| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

# Ofev (nintedanib)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1 year |

| Medications | Quantity Limit |
|---|---|
| Ofev (nintedanib) | May be subject to quantity limit |

## APPROVAL CRITERIA

Requests for Ofev (nintedanib) may be approved if the following criteria are met:

I. Individual has documented diagnosis of idiopathic pulmonary fibrosis as confirmed by (Raghu 2018):
   A. Exclusion of other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; **AND**
   B. High resolution computed tomography (HRCT) with or without lung tissue sampling;

**AND**

II. If initiating therapy, individual has documented pulmonary function tests within prior 60 days:
   A. Forced Vital Capacity (% FVC) greater than or equal to 50%;

**OR**

III. Individual has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD); **AND**

IV. Diagnosis has been confirmed by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs; **AND**

V. If initiating therapy, individual has documented pulmonary function tests within prior 60 days showing Forced Vital Capacity (% FVC) greater than or equal to 40%;

**OR**

VI. Individual has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype (including but not limited to hypersensitivity pneumonitis, autoimmune ILD, idiopathic nonspecific interstitial pneumonia); **AND**

VII. Diagnosis has been confirmed by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs; **AND**

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

VIII. If initiating therapy, progressive disease has been confirmed by one of the following within the last 24 months while on treatment:
   A. Forced Vital Capacity (FVC) decline of greater than or equal to 10%; **OR**
   B. FVC decline greater than or equal to 5% and less than 10% AND worsening respiratory symptoms or increased fibrosis on HRCT; **OR**
   C. Worsening respiratory symptoms AND increased fibrosis on HRCT;

**AND**

IX. If initiating therapy, individual has documented pulmonary function tests within prior 60 days showing FVC greater than or equal to 45%.

Requests for Ofev (nintedanib) may not be approved for the following:

I. Individuals who will be using Ofev (nintedanib) in combination with Esbriet (pirfenidone); **OR**
II. Individuals with severe renal impairment (creatinine clearance less than 30 mL/min) or end-stage renal disease (ESRD); **OR**
III. Individuals with moderate or severe hepatic impairment (Child Pugh Class B or C) or end-stage liver disease; **OR**
IV. Individual with SSc-ILD and concomitant clinically significant pulmonary hypertension;
V. Individual with chronic progressive fibrosing interstitial lung disease (ILD) and concomitant clinically significant pulmonary hypertension.

**Key References**:


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11. Varga J. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: February 7, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 25, 2019.

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

12. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: July 15, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 25, 2019.