RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	nintedanib
Policy Number:	RxA.440
Drug(s) Applied:	Ofev®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Nintedanib (Ofev®) is a kinase inhibitor.

Ofev® is indicated for:
- treatment of idiopathic pulmonary fibrosis (IPF).
- treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Nintedanib (Ofev®)	IPF, ILDs, SSc-ILD	150 mg PO BID approximately 12 hours apart (100 mgBID for patients with mild hepatic impairment or management of adverse reactions)	300 mg/day

Dosage Forms

- Capsules: 100 mg, 150 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Attestation that liver function tests in all patients and pregnancy tests in females of reproductive

potential are conducted prior to initiating treatment;
5. Member meets one of the following (a and b):*
   a. Pulmonary fibrosis on high resolution computed tomography (HRCT);
   b. Known causes of pulmonary fibrosis have been ruled out (*see Appendix D*);
6. Dose does not exceed 300 mg (2 capsules) per day.

Approval Duration
Commercial: 6 months
Medicaid/HIM: 6 months

B. Systemic Sclerosis Associated Interstitial Lung Disease (must meet all)**:**
1. Diagnosis of SSc-ILD;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Attestation that liver function tests in all patients and pregnancy tests in females of reproductive potential are conducted prior to initiating treatment;
5. Member meets one of the following (a and b):*
   a. Pulmonary fibrosis on HRCT;
   b. Additional signs of SSC are identified.
6. Dose does not exceed 300 mg (2 capsules) per day.

Approval Duration
Commercial: 6 months
Medicaid/HIM: 6 months

C. Chronic Fibrosing Interstitial Lung Disease (must meet all)**:**
1. Diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Attestation that liver function tests in all patients and pregnancy tests in females of reproductive potential are conducted prior to initiating treatment;
5. Member is a non-smoker or has been abstinent for at least 6 weeks;
6. Documented pulmonary function test within the past 60 days reflecting Forced vital Capacity (FVC)≥45% of predicted;

Approval Duration
Commercial: 6 months
Medicaid/HIM: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg (2 capsules) per day.

Approval Duration
Commercial: 12 months
Medicaid/HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IPF: idiopathic pulmonary fibrosis
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer
HRCT: high resolution computed tomography

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Existing data for the use of Ofev for non-small cell lung cancer (NSCLC) as a second- line agent show statistically significant improvement in progression free survival, but the clinical significance of the improvement (0.7 months) is questionable. Additionally, there is no significant difference in overall survival in patients treated with Ofev. The National Comprehensive Cancer Network (NCCN) guidelines do not currently mention Ofev as a treatment alternative for NSCLC.
- The following are potential risks in taking this medication: elevated liver enzymes and drug-induced liver injury, gastrointestinal disorders, embryo-fetal toxicity, arterial thromboembolic events, bleeding and gastrointestinal performation.

References

1. Ofev Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; March 2020. Available at: www.ofev.com. Accessed July 27, 2020.
2. Raghu G, Rochwerg B, Yuang Z, 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; 192(2): e3-e19. Accessed July 27, 2020.
3. Keating GM. Nintedanib: a review of its use in patients with idiopathic pulmonary fibrosis. Drugs. 2015;75:1131-1140. Accessed July 27, 2020.
4. 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: 788-824.
5. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic SclerosisAssociated Interstitial Lung Disease. N Engl J Med. 2019 Jun 27;380(26):2518-2528. Accessed July 27, 2020.
6. Esbriet® [Prescribing Information]. Genentech USA, Inc. South San Francisco, CA. July 2019. Accessed July 27, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Policy title was updated. 2) Indications were updated. 3) Dosing information updated.	07/27/2020	09/14/2020

4) Initial Approval criteria updated. 5) Continued Therapy Approval criteria II.A.1 was rephrased. 6) Appendices updated. 7) References were updated.		