Washington State Health Care Authority

Pulmonary Fibrosis Agents

Medical policy no. 45.55.00-1 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 Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

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 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. 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.

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)	100 mg capsule: #60 caps per 30-day supply 150 mg capsule: #60 caps per 30-day supply
Pirfenidone (Esbriet)	2403mg per day; • 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

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History

Date	Action and Summary of Changes
10/01/2018	Policy Implemented (Version 1)
11/09/2022	Policy Updates (Version 1): 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