Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Ofev (nintedanib) and Esbriet (pirfenidone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2015 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Ofev (nintedanib) and Esbriet (pirfenidone).

Nintedanib (Ofev) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Pirfenidone (Esbriet) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF)

DEFINITIONS

ALT- alanine aminotransferase

AST- aspartate aminotransferase

Carbon monoxide diffusing capacity (DLCO)- a test of the lungs capability to expel carbon monoxide

Forced vital capacity (FVC)- a test confirming the total volume lungs can expel.

High-resolution computed tomography (HRCT)- a scan of the lungs that is essential component of the diagnostic pathway in IPF

Honeycombing- is manifested on HRCT as clustered airspaces that resemble a honeycomb structure.

Idiopathic pulmonary fibrosis (IPF)- a specific form of chronic, progressive fibrosing interstitial pneumonia of unknown cause, occurring primarily in older adults, and limited to the lungs.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Ofev (nintedanib) and Esbriet (pirfenidone), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by a pulmonologist
- Must be age 18 years or older
- Must have a definitive diagnosis of idiopathic pulmonary fibrosis (IPF) confirmed by ONE of the following:
    - High-resolution computed tomography (HRCT) with presence of honeycombing
    - Surgical lung biopsy
- Must have all other diagnoses ruled out (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity)
- Must submit documentation of liver function test (including ALT, AST, and bilirubin)
- Must submit documentation of a recent urine or serum nicotine screening confirming that member is NOT currently smoking or recently stopped smoking
- Must have ALL of the following lung values:

- Predicted forced vital capacity (FVC) ≥ 50%
- Diffusing capacity for carbon monoxide (DLCO) 30% to 90% of predicted
- Baseline oxygen requirement (e.g. whether the member requires supplemental oxygen)

Reauthorization Criteria:

All prior authorization renewals are reviewed every 6 months to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon the following:

- Must have chart documentation from the prescriber indicating the member still is a candidate for treatment based upon the prescriber's assessment while on therapy
- Must submit documentation that liver function has been monitored within the last 3 months (including ALT, AST, and bilirubin)
- Continuation of IPF treatment is considered medically necessary if ANY of the following criteria are met:
  - <10% decline from baseline in FVC
  - <15% decline from baseline in DLCO
  - Stable oxygen requirement (e.g. Unchanged amount of supplemental oxygen)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 6 months
Quantity Level Limit	
Ofev	60 capsules per 30 days
Esbriet	270 capsules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Ofev [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Parmaceuticals, Inc; 10/2014.
2. Esbriet rprescribing information]. Brisbane, CA: InterMune, Inc.; 10/2014.

3. ATS/ERS/JRS/ALAT. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J Respir Crit Care Med. 2011 Mar 15;183
4. ATS/ERS/JRS/ALAT. The revised ATS/ERS/JRS/ALAT diagnostic criteria for idiopathic pulmonary fibrosis (IPF)--practical implications. Respir Res. 2013;14 Suppl 1:S2.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*