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

pirfenidone

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. DOCUMENTATION

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

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

III. CRITERIA FOR INITIAL APPROVAL

A. Treatment of IPF

An authorization may be granted for 6 months when the following criteria are met:

1. Prescriber is a pulmonologist or being prescribed in consultation with a pulmonologist.
2. Member is at least 18 years of age.
3. Documented diagnosis of IPF by all of the following criteria:
    a. Exclusion of other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, and drug toxicity), as documented by the following:
        i. ICD-10 Code J84.112 (Idiopathic pulmonary fibrosis); AND
    b. One of the following:
        i. In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF; OR
        ii. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern reveal IPF or probable IPF
4. Member is not concurrently taking in combination with Ofev (nintedanib).
5. Documentation of baseline liver function tests have been performed.

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IV. CRITERIA FOR CONTINUATION OF THERAPY

Authorization of 12 months may be granted when the member has documentation of a positive clinical response to the medication, is not being used in combination with Ofev (nintedanib) and is being prescribed by a pulmonologist or in consultation with a pulmonologist.

V. QUANTITY LIMIT

pirfenidone 267mg 6 tablets or capsules a day
pirfenidone 801mg 3 tablets a day

VI. REFERENCES

1. Esbriet (pirfenidone). South San Francisco, CA. FDA Package Insert. March 2023.