Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 3/2024, 3/2025 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

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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 fibrotic ILD 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

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

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.

V. QUANTITY LIMIT

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

VI. REFERENCES

1. Ofev (nintedanib). Boehringer Ingelheim Pharmaceuticals. Ridgefield, CT. FDA Package Insert. October 2024.