Clinical Policy: Pirfenidone (Esbriet)

Reference Number: PA.CP.PHAR.286
Effective Date: 01/2018
Last Review Date: 10/17
Line of Business: Medicaid

Revision Log

Description
Pirfenidone (Esbriet®) is a pyridone.

FDA Approved Indication(s)
Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Esbriet is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of idiopathic pulmonary fibrosis;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a pulmonologist;
4. High-resolution computed tomography or surgical lung biopsy findings are consistent with diagnosis;
5. Dose does not exceed:
   a. Days 1 through 7: 801 mg/day;
   b. Days 8 through 14: 1602 mg/day;
   c. Day 15 and onward: 2403 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 2403 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Idiopathic pulmonary fibrosis	Days 1 - 7: 267 mg orally three times daily Days 8 - 14: 534 mg orally three times daily Days 15 onward: 801 mg orally three times daily	Days 1 - 7: 801 mg/day Days 8 - 14: 1602 mg/day Days 15 onward: 2403 mg/day

VI. Product Availability

- Capsules: 267 mg
- Tablets: 267 mg, 801 mg

VII. References

1. Esbriet Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; January 2017. Available at www.esbriet.com. Accessed April 27, 2017.
2. Raghu G, Rochwerg B, Yuang Z, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015; 192(2): e3-e19.
3. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J Respir Crit Care Med. 2011; 183: 788-824.

Reviews, Revisions, and Approvals	Date	Approval Date