

Generic Name: Nintedanib**Preferred:** N/A**Therapeutic or Brand Name:** Ofev**Non-preferred:** N/A**Applicable Drugs (if Therapeutic Class):**

Pulmonary fibrosis agents

Date of Origin: 4/9/2020**Date Last Reviewed / Revised:** 1/17/2023**PRIOR AUTHORIZATION CRITERIA***(May be considered medically necessary when criteria I through VII are met)*

- I. Documented diagnosis of one of the following conditions A through C and must meet all criteria under the applicable diagnosis:
 - A. Idiopathic pulmonary fibrosis (IPF)
 1. IPF confirmed by high resolution computed tomography (HRCT) or lung biopsy.
 - B. Chronic fibrosis interstitial lung disease (ILDs)
 1. Documented development into a progressive phenotype (ie, self-sustaining fibrosis, worsening quality of life).
 - C. Systemic sclerosis-associated interstitial lung disease (SSc-ILD)
- II. Documented assessment of the pattern and severity of respiratory impairment on pulmonary function testing (PFT).
- III. Documentation of non-smoking status or plan for smoking cessation.
- IV. Minimum age requirement: 18 years old.
- V. Treatment is prescribed by or in consultation with a pulmonologist.
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines
- VII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Identifiable causes of interstitial lung disease have not been ruled out.
- Coadministration with Esbriet (pirfenidone).
- Moderate or severe hepatic impairment (Child Pugh B or C).

- Anticipated or current pregnancy.
- Severe renal impairment (less than 30 mL/min CrCl) and end-stage renal disease.

OTHER CRITERIA

- Elevated liver enzymes and liver induced injury: Monitor ALT, AST, and bilirubin prior to initiation of treatment, at regular intervals during the first three months of treatment, and periodically thereafter or as clinically indicated. Temporary dosage reductions or discontinuations may be required.
- Gastrointestinal disorders: Diarrhea, nausea, and vomiting have occurred with OFEV. Treat patients at first signs with adequate hydration and antidiarrheal medicine (e.g., loperamide) or anti-emetics. Discontinue OFEV if severe diarrhea, nausea, or vomiting persists despite symptomatic treatment.
- Gastrointestinal perforation has been reported. Use OFEV with caution when treating patients with recent abdominal surgery, previous history of diverticular disease or receiving concomitant corticosteroids or NSAIDs.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 60 capsules per 30 days.

APPROVAL LENGTH

- **Authorization**: 6 months.
- **Re-Authorization**: 1 year, with 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. *Eur Respir Rev*. 2019;28(151):180100. Published 2019 Feb 27. doi:10.1183/16000617.0100-2018
2. Raghu G, Collard HR, Egan JJ, et al. 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(6):788-824. doi:10.1164/rccm.2009-040GL
3. Richeldi L, Kolb M, Jouneau S, et al. Efficacy and safety of nintedanib in patients with advanced idiopathic pulmonary fibrosis. *BMC Pulm Med*. 2020;20(1):3. Published 2020 Jan 8. doi:10.1186/s12890-019-1030-4

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4. Senoo S, Miyahara N, Taniguchi A, et al. Nintedanib can be used safely and effectively for idiopathic pulmonary fibrosis with predicted forced vital capacity \leq 50%: A multi-center retrospective analysis. *PLoS One*. 2020;15(8):e0236935. Published 2020 Aug 27. doi:10.1371/journal.pone.0236935
 5. Ofev. Prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc; 2022. Accessed December 27, 2022. <https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Ofev/ofev.pdf>

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.