# Commercial/Healthcare Exchange PA Criteria

***Effective: July 27, 2016***

***Prior Authorization:*** Ofev

***Products Affected:*** Ofev (nintedanib) capsules

***Medication Description:***

Ofev, a kinase inhibitor, is indicated for the treatment of idiopathic pulmonary fibrosis (IPF). The recommended dose of Ofev is 150 mg twice daily (BID) with food given approximately 12 hours apart. Liver function tests should be performed prior to Ofev initiation. Dose modifications are recommended for adverse events (AEs) such as liver enzyme elevations. The most common AEs with Ovef are diarrhea (62%), nausea (24%), abdominal pain (15%), liver enzyme elevation (14%), vomiting (12%), decreased appetite (11%), decreased weight (10%), headache (8%), and hypertension (5%). AEs leading to permanent dose reductions occurred in 16% of Ofev-treated patients. Ofev discontinuation due to AEs occurred in 21% of patients.

***Covered Uses:***

1. Idiopathic pulmonary fibrosis (IPF)
2. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
3. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype

***Exclusion Criteria:*** Moderate (Child Pugh B) or severe (Child Pugh C) hepatic impairment

***Required Medical Information:***

***1.*** Diagnosis
***2.*** Baseline liver function test

***Age Restrictions:*** 18 years of age and older

***Prescriber Restrictions:*** Prescribed by, or in consultation with a Pulmonologist

***Coverage Duration:*** 12 months

***Other Criteria:***

Coverage of Ofev® is recommended in those who meet the following criteria:

**Food and Drug Administration (FDA)-Approved Indications:**

1. **Systemic Sclerosis-Associated Interstitial Lung Disease**. Approve if the patient meets the following criteria:
   A. Ofev is being used to slow the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

2. **Idiopathic Pulmonary Fibrosis (IPF**). Approve if the patient meets the following criteria (A and B).
   A. At baseline (before therapy initiation), patients have an forced vital capacity (FVC) ≥ 50% of the predicted value; **AND**
   B. The diagnosis of IPF is confirmed by one of the following (i or ii):

i. Findings on high-resolution computed tomography (HRCT) indicates usual interstitial pneumonia (UIP); **OR**
ii. A surgical lung biopsy demonstrates usual interstitial pneumonia (UIP).

**3. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype**

A. Ofev is being used to slow the rate of decline in pulmonary function in patients with Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype

## REFERENCES


1. Ofev® capsules [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; March 2020.
2. Richeldi L, du Bois RM, Raghu G, et al, for the INPULSIS Trial Investigators. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. *N Engl J Med*. 2014;370(22):2071-2082.
3. Richeldi L, Costabel U, Selman N, et al. Efficacy of a tyrosine kinase inhibitor in idiopathic pulmonary fibrosis. *N Engl J Med*. 2011;365(12):1079-1087.
4. Raghu G, Rochwerg B, Zhang Y, et al, on behalf of the ATS, ERS, JRS, and ALAT. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. Executive summary. An update of the 2011 clinical practice guideline. *Am J Respir Crit Care Med*. 2015;192(2):238-248.
5. Raghu G, Collard HR, Egan JJ, et al, on behalf of the ATS/ERS/JRS/ALAT Committee on Idiopathic Pulmonary Fibrosis. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med*. 2011;183:788-824.
6. Esbriet® capsules [prescribing information]. South San Francisco, CA: Genentech; September 2015.
7. Keating GM. Nintedanib: a review of its use in patients with idiopathic pulmonary fibrosis. *Drugs*. 2015;75:1131-1140.


***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 1 | New Policy | New Policy | All | 06/01/2016 |
| 2 | Policy Update | CCI Adopted EH Policy<br>CCI P&T Review History:4/15, 11/15, 11/16, 5/17, 11/17, 11/18<br>CCI P&T Revision History: 5/17<br>Added Covered Uses to match FDA Label,<br>Removed Exclusion Criteria,<br>Updated Age Restrictions<br>Added Other Criteria for new diagnosis | Covered Uses<br>Exclusion Criteria<br>Age restrictions<br>Other Criteria | 10/15/2019 |

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| 3 | Policy Update | Covered Uses<br>Exclusion Criteria<br>Required Medical Information | Covered Uses<br>Exclusion Criteria<br>Required Medical Information | 03/22/2020 |