

Clinical Pharmacy Program Guidelines for Idiopathic Pulmonary Fibrosis

Program	Prior Authorization
Medication	Esbriet (pirfenidone), Ofev (nintedanib)
Issue Date	11/2014
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Esbriet (pirfenidone) is a pyridone and Ofev (nintedanib) is a kinase inhibitor that are indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

2. Coverage Criteria:

A. Initial Authorization

1. **Esbriet or Ofev** will be approved based on **all** of the following criteria:

a. Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by **all** of the following criteria:

(1) 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-

(2) **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 computed tomography (HRCT) revealing IPF or probable IPF⁵

-OR-

ii. In patients subjected to a lung biopsy, both HRCT and surgical lung

biopsy pattern reveal IPF or probable IPF^b

-AND-

- b. The agent is not being used in combination with Esbriet or Ofev.

-AND-

- c. The prescriber is a pulmonologist

Authorization will be issued for 12 months

B. Reauthorization

1. Ofev and Esbriet will be approved based on the following criterion:
- a. Documentation of positive clinical response to Esbriet or Ofev therapy.

Authorization will be issued for 12 months

3. References:

1. Esbriet® [Prescribing Information]. Genentech USA, Inc. South San Francisco, CA. January 2017
2. King TE, Bradford WZ, Castro-Benardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *N Engl J Med.* 2014;370:2083-92.
3. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomized trials. *Lancet.* 2011;377:1760-69.
4. Ofev® [Prescribing Information]. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. February 2017.
5. Raghu G, Collard HR, Egan JJ, et al. Official ATS/ERS/JRS/ALAT Statement: Idiopathic Pulmonary Fibrosis: Evidence-based Guidelines for Diagnosis and Management", *Am J of Respir Crit Care Med.* 2011; 183: 788-824.
6. 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.
7. 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.
8. Ryerson CJ, Collard HR. Hot off the breath: a big step forward for idiopathic pulmonary fibrosis. *Thorax.* 2014;69:791-792.

9. Raghu G, Rochweg 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.

Program	Prior Authorization - Esbriet (pirfenidone), Ofev (nintedanib)
Change Control	
Date	Change
11/2014	New policy
12/2015	Annual review; no change
9/2016	Removed ICD-9 code. Updated background, references, and policy template.
9/2017	Annual Review. Updated background and references.