Pulmonary Fibrosis Agents

WA.PHAR.57 Pulmonary Fibrosis Agents Effective: October 1, 2018

Background:

Idiopathic pulmonary fibrosis (IPF) is specific form of chronic, progressive, fibrosing interstitial pneumonia of unknown cause, occurring in adults and limited to the lungs. It is associated with the histopathologic and/or radiologic pattern of usual interstitial pneumonia (UIP).

Medical necessity

Drug	Medical Necessity
Nintedanib (**Ofev**) Pirfenidone (**Esbriet**)	Pulmonary fibrosis agents may be considered medically necessary when used for treatment of a confirmed diagnosis of idiopathic pulmonary fibrosis

Clinical policy:

Clinical Criteria	
Initial authorization criteria	**1.** Diagnosis of idiopathic pulmonary fibrosis confirmed by at least **ONE** of the following: a. The presence of usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT) b. Surgical lung biopsy 2. Ofev and Esbriet will not be used in combination 3. Prescribed by or in consultation by a specialist in pulmonology **Approve for 12 months**
Reauthorization criteria	Documentation of positive clinical benefit **Approve for 12 months**

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
Nintedanib (Ofev)	300mg per day; #60 capsules per 30-day supply
Pirfenidone (Esbriet)	2403mg per day; • 267mg capsule/tablet= #270 per 30-day supply • 801mg tablets = #90 per 30-day supply

References

1. Center for Drug Evaluation and Research (CDER). March 9, 2010 Meeting of the Pulmonary-Allergy Drugs Advisory Committee. FDA Briefing Package for NDA 22-535: pirfenidone. March 9, 2010 [Archive]. [Accessed February 27, 2018]; Available from: https://wayback.archive-it.org/7993/20170405232112/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM203081.pdf.
2. Raghu, G, Collard, HR, Anstrom, KJ, et al. Idiopathic pulmonary fibrosis: clinically meaningful primary endpoints in phase 3 clinical trials. United States, 2012. p. 1044-8.
3. Raghu, G, Rochwerg, B, Zhang, Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis. An Update of the 2011 Clinical Practice Guideline. *American journal of respiratory and critical care medicine*. 2015 Jul 15;192(2):e3-19. PMID: 26177183
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. United States, 2011. p. 788-824.
5. King, TE, Jr. Treatment of idiopathic pulmonary fibrosis. In: UpToDate, Flaherty, K.R. (Ed). UpToDate, Waltham, MA, 2014.
6. Clinicaltrials.gov. [cited (updated periodically)]; Available from: http://clinicaltrials.gov/
7. Ofev® (nintedanib) [package insert]. Ridgefield, CT: Boehringer Ingelheim; January 2018.
8. Esbriet® (pirfenidone) [package insert]. South San Francisco, CA: Genentech USA; October 2014.
9. King, TE, Jr., Bradford, WZ, Castro-Bernardini, S, et al. A phase 3 trial of pirfenidone in patients with idiopathic pulmonary fibrosis. *The New England journal of medicine*. 2014 May 29;370(22):2083-92. PMID: 24836312
10. Noble, PW, Albera, C, Bradford, WZ, et al. Pirfenidone in patients with idiopathic pulmonary fibrosis (CAPACITY): two randomised trials. England, 2011. p. 1760-9.
11. Richeldi, L, du Bois, RM, Raghu, G, et al. Efficacy and safety of nintedanib in idiopathic pulmonary fibrosis. The New England journal of medicine. 2014 May 29;370(22):2071-82. PMID: 24836310
12. Raghu, G, Rochwerg, B, Zhang, Y, et al. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Treatment of Idiopathic Pulmonary Fibrosis. An Update of the 2011 Clinical Practice Guideline. American journal of respiratory and critical care medicine. 2015 Jul 15;192(2):e3-19. PMID: 26177183