Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Ofev under the patient's prescription drug benefit.

Description:

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 Indications

A. Idiopathic Pulmonary Fibrosis
   Ofev is indicated for the treatment of adults with idiopathic pulmonary fibrosis (IPF).
B. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype
   Ofev is indicated for the treatment of adults with chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
C. Systemic Sclerosis-Associated Interstitial Lung Disease
   Ofev is indicated to slow the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Ofev

Policy/Guideline:

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.

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:

A. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded AND
B. 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. AND
C. The patient is unable to take generic pirfenidone tablets for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication.

B. Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype
Authorization of 12 months may be granted for treatment of chronic fibrosing interstitial lung diseases with a progressive phenotype when the member meets both of the following criteria:

i. The member has completed a high-resolution computed tomography (HRCT) study of the chest that shows fibrosis affecting at least 10 percent of the lungs.
ii. The member has progressive disease (e.g., forced vital capacity [FVC] decline greater than or equal to 10% of the predicted value, worsening respiratory symptoms, increased extent of fibrosis on HRCT).

C. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Authorization of 12 months may be granted for treatment of systemic sclerosis-associated interstitial lung disease when the member's diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest.

Criteria for Continuation of Therapy:

All members (including new members) requesting authorization for continuation of therapy for an indication listed in criteria for initial approval may be granted an authorization of 12 months when the member is currently receiving treatment with Ofev.

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: 60 capsules per 30 days

References:

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. October 2024.
2. 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;205(9):e18-e47.
3. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for systemic sclerosis-associated interstitial lung disease. N Engl J Med. 2019;380(26):2518-2528.
4. van den Hoogen F, Khanna D, Fransen J, et al. 2013 Classification criteria for systemic sclerosis: an American College of Rheumatology/European League against Rheumatism collaborative initiative. Arthritis Rheum. 2013;65(11):2737-47.
5. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. N Engl J Med. 2019;381(18):1718-1727.
6. Rahaghi FF, Hsu VM, Kaner RJ, et al. Expert consensus on the management of systemic sclerosis-associated interstitial lung disease. Respir Res. 2023;24(1):6-16.
7. Galdo FD, Lescoat A, Conaghan PG, et al. EULAR recommendations for the treatment of systemic sclerosis: 2023 update. Ann Rheum Dis. 2024;0:1-12.