Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Revision date:	October 21, 2015 January 21, 2020, May 19, 2020, July 1, 2024

Ofev® (nintedanib)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years old.
- Patient must obtain a liver function test prior to starting treatment.
- Must be prescribed or in consultation with a pulmonologist.

Idiopathic Pulmonary Fibrosis

- Confirmation of idiopathic pulmonary fibrosis through exclusions of other known causes of interstitial lung disease: Domestic and occupational environmental exposures, drug toxicity or connective tissue disease.
- Confirmation of diagnosis via lung biopsy for idiopathic pulmonary fibrosis diagnosis **OR** high-resolution computed tomography HRCT).
- Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity (FVC) ≥ 50%.
- Baseline percent predicted diffusing capacity of the lung for carbon monoxide is ≥30% for idiopathic pulmonary fibrosis.
- Documentation submitted that the patient is a nonsmoker or has been abstinent for at least six weeks.

Systemic Sclerosis-Associated Interstitial Lung Disease

- Confirmation of systemic sclerosis-associated interstitial lung disease.
- Documentation submitted that the patient is a nonsmoker or has been abstinent for at least six weeks.
- Confirmation of diagnosis via high resolution computed tomography (HRCT).
- Documented pulmonary function tests within the past 60 days reflecting Forced Vital Capacity (FVC) ≥ 40%.

Chronic Fibrosing Interstitial Lung Diseases

- Confirmation of chronic fibrosing interstitial lung diseases with a progressive phenotype.
- Confirmation of diagnosis via high resolution computer tomography (HRCT) scan showing fibrosis affecting ≥ 10% of lungs.
- Documentation submitted that the patient is a nonsmoker or has been abstinent for at least six weeks.
- Documented pulmonary function test within the past 60 days reflecting Forced Vital Capacity (FVC) ≥45% of predicted.
- Baseline percent predicted diffusing capacity of the lung for carbon monoxide (DLCO) between 30-79%.

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Patient has not experienced any treatment-restricting adverse effects.

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- Dosing is appropriate as per labeling or is supported by compendia.
- Documentation of improvement or effectiveness of therapy (< 200ml decrease in FVC or <10% decline in percent predicted FVC) for idiopathic pulmonary fibrosis.
- Documentation of improvement or effectiveness of therapy for systemic sclerosis-associated interstitial lung disease.
- Documentation that the rate of decline of lung function has slowed for chronic fibrosing interstitial lung diseases.
- Clinical documentation that the recipient is tobacco free.

DOSING & ADMINISTRATION:

- Refer to product labeling https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 100 mg and 150 mg capsules