CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Ofev (nintedanib)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Ofev, approved by the FDA in 2014, is a kinase inhibitor indicated to treat idiopathic pulmonary fibrosis (IPF), to treat chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype, and to slow the rate of decline in pulmonary function in systemic sclerosis-associated interstitial lung disease (SSc-ILD).
Idiopathic pulmonary fibrosis (IPF), the most common of the interstitial lung diseases, is characterized by chronic, progressive scarring of the lungs and the pathological hallmark of usual interstitial pneumonia (UIP).
Systemic sclerosis (SSc), also known as scleroderma, is a rare autoimmune disease associated with vasculopathy, inflammation, and fibrosis of the skin and/or internal organs. ILD is a frequent complication and the leading cause of death in patients with SSc.
Progressive fibrosing ILDs encompass a wide range of diseases, including hypersensitivity pneumonitis, occupational diseases, granulomatous diseases, drug-induced diseases, and idiopathic pneumonitis.

Ofev (nintedanib) will be considered for coverage when the following criteria are met:

Idiopathic Pulmonary Fibrosis (IPF)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has a diagnosis of IPF confirmed by a UIP pattern on high resolution computed tomography (HRCT) or by a lung biopsy (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC); AND
5. Member does NOT have moderate to severe hepatic impairment (Child Pugh B or C); AND
6. Member is NOT a current smoker and provider attests the member will not smoke during treatment; AND
7. Ofev will not be prescribed in combination with Esbriet.
8. **Dosage allowed/Quantity limit:** 300 mg per day (150 mg twice daily)
   QL: 60 capsules per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by reduced rate of FVC decline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Fibrosing Interstitial Lung Diseases (ILD) with a Progressive Phenotype

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of Progressive Fibrosing ILD confirmed by high-resolution computed tomography (HRCT) showing fibrosis affecting at least 10% of the lungs (results must be submitted for review); AND
4. Member has at least 2 of the following:
   a) Worsening respiratory symptoms
   b) Physiological evidence of disease progression (i.e., decline in FVC ⩾5% predicted or DLCO ⩾10% predicted within the past year)
   c) Radiological evidence of disease progression within the past year (e.g., increased traction bronchiectasis, new ground glass opacity or fine reticulation, new/increased honeycombing, increased lobar volume loss); AND
5. Member does NOT have moderate to severe hepatic impairment; AND
6. Member is NOT a current smoker and provider attests the member will not smoke during treatment.
7. **Dosage allowed/Quantity limit:** 300 mg per day (150 mg twice daily)
   QL: 60 capsules per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by reduced rate of FVC decline

If all the above requirements are met, the medication will be approved for an additional 12 months.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of ILD associated with systemic sclerosis confirmed by high-resolution computed tomography (HRCT) showing fibrosis affecting at least 10% of the lungs (results must be submitted for review); AND
4. Documentation of baseline forced vital capacity (FVC); AND
5. Member meets one of the following:
   a) Lung disease has progressed despite a trial of mycophenolate mofetil or cyclophosphamide, or
   b) Initially presents with advanced or aggressive lung disease; AND
6. Member does NOT have moderate to severe hepatic impairment; AND
7. Member is NOT a current smoker and provider attests the member will not smoke during treatment.
8. **Dosage allowed/Quantity limit:** 300 mg per day (150 mg twice daily)
   QL: 60 capsules per 30 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate a slowed rate of pulmonary function decline, as evidenced by stabilized FVC or repeat HRCT.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Ofev (nintedanib) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/19/2020	New policy for Ofev created. Previously on IPF policy, now splitting from Esbriet, updating references, and adding new indications PF-ILD and SSc-ILD
05/24/2022	Policy transferred to new template. Updated references. Removed azathioprine trial option from SSc-ILD.
10/14/2024	SSc-ILD: Updated refs. Revised reauth wording and added HRCT option. Removed FVC >40 (keep baseline). Added aggressive or advanced lung disease as alternative to CYC/MMF trial requirement (Rahaghi 2023). PF-ILD: Updated refs. Removed FVC >45 and replaced with diagnostic criteria from new guideline (ATS 2022). IPF: Updated refs. Specified UIP presence on HRCT. Removed minimum FVC required. Added to not be used with Esbriet.

References:

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