

Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 3/2024
Scope: Medicaid

Ofev
(nintedanib oral tablet)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Treatment of idiopathic pulmonary fibrosis (IPF)

Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype

Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (where applicable):

- A. Result of a chest high-resolution computed tomography (HRCT) study.
- B. If a lung biopsy is conducted, submit the associated pathology report.

III. CRITERIA FOR INITIAL APPROVAL

A. Treatment of IPF

An authorization may be granted for 6 months when the following criteria are met:

- 1. Prescriber is a pulmonologist or being prescribed in consultation with a pulmonologist.
- 2. Member is at least 18 years of age.
- 3. Documented diagnosis of IPF by all of the following criteria:
 - a. Exclusion of other known causes of interstitial lung disease (e.g., domestic, and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:
 - i. ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis);
AND
 - b. One of the following:
 - i. In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution

Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 3/2024
Scope: Medicaid

computed tomography (HRCT) revealing IPF or probable IPF;
OR

- ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF
- 4. Member is not concurrently taking in combination with Esbriet (pirfenidone).
- 5. Baseline liver function tests have been performed.

B. Treatment of chronic fibrosing ILDs with a progressive phenotype

An authorization may be granted for 6 months when the following criteria are met:

- 1. Prescriber is a pulmonologist or being prescribed in consultation with a pulmonologist.
- 2. Member is at least 18 years of age.
- 3. Diagnosis of chronic ILDs with a progressive phenotype as documented by both of the following:
 - a. Presence of fibroticILD as determined by finding evidence of pulmonary fibrosis on HRCT, involving at least 10% of the lungs
 - b. Patient is presenting with clinical signs of progression as defined by one of the following in the previous 24 months:
 - i. Forced vital capacity (FVC) decline of greater than 10%; OR
 - ii. Two of the following:
 - 1. FVC decline of greater than or equal to 5%, but less than 10%
 - 2. Patient is experiencing worsening respiratory symptoms
 - 3. Patient is exhibiting increasing extent of fibrotic changes on chest imaging.
- 4. Member is not concurrently taking in combination with Esbriet (pirfenidone).
- 5. Baseline liver function tests have been performed.

C. Slowing the rate of decline in pulmonary function with SSc-ILD

An authorization may be granted for 6 months when the following criteria are met:

- 1. Prescriber is a pulmonologist or being prescribed in consultation with a pulmonologist.
- 2. Member is at least 18 years of age.
 - a. Diagnosis of SSc-ILD As documented by all of the following:
 - i. Member has completed HRCT study of the chest that shows fibrosis affecting at least 10 percent of the lungs;
 - ii. Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints; OR
 - b. At least two of the following:
 - i. Skin thickening of the fingers (e.g., puffy fingers, sclerodactyly of the fingers)
 - ii. Fingertip lesions (e.g., digital tip ulcers, fingertip pitting scars)
 - iii. Telangiectasia
 - iv. Abnormal nailfold capillaries
 - v. Pulmonary arterial hypertension
 - vi. Raynaud’s phenomenon

Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 3/2024
Scope: Medicaid

- vii. SSc-related autoantibodies (e.g., anticentromere, antitopoisomerase I, anti-RNA polymerase III)
- 3. Member is not concurrently taking in combination with Esbriet (pirfenidone).
- 4. Baseline liver function tests have been performed.

IV. CONTINUATION OF THERAPY

- V. Authorization of 12 months may be granted when the member has documentation of a positive clinical response to the medication, is not being used in combination with Esbriet (pirfenidone) and is being prescribed by a pulmonologist or in consultation with a pulmonologist.

VI. QUANTITY LIMIT

Ofev 100mg & 150mg tablets: 60 tablets per 30 days

VII. REFERENCES

- 1. Ofev (nintedanib). Boehringer Ingelheim Pharmaceuticals. Ridgefield, CT. FDA Package Insert. November 2022.