ALASKA MEDICAID
Prior Authorization Criteria

Ofev®
(nintedanib)

FDA INDICATIONS AND USAGE[1]

Ofev® is a kinase inhibitor indicated for the Treatment of idiopathic pulmonary fibrosis (IPF), treatment of 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).

APPROVAL CRITERIA[1,2,3,4,5]

1. Patient is 18 years of age or older **AND;**
2. The medication is being prescribed by or in consultation with a pulmonologist **AND;**
3. Documentation submitted shows that the patient is a nonsmoker or has been abstinent from smoking for at least six weeks **AND;**
4. A liver function test has been obtained prior to starting treatment **AND;**
5. The following for each indication:

Idiopathic Pulmonary Fibrosis

a. Patient has the diagnosis of Idiopathic Pulmonary Fibrosis confirmed by lung biopsy for idiopathic pulmonary fibrosis diagnosis OR high-resolution computed tomography **AND;**
b. Other known causes of interstitial lung disease such as, domestic and occupational environmental exposures, drug toxicity or connective tissue disease have been ruled out **AND;**
c. Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity (FVC) ≥ 40% of predicted **AND;**
d. Baseline percent predicted diffusing capacity of the lung for carbon monoxide is ≥30% for idiopathic pulmonary fibrosis.

Systemic Sclerosis-Associated Interstitial Lung Disease

a. Patient has the diagnosis of systemic sclerosis-associated interstitial lung disease confirmed by high resolution computed tomography **AND;**
b. Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity (FVC) ≥ 40%.

Chronic Fibrosing Interstitial Lung Diseases

a. Patient has the diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype **AND**;
b. Documented pulmonary function test within the past 60 days reflecting Forced Vital Capacity (FVC) ≥45% of predicted **AND;**
c. Baseline percent predicted diffusing capacity of the lung for carbon monoxide (DLCO) between 30-79%.

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DENIAL CRITERIA[1]

1. Failure to meet approval criteria **OR;**
2. Patient has moderate to severe hepatic impairment **OR;**
3. Ofev is being used in combination with Esbriet.

CAUTIONS[1]

- Monitor for elevated ALT, AST, and bilirubin and drug -induced liver injury.
- Gastrointestinal perforation and other GI disorders such as., severe diarrhea, nausea, and vomiting.
- Can cause fetal harm and is recommended women of childbearing age use highly effective contraception.
- Bleeding events have been reported.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 60 – 100mg tabs per 30 days
- 60 – 150mg tabs per 30 days

REFERENCES / FOOTNOTES:

1. Ofev® [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2020.
2. Raghu G, Remy-Jardin M, Myers JL, et al. Diagnosis of Idiopathic Pulmonary Fibrosis. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2018 Sep 1;198(5):e44-e68.
3. Richeldi L, du Boise RM, Raghu G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. N Engl J Med. 2014 May 29;370(22):2071-82.
4. Richeldi L, Cottin V, Flaherty KR, et al. Design of the INPULSIS trials: two phase 3 trials of nintedanib in patients with idiopathic pulmonary fibrosis. Resp Med. 2014;108:1023-1030.
5. Raghu G, Rochwerg B, Zhang Y, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. An update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015 Jul 15;192(2):e3-19.