceed 18 mg twice daily – dosage will be achieved using the fewest number of tablets per day

Approval duration: 6 months

Continuation of nerandomilast (Jascayd) **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for treatment of IPF or chronic fibrosing ILD with a progressive phenotype, **OR** the member has previously met all indication-specific initiation criteria
2. Member is receiving clinical benefit from treatment with nerandomilast – documentation from the medical must be provided
3. Nerandomilast is prescribed by a pulmonologist or rheumatologist
4. Dose does not exceed 18 mg twice daily – dosage will be achieved using the fewest number of tablets per day

Approval duration: 12 months

<u>Nintedanib (Ofev)</u>

Initiation of nintedanib (Ofev) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member is diagnosed with any of the following:
    a. Idiopathic pulmonary fibrosis (IPF) confirmed by **ONE** of the following:
        i. Presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) – imaging documentation must be provided
        ii. Surgical lung biopsy – lung biopsy documentation must be provided
    b. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) confirmed by **BOTH** of the following:
        i. Presence of fibrosis affecting at least 10% of the lungs on high-resolution computed tomography (HRCT) – imaging documentation must be provided

ii. One of the following – documentation from the medical record must be submitted:

1. Skin thickening of the fingers of both hand extending proximal to the metacarpophalangeal joints
2. Two or more of the following:
    a. Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
    b. Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
    c. Telangiectasia
    d. Abnormal nailfold capillaries
    e. Pulmonary arterial hypertension
    f. Raynaud's phenomenon
    g. Sc-related autoantibodies (e.g., anticentromere, anti-topoisomerase I, anti-RNA polymerase III)

c. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype confirmed by **BOTH** of the following:

i. Presence of fibrosis affecting at least 10% of the lungs on high-resolution computed tomography (HRCT) – imaging documentation must be provided

ii. Clinical signs of disease progression resulting in declining FVC, worsening symptoms, or worsening imaging – documentation from the medical record must be provided

2. Member's forced vital capacity (FVC) is equal to or greater than 40% of the predicted FVC – documentation of assessment within the most recent 6 months must be provided
3. Member does not have moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment (see table 1)
4. Nintedanib is prescribed by a pulmonologist or rheumatologist
5. Use will not be in combination with pirfenidone (Esbriet)
6. Dose does not exceed 150 mg twice daily – dosage will be achieved using the fewest number of capsules per day

Approval duration: 6 months

Continuation of nintedanib (Ofev) **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for treatment of IPF, SSc-ILD, or chronic fibrosing ILD with a progressive phenotype, **OR** the member has previously met all indication-specific initiation criteria
2. Member is receiving clinical benefit from treatment with nintedanib – documentation from the medical must be provided

3. Nintedanib is prescribed by a pulmonologist or rheumatologist
4. Use is not in combination with pirfenidone (Esbriet)
5. Dose does not exceed 150 mg twice daily – dosage will be achieved using the fewest number of capsules per day

Duration of approval: 12 months

Pirfenidone (Esbriet)

Initiation of pirfenidone (Esbriet®) **meets the definition of medical necessity** when **ALL** of the following criteria are met:

1. Member is diagnosed with idiopathic pulmonary fibrosis (IPF) confirmed by **ONE** of the following:
    a. Presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) – imaging documentation must be provided
    b. Surgical lung biopsy – lung biopsy documentation must be provided
2. Member's interstitial lung disease has not resulted from known causes (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity)
3. Member's forced vital capacity (FVC) is equal to or greater than 50% of the predicted FVC – documentation of assessment within the most recent 6 months must be provided
4. Member does not have severe (Child Pugh C) hepatic impairment (see Table 1)
5. Pirfenidone is prescribed by a pulmonologist
6. Use is not in combination with nintedanib (Ofev)
7. Member meets one of the following:
    a. Requested product is generic pirfenidone
    b. Requested product is brand Esbriet **AND** the member has tried and had intolerable adverse effects to generic pirfenidone – **ALL** of the following must be submitted:
        i. The specific intolerance(s) and rationale for using brand Esbriet must be specified
        ii. Completed Medwatch reporting form (FDA 3500) – https://www.fda.gov/safety/medical-product-safety-information/formsreporting-fda
        iii. Completed Naranjo Adverse Drug reaction probability scale - https://assets.guidewell.com/m/2736e82ff52fe22d/original/mcgnaranjoalgorithm.pdf
8. Dose does not exceed 801 mg three times daily – dosage will be achieved using the fewest number of capsules or tablets per day

Approval duration: 6 months

Continuation of pirfenidone (Esbriet®) **meets the definition of medical necessity** for members meeting the following criteria:

1. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years for treatment of IPF, **OR** the member has previously met all indication-specific initiation criteria
2. Member is receiving clinical benefit from treatment with pirfenidone – documentation from the medical must be provided
3. Pirfenidone is prescribed by a pulmonologist
4. Use is not in combination with nintedanib (Ofev)
5. Member meets one of the following:
    a. Requested product is generic pirfenidone
    b. Requested product is brand Esbriet **AND** the member has tried and had intolerable adverse effects to generic pirfenidone – **ALL** of the following must be submitted:
        i. The specific intolerance(s) and rationale for using brand Esbriet must be specified
        ii. Completed Medwatch reporting form (FDA 3500) – https://www.fda.gov/safety/medical-product-safety-information/formsreporting-fda
        iii. Completed Naranjo Adverse Drug reaction probability scale - https://assets.guidewell.com/m/2736e82ff52fe22d/original/mcgnaranjoalgorithm.pdf
6. Dose does not exceed 801 mg three daily – dosage will be achieved using the fewest number of capsules or tablets per day

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

FDA-approved

Nerandomilast (Jascayd)

- 18 mg twice daily, administered orally (swallow tablets whole or dispersed in water) approximately 12 hours apart, with or without food

Nintedanib (Ofev)

- 150 mg twice daily, with food

Pirfenidone (Esbriet)

- 801 mg (three capsules) three times daily, with food
- Upon initiation of treatment, titrate to the full dosage of 2403 mg/day over a 14-day period

Dose Adjustments

Nerandomilast (Jascayd)

- Reduce to 9 mg twice daily for patients who are unable to tolerate 18 mg twice daily, except in patients who concomitantly use with pirfenidone.
- Strong CYP3A Inhibitors: Reduce dosage to 9 mg twice daily.
- Moderate or Strong CYP3A Inducers: Avoid concomitant use

Nintedanib (Ofev)

- Recommended dosage in patients with mild hepatic impairment (Child Pugh A): 100 mg twice daily approximately 12 hours apart taken with food
- Consider temporary dose reduction to 100 mg, treatment interruption, or discontinuation for management of adverse reactions

Pirfenidone (Esbriet)

- Consider temporary dosage reduction, treatment interruption, or discontinuation for management of adverse reactions

Drug Availability

Nerandomilast (Jascayd)

- Tablets: 9 mg and 18 mg

Nintedanib (Ofev)

- Capsules: 150 mg and 100 mg

Pirfenidone (Esbriet)

- Capsules: 267 mg
- Tablets: 267 mg, 801 mg

PRECAUTIONS:

Boxed Warning

Nerandomilast (Jascayd)

- None

Nintedanib (Ofev)

- None

Pirfenidone (Esbriet)

- None

Contraindications

Nerandomilast (Jascayd)

- None

Nintedanib (Ofev)

- None

Pirfenidone (Esbriet)

- None

Precautions/Warnings

Nerandomilast (Jascayd)

- Diarrhea
- Weight decrease
- Decreased appetite

Nintedanib (Ofev)

- Elevated liver enzymes
- Gastrointestinal disorders, including perforation
- Embryofetal toxicity
- Arterial thromboembolic events
- Bleeding events

Pirfenidone (Esbriet)

- Elevated liver enzymes
- Gastrointestinal disorders, including perforation
- Photosensitivity

BILLING/CODING INFORMATION:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity: Nerandomilast

J84.112	Idiopathic pulmonary fibrosis
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere

ICD-10 Diagnosis Codes That Support Medical Necessity: Nintedanib

J84.112	Idiopathic pulmonary fibrosis
J84.10	Pulmonary fibrosis, unspecified
M34.81	Systemic sclerosis with lung involvement

ICD-10 Diagnosis Codes That Support Medical Necessity: Pirfenidone

J84.112	Idiopathic pulmonary fibrosis

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date. The Site of Care Policy for Select Specialty Medications does not apply to Medicare Advantage members.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

Table 1. Child-Pugh Classification of Severity of Liver Disease

Using the table below, a total score of 5-6 is considered grade A (well-compensated disease); 7-9 is grade B (significant functional compromise); and 10-15 is grade C (decompensated disease):

Parameter	Points Assigned		
	1	**2**	**3**
Ascites	Absent	Slight	Moderate
Bilirubin, mg/dL	</=2	2-3	>3
Albumin, g/dL	>3.5	2.8-3.5	<2.8
Prothrombin time • Seconds over control • INR	 1-3 <1.8	 4-6 1.8-2.3	 >6 >2.3
Encephalopathy	None	Grade 1-2	Grade 3-4

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 02/11/26.

GUIDELINE UPDATE INFORMATION:

04/01/26	New Medical Coverage Guideline: Merging MCGs 09-J2000-25, Nintedanib (Ofev®) Oral Capsules and 09-J2000-24, Pirfenidone (Esbriet®); Adding nerandomilast to position statement.