

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

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

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%.

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.

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.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 4, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J Respir Crit Care Med.* 2011;183:788-824.
6. 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.
7. Raghu G, Rochweg 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.

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