MEDICATION POLICY:

Ofev®

Generic Name: Nintedanib

Therapeutic or Brand Name: Ofev®

Applicable Drugs (if Therapeutic Class):
Pulmonary fibrosis agents

GPI Code: 455540502001

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/9/2020

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following conditions A through C and must meet criteria under the applicable diagnosis:

   A. Idiopathic pulmonary fibrosis (IPF) and criteria 1 through 6 are met:

      1. Exclusion of other known causes of ILD.
      2. Presence of high-resolution CT pattern of usual interstitial pneumonia (UIP).
      3. Specific combinations of high-resolution CT patterns and histopathology patterns in lung tissue sampling.
      4. Documentation that patient has a baseline percent predicted forced vital capacity (%FVC) greater than or equal to 50%.
      5. Documentation that the patient has a baseline carbon monoxide (%DLCO) greater than or equal to 30%.
      6. Documentation that patient does not smoke and has not smoked for a minimum of six weeks.

   B. Chronic fibrosis interstitial lung disease (ILDs) and the following criteria is met:

      1. Documented development into a progressive phenotype (e.g. self-sustaining fibrosis, worsening quality of life).

   C. Systemic sclerosis-associated interstitial lung disease (SSc-ILD).

II. Minimum age requirement: 18 years of age and older.

III. Prescriber must be a pulmonologist.

EXCLUSION CRITERIA

- Coadministration of Esbriet® with Ofev® (nintedanib).
- OFEV is not recommended for use in patients with moderate or severe hepatic impairment.

- Documented history of complicated hemorrhagic events OR known coagulopathic disorders.
- Anticipated or current pregnancy.
- Safety and efficacy of Ofev have not been studied in patients with severe renal impairment and in ESRD.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Idiopathic pulmonary fibrosis or progressive interstitial lung disease:
  - Bottle of 100 mg tablets (#60) for 30 days.
  - Bottle of 150 mg tablets (#60) for 30 days.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Cottin V, Wollin L, Fischer A, Quaresma M, Stowasser S, Harari S. Fibrosing interstitial lung diseases: knowns and unknowns. *European Respiratory Review*. 2019;28(151):180100.
2. Nintedanib (Ofev®) [package insert]. Ridgefield, CT, Boehringer Ingelheim Pharmaceuticals, Inc.
3. Medi-Span.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
4/9/2020	New policy created.