AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: OFEV® (nintedanib)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

❑ Diagnosis: Idiopathic Pulmonary Fibrosis (IPF)

- ❑ Prescribed by or in consultation with a pulmonology specialist
- ❑ Diagnosis confirmed by:
  - ❑ Excluding any other causes of interstitial lung disease (i.e. environmental exposure, drug toxicity, and connective tissue disease)
  - ❑ High-resolution computed tomography (HRCT) revealing idiopathic fibrosis or probable IPF
  - ❑ If IPF is not definitive, a lung biopsy has also been done to confirm IPF

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- ❑ For initiating therapy:
  - ❑ The patient's forced vital capacity (FVC) ≥ 50% of the predicted value **(Please provide supporting documentation including a pulmonary function test (PFT) report and/or chart notes)**
  - ❑ The patient's carbon monoxide (CO) diffusing capacity 30-79% of the predicted value **(Please provide supporting documentation including a pulmonary function test (PFT) report and/or chart notes)**
  - ❑ No concomitant use of OFEV and Esbriet

❑ Diagnosis: Chronic Fibrosing Interstitial Lung Disease

- ❑ Prescribed by or in consultation with a pulmonology specialist
- ❑ Diagnosis confirmed by:
  - ❑ Chronic fibrosing interstitial lung disease with a progressive phenotype with both of the following:
    - ❑ Fibrotic ILD observed involving at least 10% of the lungs as detected by HRCT in the past 24 months
    - ❑ Clinical signs of progression in the previous 24 months observed by one of the following:
      - ❑ Forced vital capacity (FVC) decline greater than 10%
      - ❑ FVC decline of greater than or equal to 5%, but less than 10% and patient is experiencing worsening respiratory symptoms or patient is exhibiting increasing extent of fibrotic changes on chest imaging
- ❑ For initiating therapy:
  - ❑ The patient's forced vital capacity (FVC) ≥ 45% of the predicted value **(Please provide supporting documentation including a pulmonary function test (PFT) report and/or chart notes)**
  - ❑ The patient's carbon monoxide (CO) diffusing capacity 30-80% of the predicted value **(Please provide supporting documentation including a pulmonary function test (PFT) report and/or chart notes)**
- ❑ No concomitant use of OFEV and Esbriet

❑ Diagnosis: Systemic Sclerosis-associated Interstitial Lung Disease

All of the following criteria must be met:

- ❑ Medication is prescribed by or in consultation with a pulmonology specialist
- ❑ Diagnosis of systemic sclerosis has been confirmed with an American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) classification criteria score ≥ 9
- ❑ Onset of disease (first non-Raynaud symptom) occurred ≤ 5 years ago
- ❑ Member has worsening disease despite concomitant use of low-dose corticosteroids (e.g., prednisone ≤ 10mg/day) and stable doses of immunosuppressant therapy (e.g., mycophenolate, methotrexate, cyclophosphamide)

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- ❑ Member's baseline percent forced vital capacity (%FVC) must be ≥ 40%
- ❑ Member's baseline percent predicted diffusing capacity of the lungs for carbon monoxide (%DLCO, corrected for hemoglobin) must be between 30-89%
- ❑ Documentation of High-resolution computed tomography (HRCT) revealing pulmonary fibrosis involving at least 10% of the lungs has been submitted
- ❑ Member has tried and failed Actemra **(verified by chart notes or pharmacy paid claims; Actemra also requires prior authorization)**

Reauthorization: 6 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Continues to meet diagnostic criteria
- ❑ Not experiencing any toxicity of drug treatment
  - ❑ Liver toxicity performed at regular intervals; for female patients, periodic pregnancy test to rule out
  - ❑ GI (D/N/V, perforation), arterial thromboembolic events
- ❑ Current state of disease and symptomology has been determined to be stable **(please provide supporting documentation that the disease has responded by reduction in the rate of decline in forced vital capacity (%FVC) compared to pre-treatment baseline)**

Medication being provided by Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: ~~1/17/2019;~~ 10/15/2020
REVISED/UPDATED/REFORMATTED: ~~3/20/2019; 4/1/2021; **6/14/2021**; 9/10/2021; 11/8/2021;11/22/2021;~~ **10/27/2023**