CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Ofev (nintedanib)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 60 capsules per 30 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Ofev (nintedanib) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

IDIOPATHIC PULMONARY FIBROSIS (IPF)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has diagnosis of IPF confirmed by high resolution computed tomography (HRCT) or lung biopsy[3] (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 50% predicted; AND
5. Member does not have moderate to severe hepatic impairment; AND
6. Member is not a current smoker and provider attests the member will not smoke during treatment.
7. **Dosage allowed:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[7].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CHRONIC FIBROSING INTERSTITIAL LUNG DISEASES (ILD) WITH A PROGRESSIVE PHENOTYPE

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of Progressive Fibrosing ILD presenting with features of diffuse fibrosing lung disease of >10% extent on high-resolution computed tomography (HRCT)[8] (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 45% predicted[8]; AND

5. Member does not have moderate to severe hepatic impairment; AND
6. Member is not a current smoker and provider attests the member will not smoke during treatment.
7. **Dosage allowed:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[8].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or rheumatologist; AND
3. Member has a diagnosis of ILD associated with systemic sclerosis, presenting with high-resolution computed tomography (HRCT) showing fibrosis affecting at least 10% of the lungs[12] (results must be submitted for review); AND
4. Documentation of member's baseline forced vital capacity (FVC) must be equal to or greater than 40% predicted[12]; AND
5. Member's lung disease has progressed despite at least a 3 month trial of mycophenolate mofetil (MMF), cyclophosphamide, or azathioprine (MMF preferred)[10,13] unless contraindicated; AND
6. Member does not have moderate to severe hepatic impairment; AND
7. Member is not a current smoker and provider attests the member will not smoke during treatment.
8. **Dosage allowed:** 300mg per day (150mg twice daily)

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:
1. Member continues to abstain from smoking; AND
2. Chart notes must demonstrate reduced rate of FVC decline[12].

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Ofev (nintedanib) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/19/2020	New policy for Ofev created. Previously on IPF policy, now splitting from Esbriet, updating references, and adding new indications PF-ILD and SSc-ILD

References:

1. Ofev [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2020.
2. Nintedanib. Greenwood Village, CO: Truven Health Analytics. http://micromedex.com/. Updated May 7, 2020. Accessed June 19, 2020.
3. 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. *American Journal of Respiratory and Critical Care Medicine*. 2011;183(6):788-824. doi:10.1164/rccm.2009-040gl

4. 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. *American Journal of Respiratory and Critical Care Medicine*. 2015;192(2). doi:10.1164/rccm.201506-1063st
5. Canestaro WJ, Forrester SH, Raghu G, Ho L, Devine BE. Drug Treatment of Idiopathic Pulmonary Fibrosis. *Chest*. 2016;149(3):756-766. doi:10.1016/j.chest.2015.11.013
6. Rogliani P, Calzetta L, Cavalli F, Matera MG, Cazzola M. Pirfenidone, nintedanib and N-acetylcysteine for the treatment of idiopathic pulmonary fibrosis: A systematic review and meta-analysis. *Pulmonary Pharmacology & Therapeutics*. 2016;40:95-103. doi:10.1016/j.pupt.2016.07.009
7. Richeldi L, Bois RMD, Raghu G, et al. Efficacy and Safety of Nintedanib in Idiopathic Pulmonary Fibrosis. *New England Journal of Medicine*. 2014;370(22):2071-2082. doi:10.1056/nejmoa1402584
8. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in Progressive Fibrosing Interstitial Lung Diseases. *New England Journal of Medicine*. 2019;381(18):1718-1727. doi:10.1056/nejmoa1908681
9. Cottin V, Hirani NA, Hotchkin DL, et al. Presentation, diagnosis and clinical course of the spectrum of progressive-fibrosing interstitial lung diseases. *European Respiratory Review*. 2018;27(150):180076. doi:10.1183/16000617.0076-2018
10. Cottin V, Wollin L, Fischer A, Quaresma M, Stowasser S, Harari S. Fibrosing interstitial lung diseases: knowns and unknowns. *European Respiratory Review*. 2019;28(151):180100. doi:10.1183/16000617.0100-2018
11. Wells AU, Flaherty KR, Brown KK, et al. Nintedanib in patients with progressive fibrosing interstitial lung diseases-subgroup analyses by interstitial lung disease diagnosis in the INBUILD trial: a randomised, double-blind, placebo-controlled, parallel-group trial. *Lancet Respir Med*. 2020;8(5):453-460. doi:10.1016/S2213-2600(20)30036-9
12. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic Sclerosis–Associated Interstitial Lung Disease. *New England Journal of Medicine*. 2019;380(26):2518-2528. doi:10.1056/nejmoa1903076
13. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). *UpToDate.* https://www.uptodate.com/. Updated October 8, 2019. Accessed June 22, 2020.

Effective date: 10/20/2020
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