Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 3/2024, 3/2025, 01/2026 Scope: Medicaid

nintedanib (generic Ofev)

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. CRITERIA FOR INITIAL APPROVAL

A. Treatment of IPF

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

1. The requested drug is prescribed by or in consultation with a pulmonologist
2. Member is at least 18 years of age.
3. Documented diagnosis of IPF by both of the following:
    a. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded.
    b. The member meets either of the following:
        i. Member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP) pattern.
        ii. Member has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.
4. Documentation of the member's baseline forced vital capacity (FVC).
5. Documentation of the member's baseline liver function tests.
6. Documentation that the member is not concurrently taking in combination with pirfenidone (generic Esbriet).

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. The requested drug is prescribed by or in consultation with a pulmonologist
2. Member is at least 18 years of age.
3. Documented diagnosis of ILDs by both of the following:
    a. Member has completed high-resolution computed tomography (HRCT) study of the chest that shows fibrosis affecting at least 10% of the lungs.
    b. Member has progressive disease, defined as forced vital capacity [FVC] decline ≥ 10% of the predicted value, FVC decline ≥ 5% and <10% with worsening respiratory symptoms or imaging, OR worsening of respiratory symptoms and imaging with increased extent of fibrosis on HRCT.
4. Documentation of the member's baseline forced vital capacity (FVC).
5. Documentation of the member's baseline liver function tests.
6. Documentation that the member is not concurrently taking in combination with pirfenidone (generic Esbriet).

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. The requested drug is prescribed by or in consultation with a pulmonologist
2. Member is at least 18 years of age.
3. Documented diagnosis of SSc-ILD confirmed by a high-resolution computed tomography (HRCT) study of the chest.
4. Documentation of the member's baseline forced vital capacity (FVC).
5. Documentation of the member's baseline liver function tests.
6. Documentation that the member is not concurrently taking in combination with pirfenidone (generic Esbriet).

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted when the member has documentation of a positive clinical response to the medication (e.g., reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of exacerbations), is not being used in combination with pirfenidone, and is being prescribed by or in consultation with a pulmonologist.

IV. QUANTITY LIMIT

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

V. REFERENCES

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