PRIOR AUTHORIZATION POLICY

POLICY: Idiopathic Pulmonary Fibrosis and Related Lung Disease – Esbriet Prior Authorization Policy

- Esbriet® (pirfenidone capsules – Genentech)

REVIEW DATE: 06/16/2021

OVERVIEW

Esbriet, a pyridone, is indicated for the treatment of **idiopathic pulmonary fibrosis** (IPF).[1] The safety and effectiveness of Esbriet in pediatric patients have not been established.

Disease Overview

IPF is a form of chronic interstitial lung pneumonia associated with histologic pattern of usual interstitial pneumonia (UIP).[2] The condition is specific for patients that have clinical features and the histologic pattern of UIP or a classical high-resolution computed tomography scan for IPF. In this lung condition there is cellular proliferation, interstitial inflammation, fibrosis, or the combination of these findings, within the alveolar wall that is not due to infection or cancer.[3] IPF is rather rare and the prevalence in the US ranges from 10 to 60 cases per 100,000. However, in one study, the prevalence was 494 cases per 100,000 in 2011 in adults > 65 years of age, which is higher than previous information. The disease mainly impacts older adults.[2] Symptoms include a progressive dry cough and exertional dyspnea. Patients experience a high disease burden with hospital admissions. The clinical course varies among patients but the mean survival after symptom onset is usually 3 to 5 years. The cause is unknown but environmental and occupational hazards may play a role, as well as a history of smoking. Medical therapy is only modestly effective and mainly shows the rate of disease progression. Agents FDA-approved for IPF are Ofev® (nintedanib capsules) and Esbriet. Lung transplantation is a therapeutic option.

Clinical Efficacy

The efficacy of Esbriet was assessed in patients with IPF in three Phase III, randomized, double-blind, placebo-controlled, multicenter, multinational trials (n = 1,247).[1,4,5] In ASCEND (Assessment of Pirfenidone to Confirm Efficacy and Safety in Idiopathic Pulmonary Fibrosis),[1,4] and CAPACITY 004 (Clinical Studies Assessing Pirfenidone in idiopathic pulmonary fibrosis: Research of Efficacy and Safety Outcomes)[1,5] patients were required to have a percent predicted forced vital capacity (%FVC) ≥ 50% at baseline. Esbriet 2,403 mg/day led to a statistically significant treatment effect regarding the primary efficacy analysis for the change in the %FVC over the study duration of 52 weeks and 72 weeks, respectively. Also, a reduction in the mean decline in forced vital capacity (in mL) was observed in both studies for patients receiving Esbriet 2,403 mg/day compared with placebo.[1-3] Some information suggests that patients who have %FVC < 50% may also have some benefits from therapy.[6-9]

Guidelines

In 2015, the clinical practice guideline from the American Thoracic Society (ATS), European Respiratory Society (ERS), the Japanese Respiratory Society (JRS), and Latin American Thoracic Association (ALAT) on the treatment of idiopathic pulmonary fibrosis were updated.[10] Regarding Esbriet, the guideline suggests use of this medication (conditional recommendation, moderate confidence in estimates of effect). The guideline notes that the data with Esbriet cannot be generalized to patients with IPF who have more severe impairment of pulmonary function tests or for patients with other significant comorbidities.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Esbriet. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Esbriet, initial approval requires Esbriet to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Idiopathic Pulmonary Fibrosis (IPF).** Approve for the duration noted below if the patient meets the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Forced vital capacity is ≥ 40% of the predicted value; AND
     - **iii.** Diagnosis of idiopathic pulmonary fibrosis is confirmed by one of the following (a or b):
       - **a)** Findings on high-resolution computed tomography indicates usual interstitial pneumonia; OR
       - **b)** A surgical lung biopsy demonstrates usual interstitial pneumonia; AND
     - **iv.** Medication is prescribed by, or in consultation with, a pulmonologist.
   - **B)** Patient is Currently Receiving Esbriet. Approve for 1 year if the patient meets the following (i, ii and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has experienced a beneficial response to therapy over the last year while receiving Esbriet; AND

       Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Esbriet. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or a reduction in the number or severity of idiopathic pulmonary fibrosis exacerbations.
     - **iii.** Medication is prescribed by, or in consultation, with a pulmonologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Esbriet is not recommended in the following situations:

1. **Esbriet is Being Used Concomitantly with Ofev (nintedanib capsules).** Ofev is another medication indicated for the treatment of 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 Ofev and Esbriet in combination.[10] A small exploratory study was done in which patients with IPF receiving Ofev added on Esbriet.[11] Further research is needed to determine the utility of this combination regimen.

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

REFERENCES

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