Clinical Policy: Nintedanib (Ofev)

Reference Number: PA.CP.PHAR.285
Effective Date: 01/18
Last Review Date: 07/17/19 Revision Log

Description
Nintedanib (Ofev®) is a kinase inhibitor.

FDA approved indication
Ofev is indicated for the treatment of idiopathic pulmonary fibrosis.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Ofev is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of idiopathic pulmonary fibrosis;
2. Age > 18 years;
3. Prescribed by or in consultation with a pulmonologist;
4. Dose does not exceed 300 mg/day (2 capsules/day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Idiopathic pulmonary fibrosis	150 mg twice daily approximately 12 hours apart (100 mg twice daily for patients with mild hepatic impairment or management of adverse reactions)	300 mg/day

VI. Product Availability

Capsules: 100 mg, 150 mg

VII. References

1. Ofev Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; January 2018. Available at www.ofev.com. Accessed April 3, 2018.
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.
3. 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.

Reviews, Revisions, and Approvals	Date	Approval Date
Removed requirement for high-resolution computed tomography or surgical lung biopsy findings confirming diagnosis; references reviewed and updated.	05.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	