PHARMACY POLICY STATEMENT
North Carolina Marketplace

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.

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 comp283 0 Td[(hi)2q6.6 (i)d /LBod rionb ogutaphc
   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 treatm
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**:

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:

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2022.
2.

18. Hoffmann-Vold AM, Maher TM, Philpot EE, Ashrafzadeh A, Distler O. Assessment of recent evidence for the management of patients with systemic sclerosis-associated interstitial lung disease: a systematic review. *ERJ Open Res*. 2021;7(1):00235-2020. Published 2021 Feb 22. doi:10.1183/23120541.00235-2020

Effective date: 01/01/2023
Revised date: 05/24/2022