

## Pharmacy Medical Necessity Guidelines: Ofev® (nintedanib)

Effective: March 8, 2016

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
This Pharmacy Medical Necessity Guideline applies to the following: <b>Tufts Health Plan Commercial Plans</b> <input type="checkbox"/> Tufts Health Plan Commercial Plans – large group plans <input type="checkbox"/> Tufts Health Plan Commercial Plans – small group and individual plans <b>Tufts Health Public Plans</b> <input type="checkbox"/> Tufts Health Direct – Health Connector <input checked="" type="checkbox"/> Tufts Health Together – A MassHealth Plan <b>Tufts Health Freedom Plan products</b> <input type="checkbox"/> Tufts Health Freedom Plan - large group plans <input type="checkbox"/> Tufts Health Freedom Plan - small group plans		<b>Fax Numbers:</b>  RXUM: 617.673.0988	

### OVERVIEW

Pulmonary fibrosis is characterized by thickening and stiffness of lung tissue, which may result in scarring over time. The formation of scar tissue is called fibrosis. The term idiopathic pulmonary fibrosis (IPF) is used when a cause for the disease cannot be identified.

Ofev (nintedanib) targets three growth factor receptors involved in pulmonary fibrosis. It is believed to block the signaling pathways involved in fibrotic processes, and may reduce disease progression by slowing the decline of lung function.

### FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Ofev (nintedanib) is a kinase inhibitor indicated for the treatment of IPF.

### COVERAGE GUIDELINES

The plan may authorize coverage of Ofev (nintedanib) for Members, when **all** of the following criteria are met:

1. Documented diagnosis of idiopathic pulmonary fibrosis
- AND**
2. The prescribing physician is a pulmonologist
- AND**
3. Documentation the Member is not currently taking Esbriet (pirfenidone)

### Upon renewal.

1. The Member has had an office visit and has been re-assessed for this condition within the past year
- AND**
2. There is clinical documentation of efficacy

### LIMITATIONS

1. The initial authorization will be for 1 year; subsequent approval will require a new authorization. Subsequent authorizations will be for 1 year.
2. Ofev (nintedanib) will be limited to a 30 day supply as follows: 60 capsules per 30 days.
3. The plan will not allow coverage of Ofev (nintedanib) to be used in conjunction with Esbriet (prifenidone).

### CODES

None

### REFERENCES

1. Al-Ashkar F, Mehra R, Mazzone PJ. Interpreting pulmonary function tests: recognize the pattern, and the diagnosis will follow. *Cleve Clin J Med*. 2003;70(10):866-73.
2. Esbriet (pirfenidone) [prescribing information]. Brisbane, CA: InterMune, Inc. September 2015.
3. Food and Drug Administration Safety and Innovation Act (FDASIA). URL: <http://www.fda.gov/regulatoryinformation/legislation/significantamendmentstothehdact/fdasia/ucm20027187.htm>. Available from Internet. Accessed 2016 January 29.

4. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. October 2014.
5. Ofev Academy of Managed Care Pharmacy (AMCP) Formulary Submission Dossier. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. 2014 Oct.
6. King TE, Jr., Bradford WZ, Castro-Bernardini S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *N Engl J Med*. 2014; 370(22):2083-92.
7. National Heart, Lung, and Blood Institute. Explore Idiopathic Pulmonary Fibrosis. 2011. <http://www.nhlbi.nih.gov/health/health-topics/topics/ipf/>. Accessed 2016 February 12.
8. National Institute for Health and Care Excellence. <http://www.nice.org.uk/guidance/ta379>. 2016 January. Accessed 2016 February 12.
9. Raghu G, Collard HR, Egan JJ, et al. ATS/ERS/JRS/ALAT committee on idiopathic pulmonary fibrosis. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for the diagnosis and management. *Am J Respir Crit Care Med*. 2011; 183(6): 788-824.
10. Richeldi L, Costabel U, Selman M, et al. Efficacy of a tyrosine kinase inhibitor in idiopathic pulmonary fibrosis. *N Engl J Med*. 2011;365(12):1079-87.
11. Richeldi L, du Bois RM, Raghu G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. *N Engl J Med*. 2014;370(22):2071-82.
12. Wells AU. The revised ATS/ERS/JRS/ALAT diagnostic criteria for idiopathic pulmonary fibrosis (IPF)--practical implications. *Respir Res*. 2013;14(Suppl 1):S2.

#### **APPROVAL HISTORY**

April 14, 2015: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template.
- March 8, 2016: No changes

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink<sup>SM</sup> Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.