Effective Date: 12/01/2020
Last Reviewed: 9/2020, 4/2021, 3/2022, 3/2023, 03/2024, 07/2025, 01/2026 Scope: Medicaid

pirfenidone (generic Esbriet)

POLICY

I. INDICATIONS

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
Treatment of idiopathic pulmonary fibrosis (IPF)

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Treatment of IPF

An authorization may be granted for 12 months when the following criteria are met:

1. The requested drug is prescribed by or in consultation with a pulmonologist
2. Member is at least 18 years of age.
3. Documented diagnosis of IPF by both of the following:
    a. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded.
    b. The member meets either of the following:
        i. 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.
        ii. Member 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.
4. Documentation of the member's baseline forced vital capacity (FVC).
5. Documentation of the member's baseline liver function tests.
6. Documentation that the member is not concurrently taking in combination with Ofev (nintedanib).

III. CRITERIA FOR CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted when the member has documentation of a positive clinical response to the medication (e.g., reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of exacerbations), is not being used in combination with Ofev (nintedanib), and is being prescribed by a pulmonologist or in consultation with a pulmonologist.

IV. QUANTITY LIMIT

pirfenidone 267mg - 6 tablets or capsules per day
pirfenidone 801mg - 3 tablets per day

V. REFERENCES

1. Esbriet (pirfenidone). South San Francisco, CA. FDA Package Insert. June 2025.