Clinical Policy: Pirfenidone (Esbriet)

Reference Number: CP.PHAR.286
Effective Date: 10.01.16
Last Review Date: 08.21
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Pirfenidone (Esbriet®) is a pyridone.

FDA Approved Indication(s)

Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation® 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 IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets (a and b):
   a. Pulmonary fibrosis on high resolution computed tomography (HRCT) with one of the following (i or ii):
      i. Usual interstitial pneumonia (UIP) pattern;
      ii. Probable or indeterminate UIP pattern, and surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid confirms the diagnosis of IPF;
   b. Known causes of pulmonary fibrosis have been ruled out *(see Appendix D);*
5. Baseline forced vital capacity (FVC) ≥ 50% of predicted;
6. Baseline carbon monoxide diffusing capacity (DLCO) ≥ 30% of predicted;
7. Esbriet is not prescribed concurrently with Ofev®;
8. Member is not an active smoker as evidenced by recent (within the last 30 days) negative nicotine metabolite (i.e., cotinine) test;
9. Dose does not exceed:
   a. Days 1 through 7: 801 mg (3 capsules or 1 tablet) per day;
   b. Days 8 through 14: 1,602 mg (6 capsules or 2 tablets) per day;
   c. Day 15 and onward: 2,403 mg (9 capsules or 3 tablets) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Esbriet is not prescribed concurrently with Ofev;
4. If request is for a dose increase, new dose does not exceed 2,403 mg (9 capsules or 3 tablets) per day.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DLCO: carbon monoxide diffusing capacity
FDA: Food and Drug Administration
FVC: forced vital capacity
HCRT: high resolution computed tomography
IPF: idiopathic pulmonary fibrosis
UIP: usual interstitial pneumonia

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: American Thoracic Society (ATS) 2018 IPF Guidelines

- ATS diagnostic criteria for IPF are built around pulmonary fibrosis findings on HRCT and exclusion of known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity).
- UIP is the hallmark radiologic pattern of IPF. Honeycombing is a distinguishing feature of UIP and must be present for a definite HRCT diagnosis of UIP to be made.
- In patients with a probable or indeterminate UIP pattern, surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid is recommended to confirm the diagnosis of IPF.

Appendix E: General Information

- Smoking causes decreased exposure to Esbriet, which may alter the efficacy profile of Esbriet. Instruct patients to stop smoking prior to treatment with Esbriet and to avoid smoking when using Esbriet.
- The Esbriet pivotal studies included only patients with mild to moderate lung impairment per FVC and DLCO.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IPF	Days 1 through 7: 267 mg PO TID Days 8 through 14: 534 mg PO TID Days 15 onward: 801 mg PO TID	Days 1 through 7: 801 mg/day Days 8 through 14: 1,602 mg/day Days 15 onward: 2,403 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.; July 2019. Available at: www.esbriet.com. Accessed June 30, 2021.
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.
4. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Diagnosis of Idiopathic Pulmonary Fibrosis. Am J Respir Crit Care Med. 2018 September; 198(5): e44-68.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Safety criteria applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Added dosing information related to initial titration period.	09.17	10.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policies combined for Centene Medicaid and Commercial lines of business; no significant changes from previously approved corporate policy; Medicaid: removed requirement for high-resolution computed tomography or surgical lung biopsy findings confirming diagnosis; commercial: added age requirement and dose related to initial titration period, modified approval durations from length of benefit to 6/12 months; references reviewed and updated.	05.10.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: added HIM line of business; for IPF added HRCT and rule-out criteria to align with previously Corporate-approved approach for IPF for Ofev; references reviewed and updated.	06.22.20	08.20
3Q 2021 annual review: added requirements for HRCT UIP pattern and surgical biopsy/bronchoalveolar lavage per ATS guidelines; added baseline FVC/DLCO requirements per pivotal trial inclusion criteria; added requirement against concurrent use with Ofev; added requirement that member is not an active smoker; modified HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	06.30.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.