Commercial/Healthcare Exchange PA Criteria

Effective: May 8th, 2019

Prior Authorization: Esbriet (pirfenidone)

Products Affected: Esbriet (pirfenidone) 267 mg oral capsule, Esbriet (pirfenidone) 267 mg, and 801 mg oral tablets, Pirfenidone tablets

Medication Description: Esbriet (pirfenidone) belongs to the chemical class of pyridine and it is indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Pirfenidone works by multiple mechanisms to mitigate fibrosis and scarring and inhibit transforming growth factor beta, thereby slowing the progression of IPF.

Covered Uses: Treatment of idiopathic pulmonary fibrosis (IPF).

Exclusion Criteria:
Esbriet has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. **Esbriet is Being Used Concomitantly with Ofev® (nintedanib capsules).** Ofev is another medication indicated for IPF. The effectiveness and safety of concomitant use of Esbriet with Ofev have not been established. The 2015 ATS/ERS/JRS, ALAT clinical practice guideline regarding the treatment of idiopathic pulmonary fibrosis (an update of the 2011 clinical practice guidelines) do not recommend taking Esbriet and Ofev in combination.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Required Medical Information: Diagnosis

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with a pulmonologist

Coverage Duration: 12 months

Other Criteria:
Coverage of Esbriet® is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications:

1. **Idiopathic Pulmonary Fibrosis (IPF**). Approve if the patient meets the following criteria (A, B, and C):
   A. The patient is aged ≥ 18 years;
   AND

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B. At baseline (before therapy initiation), patients have a forced vital capacity (FVC) ≥ 50% of the predicted value; **AND**

C. The diagnosis of IPF is confirmed by one of the following (i or ii):

i. Findings on high-resolution computed tomography (HRCT) indicates usual interstitial pneumonia (UIP); **OR**

ii. A surgical lung biopsy demonstrates usual interstitial pneumonia (UIP).

References:

1. Esbriet® capsules [prescribing information]. South San Francisco, CA: Genentech; April 2019.
2. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. April 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy, adopted EH criteria, removed Esbriet from previous location on "PA to Indication Policy"	All	4/17/2019
2	Policy Update	Updated age restriction from 40 and older to 18 and older	Age Restriction	10/15/2019
3	Policy Update	Added Pirfenidone Tablets to affected products	Affected Products	9/7/2022

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