PIRFENIDONE

Generic	Brand	HICL	GCN	Exception/Other
PIRFENIDONE	ESBRIET	40237		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient does not have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
   - Treatment is prescribed by or given in consultation with a pulmonologist
   - The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
   - The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
   - The patient does not currently smoke cigarettes
   - The patient is NOT receiving therapy with Ofev

   If yes, **approve for 12 months by GPID for all dosage strengths with the following quantity limits:**
   - **267mg capsule: #9 capsules (2403mg) per day.**
   - **267mg tablet: #9 tablets (2403mg) per day.**
   - **801mg tablet: #3 tablets (2403mg) per day.**

   APPROVAL TEXT: Renewal requires that the patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **PIRFENIDONE (Esbriet)** requires a diagnosis of idiopathic pulmonary fibrosis (IPF). In addition, the following must be met.

- The patient is 18 years of age or older
- The patient does NOT have other known causes of interstitial lung disease (e.g., connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis, systemic sclerosis, rheumatoid arthritis, radiation, sarcoidosis, bronchiolitis obliterans organizing pneumonia, human immunodeficiency virus (HIV) infection, viral hepatitis, or cancer)
- Treatment is prescribed by or given in consultation with a pulmonologist
- The patient has a usual interstitial pneumonia (UIP) pattern as evidenced by high-resolution computed tomography (HRCT) alone or via a combination of surgical lung biopsy and HRCT
- The patient has a predicted forced vital capacity (FVC) of at least 50% at baseline
- The patient does not currently smoke cigarettes
- The patient is NOT receiving therapy with Ofev

RENEWAL CRITERIA

1. Does the patient have a diagnosis of idiopathic pulmonary fibrosis (IPF) **AND** meet the following criterion?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by GPID for all dosage strengths with the following quantity limits:**
   - **267mg capsule: #9 capsules (2403mg) per day.**
   - **267mg tablet: #9 tablets (2403mg) per day.**
   - **801mg tablet: #3 tablets (2403mg) per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **PIRFENIDONE (Esbriet)** requires a diagnosis of idiopathic pulmonary fibrosis (IPF). In addition, the following must be met.
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

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PIRFENIDONE

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Esbriet.

REFERENCES

- Esbriet [Prescribing Information]. South San Francisco, CA: Genentech USA, Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 02/15
Client Approval: 11/19
P&T Approval: 10/19