Pharmacy Medical Necessity Guidelines: Esbriet® (pirfenidone)

Effective: February 13, 2018

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:	**Fax Numbers:**
Tufts Health Plan Commercial Plans	
☒ Tufts Health Plan Commercial Plans – large group plans	
☒ Tufts Health Plan Commercial Plans – small group and individual plans	
Tufts Health Public Plans	
☒ Tufts Health Direct – Health Connector	RXUM: 617.673.0988
☒ Tufts Health Together – A MassHealth Plan	
☒ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan	
Tufts Health Freedom Plan products	
☒ Tufts Health Freedom Plan - large group plans	
☒ Tufts Health Freedom Plan - small group plans	

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

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. Esbriet (pirfenidone) is an immunosuppressant thought to have anti-inflammatory and antifibrotic effects. Esbriet (pirfenidone) exerts its effects by suppressing fibroblast proliferation, reducing the production of fibrosis-associated proteins and cytokines, and reducing the response to growth factors.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Esbriet (pirfenidone) is indicated for the treatment of IPF.

COVERAGE GUIDELINES

The plan may authorize coverage of Esbriet (pirfenidone) 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 Ofev (nintedanib)

LIMITATIONS

1. The initial authorization will be for 1 year; subsequent approval will require clinical documentation of efficacy. Subsequent authorizations will be for 1 year.
2. Esbriet (pirfenidone) will be limited to a 30 day supply as follows:
    a. 267 mg capsules or tablets: 270 units
    b. 801 mg tablets: 90 units
3. The plan will not allow coverage of Esbriet (pirfenidone) to be used in conjunction with Ofev (nintedanib).

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. January 2017.
3. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. December 2017.
4. 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.

5. National Heart, Lung, and Blood Institute. Explore Idiopathic Pulmonary Fibrosis. 2011. URL: nhlbi.nih.gov/health/health-topics/topics/ipf/. Available from Internet. Accessed 2016 February 12.
6. National Institute for Health and Care Excellence. URL: nice.org.uk/guidance/ta282. 2013 April. Available from Internet. Accessed 2016 February 12.
7. Noble PW, Albera C, Bradford WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomized trials. *Lancet.* 2011; 377(9779):1760-9.
8. 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.
9. 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

March 10, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- March 8, 2016: No changes
- March 14, 2017: Effective 3/14/17, Medical Necessity Guidelines apply to Tufts Health Together.
- April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- February 13, 2018: Medical Necessity Guideline applies to Tufts Health RITogether. Administrative update to update the quantity limit of Esbriet (no change from current coverage).

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℠ 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.