Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X

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 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. Individual has had pulmonary function tests within prior 60 days:
   A. Forced Vital Capacity (% FVC) greater than or equal to 50%, and documentation is provided;

OR

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

IV. Documentation is provided that 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. Documentation is provided that individual has 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**

Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X

VII. Documentation is provided that 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**

VIII. 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. 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

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

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

I. There is confirmation of 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; **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:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 15, 2020.
2. 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.

Market Applicability				
Market	**GA**	**MD**	**NJ**	**NY**
Applicable	X	X	X	X

3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. King TE. Treatment of idiopathic pulmonary fibrosis. Last updated: January 7, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 16, 2020.
5. Lederer DJ, Martinez FJ. Idiopathic Pulmonary Fibrosis. *NEJM.* 2018;379(8): 797-798.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
7. Raghu G, Remy-Jardin M, Myers JL, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: Diagnosis of idiopathic pulmonary fibrosis. *Am J Respir Crit Care Med.* 2018;198(5):e44-e68.
8. Raghu G, Rochwerg B, Zhang Y, et al. An official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis: An update of the 2011 clinical practice guideline. *Am J Respir Crit Care Med.* 2015;192:e3-e19.
9. Ryerson C, Ley B. Prognosis and monitoring of idiopathic pulmonary fibrosis. Last updated: August 4, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 16, 2020.
10. 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: October 16, 2020.
11. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Last updated: October 8, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 16, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.