MEDICAL MUTUAL®

Drug Policy

Policy:	Ofev (nintedanib)	Annual Review Date: 08/15/2024 Last Revised Date: 08/15/2024

OVERVIEW

Ofev, a kinase inhibitor, is indicated for the treatment of idiopathic pulmonary fibrosis (IPF). The recommended dose of Ofev is 150 mg twice daily (BID) with food given approximately 12 hours apart. Liver function tests should be performed prior to Ofev initiation. Dose modifications are recommended for adverse events (AEs) such as liver enzyme elevations.

POLICY STATEMENT

This policy involves the use of Ofev Prior authorization is recommended for pharmacy benefit coverage of Ofev. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Ofev as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Ofev be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ofev is recommended in those who meet the following criteria:

1. **Idiopathic Pulmonary Fibrosis**. Approve for the duration noted below if the patient meets the following criteria (A or B):
   - **a)** Initial Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, and iv):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Forced vital capacity is ≥ 40% of the predicted value; AND
     - **iii.** The diagnosis is confirmed by one of the following (a or b):
       - **a)** Findings on high-resolution computed tomography indicates usual interstitial pneumonia; OR
       - **b)** A surgical lung biopsy demonstrates usual interstitial pneumonia; AND
     - **iv.** Medication is prescribed by or in consultation with a pulmonologist; OR
   - **b)** Patient is Currently Receiving Ofev. Approve for 1 year if the patient meets the following (i, ii and iii):
     - **i.** Patient is ≥ 18 years of age; AND

ii. Patient has experienced a beneficial response to therapy over the last year while receiving Ofev; AND
Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Ofev. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of idiopathic pulmonary fibrosis exacerbations.
iii. Medication is prescribed by or in consultation with a pulmonologist.

2. **Interstitial Lung Diseases, Chronic Fibrosing with a Progressive Phenotype.** Approve for the duration noted below if the patient meets the following criteria (A or B):
Note: Examples of conditions include hypersensitivity pneumonitis; idiopathic non-specific interstitial pneumonitis; idiopathic non-specific interstitial pneumonia; unclassifiable idiopathic interstitial pneumonia; autoimmune interstitial lung disease (e.g., rheumatoid arthritis interstitial lung disease); exposure-related interstitial lung disease; and mixed connective tissue disease interstitial lung disease. This is not associated with idiopathic pulmonary fibrosis (see indication above).
   A) Initial Therapy. Approve for 1 year if the patient meets the following criteria (i, ii, iii, iv, and v):
      i. Patient is ≥ 18 years of age; AND
      ii. Forced vital capacity is ≥ 40% of the predicted value; AND
      iii. According to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography; AND
      iv. According to the prescriber the patient has clinical signs of progression; AND
      Note: Examples of clinical signs of progression include a forced vital capacity decline ≥ 10% of the predicted value or forced vital capacity decline ≥ 5% to < 10% with worsening symptoms and/or worsening imaging.
      v. Medication is prescribed by or in consultation with a pulmonologist; OR
   B) Patient is Currently Receiving Ofev. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
      i. Patient is ≥ 18 years of age; AND
      ii. Patient had experienced a beneficial response to therapy over the last year while receiving Ofev; AND
      Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Ofev. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of interstitial lung disease-related exacerbations.
      iii. Medication is prescribed by or in consultation with a pulmonologist.

3. **Interstitial Lung Disease Associated with Systemic Sclerosis.** Approve for the duration noted below if the patient meets the following criteria (A or B):
   A) Initial Therapy. Approve for 1 year if the patient meets the following (i, ii, iii, and iv):
      i. Patient is ≥ 18 years of age; AND
      ii. Forced vital capacity is ≥ 40% of the predicted value; AND

iii. Diagnosis is confirmed by high-resolution computed tomography; AND
iv. Medication is prescribed by or in consultation with a pulmonologist or a rheumatologist; OR

B) Patient is Currently Receiving Ofev. Approve for 1 year if the patient meets the following (i, ii, and iii):
i. Patient is ≥ 18 years of age; AND
ii. Patient had experienced a beneficial response to therapy over the last year while receiving Ofev; AND
Note: For a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Ofev. Examples of a beneficial response include a reduction in the anticipated decline in forced vital capacity, six-minute walk distance, and/or in the number or severity of disease-related exacerbations.
iii. Medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ofev has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Ofev is Being Used Concomitantly with Esbriet (pirfenidone capsules**). Esbriet is another medication indicated for IPF. The effectiveness and safety of concomitant use of Ofev with Esbriet have not been established. The 2015 ATS/ERS/JRS, ALAT clinical practice guideline regarding the treatment of idiopathic pulmonary fibrosis (an update of the 2011 clinical practice guidelines) do not recommend taking Ofev and Esbriet in combination.[16] A small exploratory study was done in which patients with IPF receiving Ofev added-on Esbriet.[17] Further research is needed to determine the utility of this combination regimen. Ofev and Esbriet have not been used concomitantly in the management of systemic sclerosis-associated interstitial lung disease.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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