Clinical Policy Title:	nintedanib
Policy Number:	RxA.440
Drug(s) Applied:	Ofev®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Idiopathic Pulmonary Fibrosis (must meet all)**:**

1. Diagnosis of IPF;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets all of the following (a and b):
   a. Pulmonary fibrosis on high resolution computed tomography (HRCT) with one of the following (i or ii);
      i. Usual interstitial pneumonia (UIP) pattern;
      ii. Probable or indeterminate UIP pattern, and surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid confirms the diagnosis of IPF;
   b. Known causes of pulmonary fibrosis have been ruled out (e.g., domestic and occupational environmental exposures, CTD, drug toxicity);
5. Ofev® is not prescribed concurrently with Esbriet®;
6. Dose does not exceed 300 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

B. Systemic Sclerosis Associated Interstitial Lung Disease (must meet all)**:**

1. Diagnosis of SSc-ILD;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets (a and b):
   a. Pulmonary fibrosis affecting ≥ 10% of lung volume on HRCT;
   b. Additional signs of SSc are identified;
5. Ofev® is not prescribed concurrently with Esbriet®;
6. Dose does not exceed 300 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

C. Chronic Fibrosing Interstitial Lung Disease (must meet all)**:**

1. Diagnosis of chronic fibrosing interstitial lung diseases with a progressive phenotype ;
2. Prescribed by or in consultation with a pulmonologist;
3. Age ≥ 18 years;
4. Member meets both of the following (a and b)
   a. Pulmonary fibrosis affecting > 10% of lung volume on HRCT;
   b. Member meets one of the following (i or ii):
      i. A relative decline in the forced vital capacity (FVC) of ≥ 10% of the predicted value;
      ii. A relative decline in the FVC of 5% to < 10% of the predicted value plus either worsening of respiratory symptoms or an increased extent of fibrosis on HRCT;
5. Ofev® is not prescribed concurrently with Esbriet®;
6. Dose does not exceed 300 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

References

1. Keating GM. Nintedanib: a review of its use in patients with idiopathic pulmonary fibrosis. Drugs. 2015;75:1131-1140. Available at: https://pubmed.ncbi.nlm.nih.gov/26063212/. Accessed April 25, 2023.
2. 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. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5450933/. Accessed April 25, 2023.
3. Distler O, Highland KB, Gahlemann M, et al. Nintedanib for Systemic Sclerosis Associated Interstitial Lung Disease. N Engl J Med. 2019 Jun 27;380(26):2518-2528. Available at: https://www.nejm.org/doi/10.1056/NEJMoa1903076. Accessed April 25, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title was updated. 2. Indications were updated. 3. Initial Approval criteria updated. 4. Continued Therapy Approval criteria II.A.1 was rephrased. 5. References were updated.	07/27/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.C.7 was updated to	06/30/2021	09/14/2021

include “Dose does not exceed 300 mg per day…”. 2. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…” 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.b: Updated diagnostic criteria from Known causes of pulmonary fibrosis have been ruled out to Known causes of pulmonary fibrosis have been ruled out (e.g., domestic and occupational environmental exposures, CTD, drug toxicity). 2. Initial Approval Criteria, I.C.5: Updated to remove prior smoking criteria "Member is a non-smoker or has been abstinent for at least 6 weeks". 3. Initial Approval Criteria, I.C.5: Updated to remove prior diagnostic criteria "Documented pulmonary function test within the past 60 days reflecting Forced vital Capacity (FVC)≥45% of predicted". 4. Initial Approval Criteria, I.C.5: Updated to include new diagnostic criteria Member meets both of the following (a and b): a. Pulmonary fibrosis affecting > 10% of lung volume on HRCT; b. Documentation of one of the following (i or ii): i. A relative decline in the forced vital capacity (FVC) of ≥ 10% of the predicted value; ii. A relative decline in the FVC of 5% to < 10% of the predicted value plus either worsening of respiratory symptoms or an increased extent of fibrosis on HRCT; 5. References were reviewed and updated.	03/28/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5.a: Updated to include new eligibility criteria i. Usual interstitial pneumonia (UIP) pattern; ii. Probable or indeterminate UIP pattern, and	04/25/2023	07/13/2023

surgical lung biopsy or cellular analysis of bronchoalveolar lavage fluid confirms the diagnosis of IPF. 2. Initial Approval Criteria, I.A.4, I.B.4 and I.C.4: Updated to remove prior Attestation criteria Attestation that liver function tests in all patients and pregnancy tests in females of reproductive potential are conducted prior to initiating treatment. 3. Initial Approval Criteria, I.A.8, I.B.8. I.C.8: Updated to include new concurrent therapy criteria Ofev® is not prescribed concurrently with Esbriet. 4. Initial Approval Criteria, I.B.4.a: Updated requesting criteria from Pulmonary fibrosis on HRCT to Pulmonary fibrosis affecting ≥ 10% of lung volume on HRCT. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023