



coordinated care™

Pulmonary Fibrosis Agents

WA.PHAR.57

Effective: October 1, 2018

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the list of the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

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)	<p>Pulmonary fibrosis agents may be considered medically necessary when used for treatment of a confirmed diagnosis of idiopathic pulmonary fibrosis</p> <p>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration.</p> <p>Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.</p>

Clinical policy:

Clinical Criteria	
Initial authorization criteria	<ol style="list-style-type: none">1. Diagnosis of idiopathic pulmonary fibrosis confirmed by at least ONE of the following:<ol style="list-style-type: none">a. The presence of usual interstitial pneumonia (UIP) on high-resolution computed tomography (HRCT)b. Surgical lung biopsy2. Ofev and Esbriet will not be used in combination3. 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)	100 mg capsule: #60 caps per 30-day supply 150 mg capsule: #60 caps per 30-day supply
Pirfenidone (Esbriet)	2403mg per day; <ul style="list-style-type: none"> • 267mg capsule/tablet: #270 caps/tabs per 30-day supply • 534 mg tablets: #90 tabs per 30-day supply • 801 mg tablets: #90 tabs 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

History

Date	Action and Summary of Changes
10/01/2018	Policy Implemented (Version 1)

11/09/2022	Policy Updates (Version 1): <ol style="list-style-type: none">1. Added note and link to AHPDL publication to the top of policy.2. Added case-by-case approval and continuation of therapy language to policy.3. Updated dosage and quantity limits
-------------------	--