Ofev (nintedanib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

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

APPROVAL CRITERIA

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

I. Individual has a diagnosis of idiopathic pulmonary fibrosis as demonstrated 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. Documentation is provided that individual has had pulmonary function tests within prior 60 days demonstrating 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. Documentation is provided that diagnosis has been demonstrated by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs; **AND**

V. Documentation is provided that individual has pulmonary function tests within prior 60 days demonstrating Forced Vital Capacity (% FVC) greater than or equal to 40%; **AND**

VI. Individual has had a trial and inadequate response or intolerance to one of the following (ATS 2023). Medication samples/coupons/discount cards are excluded from consideration as a trial.;
   A. Mycophenolate; **OR**
   B. Cyclophosphamide;

OR

VII. 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**

VIII. Documentation is provided that diagnosis has been demonstrated by chest high resolution computed tomography (HRCT) scan showing fibrosis affecting greater than or equal to 10% of the lungs; **AND**

IX. Progressive disease has been demonstrated 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. Two of the following:
      i. FVC decline greater than or equal to 5% and less than 10%; **OR**
      ii. Worsening respiratory symptoms; **OR**
      iii. Increased fibrosis on HRCT;

AND

X. Documentation is provided that individual has pulmonary function tests within prior 60 days demonstrating FVC greater than or equal to 45%.

Continuation requests for Ofev (nintedanib) may be approved if the following criterion is met:

I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to decreased frequency of exacerbations, slowed rate of FVC decline or improvement in respiratory symptom burden).

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.

Key References:

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14. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: February 13, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 8, 2023.