CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Ofev (nintedanib)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Ofev is a kinase inhibitor indicated in adults initially approved by the FDA in 2014. It is used to treat multiple diseases affecting the lungs including idiopathic pulmonary fibrosis (IPF), chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype, and slowing the rate of decline in pulmonary function in patients with 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 high resolution computed tomography (HRCT) or lung biopsy (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 50% predicted; 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
7. **Dosage allowed/Quantity limit:** 300 mg per day (150 mg twice daily) (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 diffuse fibrosing lung disease of >10% extent on high-resolution computed tomography (HRCT) (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 45% predicted; 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) (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 member's baseline forced vital capacity (FVC) equal to or greater than 40% predicted; AND
5. Member's lung disease has progressed despite at least a 3-month trial of mycophenolate mofetil or cyclophosphamide, unless contraindicated; 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) (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.

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.

References:

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