

**Nintedanib (generic Ofev)**  
**Effective 06/01/2026**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b>	Phone: 833-895-2611	Fax: 888-656-6671
	<b>Pharmacy Benefit</b>	Phone: 800-711-4555	Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

Nintedanib (generic Ofev) is a kinase inhibitor indicated in adults for:

- Treatment of idiopathic pulmonary fibrosis
- Treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
- Slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD)

### Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with the requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

**OR**

Authorization may be granted when all of the following diagnosis-specific criteria are met:

#### Idiopathic Pulmonary Fibrosis (IPF)

1. Diagnosis of idiopathic pulmonary fibrosis (IPF)
2. Other known causes of interstitial lung disease (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity) have been excluded
3. ONE of the following:
  - a. 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
  - b. BOTH of the following:
    - i. Member has completed an HRCT study of the chest which reveals a result other than the UIP pattern (e.g., probable UIP, indeterminate for UIP, alternative diagnosis)
    - ii. ONE of the following:
      1. Diagnosis is supported by a lung biopsy
      2. 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

**Chronic Fibrosing Interstitial Lung Diseases with a Progressive Phenotype**

- 1. Diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype
- 2. Member has completed a high-resolution computed tomography (HRCT) study of the chest that shows fibrosis affecting at least 10 percent of the lungs
- 3. 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)

**Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)**

- 1. Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD)
- 2. Diagnosis was confirmed by a high-resolution computed tomography (HRCT) study of the chest

**Continuation of Therapy**

Requests for reauthorization may be approved when all of the following criteria are met:

- 1. Member demonstrates a positive clinical response to therapy

**Limitations**

- 1. Approvals will be granted for 12 months.
- 2. The following quantity limits apply:

Drug Name and Dosage Form	Quantity Limit
Nintedanib (generic Ofev) capsule	2 capsules per day

**References**

- 1. 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.
- 2. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in progressive fibrosing interstitial lung diseases. *N Engl J Med.* 2019;381(18):1718-1727.
- 3. Ofev (nintedanib) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. May 2025.
- 4. 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.
- 5. 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.

**Review History**

12/13/2023 - Reviewed at Dec P&T, switched from SGM to Custom. Effective 1/1/2024.

03/11/2026 – Reviewed and updated at March P&T. Administrative update to language for members who are new to the Plan and add quantity limits to policy. Updated reauthorization criteria to require that the member has had a positive clinical response to therapy. Effective 06/01/2026.

