



**STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES**

**PIRFENIDONE**

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PIRFENIDONE	ESBRIET, PIRFENIDONE	40237		GPI-10 (4555006000)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

- 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
  - Therapy is prescribed by or in consultation with a pulmonologist
  - 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)
  - 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

If yes, enter two authorizations for a total of 12 months as follows:

**FIRST APPROVAL:** Approve for 1 month by GPID or GPI-14 for all dosage strengths with the following quantity limits:

- 267mg: #9 per day.
- 534mg: #3 per day.
- 801mg: #3 per day.

**SECOND APPROVAL:** Approve for 11 months by HICL or GPI-10 with a quantity limit of #3 per day (enter a start date of 2 days before the end of the first approval).

If no, do not approve.

**INITIAL DENIAL TEXT:** *\*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for approval:

- You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
  - You are 18 years of age or older
  - Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor)
- (Initial denial text continued on next page)**

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PIRFENIDONE

INITIAL CRITERIA (CONTINUED)

- D. You do NOT have other known causes of interstitial lung disease. Other causes may include connective tissue disease, drug toxicity, asbestos or beryllium exposure, hypersensitivity pneumonitis (type of lung infection), systemic sclerosis (chronic hardening and tightening of the skin and connective tissues), rheumatoid arthritis (a type of joint condition), radiation, sarcoidosis (a type of inflammatory disorder), bronchiolitis obliterans organizing pneumonia (infection affecting the small airways of the lung), human immunodeficiency virus infection (HIV: a type of immune disorder), viral hepatitis (a type of liver inflammation), or cancer
- E. You have a usual interstitial pneumonia (type of lung infection) pattern as evidenced by high-resolution computed tomography (HRCT: type of imaging test) alone or via a combination of surgical lung biopsy (removal of cells or tissue from the body for examination) and HRCT
- F. You have a predicted forced vital capacity (FVC: amount of air exhaled from lungs) of at least 50% at baseline
- G. You do NOT currently smoke cigarettes

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

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

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 per day.**

If no, do not approve.

**RENEWAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **PIRFENIDONE (Esbriet)** requires the following rule(s) be met for renewal:

- A. You have idiopathic pulmonary fibrosis (IPF: a type of lung condition)
- B. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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**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.; February 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/23

Created: 02/15

Client Approval: 11/22

P&T Approval: 10/22