CareSource

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Ofev (nintedanib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 60 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ofev (nintedanib) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IDIOPATHIC PULMONARY FIBROSIS (IPF)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has diagnosis of IPF confirmed by high resolution computed tomography (HRCT) or lung biopsy[3] (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; AND
6. Member is not a current smoker and provider attests the member will not smoke during treatment.
7. **Dosage allowed:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[7].

If member meets all the reauthorization requirements above, 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 18 years old or older; 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 presenting with features of diffuse fibrosing lung disease of >10% extent on high-resolution computed tomography (HRCT)[8] (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[8]; 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:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[8].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD)

For **initial** authorization:
1. Member is 18 years old or older; 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, presenting with high-resolution computed tomography (HRCT) showing fibrosis affecting at least 10% of the lungs[12] (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 40% predicted[12]; AND
5. Member's lung disease has progressed despite at least a 3 month trial of mycophenolate mofetil (MMF), cyclophosphamide, or azathioprine (MMF preferred)[10,13] 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:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[12].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ofev (nintedanib) not medically necessary for the treatment of the diseases that are not listed in this document.

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
11/17/2021	Annual review, no changes

References:

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