curative

Interstitial Lung Disease Prior Authorization

Drug(s) Applied:	**nintedanib** (generic Ofev)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Idiopathic pulmonary fibrosis (IPF) as indicated by chart notes within past 120 days

1. Other known causes of interstitial lung disease (ILD) have been excluded (e.g., domestic/occupational environmental exposures, connective tissue diseases, drug toxicities, alternative diagnoses, etc) (documentation required) **and**
2. Diagnosis confirmed by ONE of the following:
   a) High-resolution computed tomography (HRCT) scan with results showing a pattern for usual interstitial pneumonia (UIP) or honeycombing **or**
   b) Surgical lung biopsy with pathology confirming UIP or honeycombing **or**
   c) Transbronchial Lung Cryobiopsy (TBLC) with pathology confirming UIP or honeycombing **and**
3. Patient has failed or had disease progression on an adequate trial of pirfenidone **and**
4. Prescriber is a specialist in the area of the patient's diagnosis (e.g., pulmonologist, rheumatologist) **and**
5. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to nintedanib or moderate to severe hepatic impairment

Approval Duration: 12 months

B. Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD) or Rheumatoid Arthritis Interstitial Lung Disease (RA-ILD) as indicated by chart notes within past 120 days

1. Diagnosis of ILD confirmed by high-resolution computed tomography (HRCT) and pulmonary function test (PFT) **and**
2. ONE of the following:
   a) Patient has failed or had disease progression on an adequate trial of THREE alternatives:
      (1) A conventional agent (mycophenolate mofetil, cyclophosphamide, azathioprine) **and**

(2) Rituximab **and**
(3) Tyenne **or**

b) Patient has an intolerance or FDA labeled contraindication to ALL three alternatives (a conventional agent, rituximab, and Tyenne) **and**

3. Prescriber is a specialist in the area of the patient's diagnosis (e.g., pulmonologist, rheumatologist) **and**
4. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to nintedanib or moderate to severe hepatic impairment

Approval Duration: 12 months

C. Progressive Pulmonary Fibrosis (PPF) or Progressive Fibrosing Interstitial Lung Disease (PF-ILD) as indicated by chart notes within past 120 days

1. Patient has greater than 10% fibrotic features on HRCT **and**
2. There are clinical signs of progression by at least ONE of the following:
   a) FVC decline greater than or equal to 10% **or**
   b) FVC decline greater than or equal to 5% and less than 10% with worsening symptoms or imaging **or**
   c) Worsening symptoms and worsening imaging within the past 24 months **and**
3. Patient has failed or had disease progression on an adequate trial of standard alternatives based on the identified underlying condition **and**
4. Prescriber is a specialist in the area of the patient's diagnosis (e.g., pulmonologist, rheumatologist) **and**
5. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to nintedanib or moderate to severe hepatic impairment

Approval Duration: 12 months

II. Continued Therapy Criteria

A. IPF, SSc-ILD, RA-ILD, or PPF as indicated by chart notes within past 12 months

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
2. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., pulmonologist, rheumatologist) **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications to nintedanib

Approval Duration: 12 months

References:

1. Esbriet (pirfenidone) prescribing information. Genentech USA, Inc. February 2023.
2. Ofev (nintedanib) prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. May 2025.
3. Raghu G, Remy-Jardin M, Richeldi L, et al. Idiopathic Pulmonary Fibrosis (an Update) and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline. May 2022. Link.
4. 2023 ACR/CHEST Guideline for the Screening and Monitoring of Interstitial Lung Disease in People with Systemic Autoimmune Rheumatic Diseases. Link.
5. 2023 ACR/CHEST Guideline for the Treatment of Interstitial Lung Disease in People with Systemic Autoimmune Rheumatic Diseases. Link.

Policy Owned by: Curative PBM team