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| <b>Clinical Policy Title:</b>              | pirfenidone           |
| <b>Policy Number:</b>                      | RxA.378               |
| <b>Drug(s) Applied:</b>                    | Esbriet®              |
| <b>Original Policy Date:</b>               | 03/06/2020            |
| <b>Last Review Date:</b>                   | 09/14/2020            |
| <b>Line of Business Policy Applies to:</b> | All lines of Business |

## Background

Pirfenidone (Esbriet®) is a pyridone. It is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

## Dosing Information

| Drug Name              | Indication | Dosing Regimen   | Maximum Dose  |
|------------------------|------------|--|---|
| Pirfenidone (Esbriet®) | IPF        | Days 1 through 7: 267 mg PO TID with meal<br>Days 8 through 14: 534 mg PO TID with meal<br>Days 15 onward: 801 mg PO TID with meal | Days 1 through 7: 801 mg/day<br>Days 8 through 14: 1602 mg/day<br>Days 15 onward: 2403 mg/day |

## Dosage Forms

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

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

### I. Initial Approval Criteria

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

1. Diagnosis of IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age 18 years of age or older;
4. Dose does not exceed:
  - a. Days 1 through 7: 801 mg (3 capsules or 1 tablet) per day;
  - b. Days 8 through 14: 1602 mg (6 capsules or 2 tablets) per day;
  - c. Day 15 and onward: 2403 mg (9 capsules or 3 tablets) per day.

#### Approval duration

**Commercial:** 6 months

**Medicaid:** 6 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

## II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2403 mg per day.

#### Approval duration

**Commercial:** 12 months

**Medicaid:** 12 months

## III. Appendices

### APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

IPF: idiopathic pulmonary fibrosis

ULN: upper limit of normal

### APPENDIX B: Therapeutic Alternatives

- Not applicable

### APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - none reported
- Boxed warning(s):
  - none reported

### APPENDIX D: General Information

Elevated liver enzymes and drug-induced liver injury has been observed with Esbriet. ALT, AST, and bilirubin elevations have occurred with ESBRIET including cases of drug induced liver injury. In the post marketing period, non-serious and serious cases of drug-induced liver injury, including severe liver injury with fatal outcome, have been reported. Patients treated with Esbriet had a higher incidence of ALT and/or AST elevations of  $\geq 3x$  ULN (3.7%) compared with placebo patients (0.8%). Increases in ALT and AST  $\geq 3x$  ULN were reversible with dose modification or treatment discontinuation.

Conduct liver function tests (ALT, AST, and bilirubin) prior to the initiation of therapy with Esbriet, monthly for the first 6 months, every 3 months thereafter, and as clinically indicated. Measure liver function promptly in patients who report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. Dosage modification or interruption may be necessary for liver enzyme elevations.

## References

1. Esbriet Prescribing Information. South San Francisco, CA: Genentech USA, Inc.; July 2019. Available at: [www.esbriet.com](http://www.esbriet.com). Accessed July 22, 2020.
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.

| Review/Revision History   | Review/Revised Date | P&T Approval Date |
|---|---------------------|-------------------|
| Policy established.   | 01/2020             | 03/06/2020        |
| <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Line of Business Policy Applies to was update to all lines of business.</li> <li>3. Dosing information: Dosing Regime updated to include "with meal". Approval duration was updated to specify Medicaid and Commercial.</li> <li>4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."</li> <li>5. Added APPENDIX D: General Information.</li> <li>6. References were updated.</li> </ol> | 7/22/2020           | 09/14/2020        |