

# 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:** nintedanib (generic OFEV®)

**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: \_\_\_\_\_

NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

**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)  $\geq$  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)  $\geq$  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**

- ☐ 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  $\geq$  9
- ☐ Onset of disease (first non-Raynaud symptom) occurred  $\leq$  5 years ago
- ☐ Member has worsening disease despite concomitant use of low-dose corticosteroids (e.g., prednisone  $\leq$  10 mg/day) and stable doses of immunosuppressant therapy (e.g., mycophenolate, methotrexate, cyclophosphamide)
- ☐ Member's baseline percent forced vital capacity (%FVC) must be  $\geq$  40%

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- ☐ 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.

- ☐ Member continues to meet diagnostic criteria
- ☐ Member is **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.\****