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DRUG POLICY

Esbriet (pirfenidone)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Esbriet (pirfenidone) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

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

POLICY

Criteria for Initial Approval

Submission of the following information is necessary to initiate the prior authorization review (where applicable):

- Result of a chest high-resolution computed tomography (HRCT) study.
- If a lung biopsy is conducted, submit the associated pathology report.

Criteria for Initial Approval

A. Idiopathic Pulmonary Fibrosis (IPF)

Authorization of 12 months may be granted for treatment of idiopathic pulmonary fibrosis when the member has undergone a diagnostic work-up which includes the following:

1. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded.

AND

2. The member has completed a high-resolution computed tomography (HRCT) study of the chest or a lung biopsy which reveals a result consistent with the usual interstitial pneumonia (UIP)

pattern, OR has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP) and the diagnosis is supported by a lung biopsy. If a lung biopsy has not been previously conducted, the diagnosis is supported by a multidisciplinary discussion between a radiologist and pulmonologist who are experienced in IPF.

Continuation of Therapy

A. Idiopathic Pulmonary Fibrosis (IPF)

All members (including new members) requesting authorization for continuation of therapy may be granted an authorization of 12 months when the member is currently receiving treatment with Esbriet (pirfenidone), excluding when Esbriet (pirfenidone) is obtained as samples or via manufacturer’s patient assistance programs.

Brand and generic Esbriet (pirfenidone) are considered **not medically necessary** for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking/vaping cessation options.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

| Medication | Quantity Limit | FDA-recommended dosing |
|---|----------------|---|
| Esbriet (pirfenidone) 267 mg tablets/capsules | 9 per day | Days 1 through 7: 267 mg three times daily (801 mg/day) |
| Esbriet (pirfenidone) 801 mg tablets | 3 per day | Days 8 through 14: 534 mg three times daily (1602 mg/day) Days 15 onward: 801 mg three times daily (2403 mg/day) |

REFERENCES

- Esbriet [package insert]. South San Francisco, CA: Genentech USA, Inc.; February 2022.
- Pirfenidone [package insert]. Berkeley Heights, NJ: Laurus Labs Limited; July 2022.
- Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. Am J Respir Crit Care Med. 2022 May 1;205(9):e18-e47.
- Vancheri C, Kreuter M, Richeldi L, et al. Nintedanib with add-on pirfenidone in idiopathic pulmonary fibrosis: results of the Injourney trial. Am J Respir Crit Care Med. 2017 Sept 10. doi: 10.1164/rccm.201706-1301OC. [Epub ahead of print].

POLICY HISTORY

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