MOLINA HEALTHCARE

Iowa Health Link IOWA HHS Hawki Iowa HHS

Iowa Department of Human Services

Request for Prior Authorization
PIRFENIDONE (ESBRIET) & NINTEDANIB (OFEV)

(PLEASE PRINT – ACCURACY IS IMPORTANT)

FAX Completed Form To
1 (877) 733-3195
IOWA Provider Services
1 (844) 236-1464

IA Medicaid Member ID #	Patient name	DOB
Patient address		
Provider NPI	Prescriber name	Phone
Prescriber address		Fax
Pharmacy name	Address	Phone

Prescriber must complete all information above. It must be legible, correct, and complete or form will be returned.

Pharmacy NPI	Pharmacy fax	NDC

Prior authorization is required for pirfenidone (Esbriet®) and nintedanib (Ofev®). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1) Patient meets the FDA approved age; and

2) Is prescribed by a pulmonologist; and

3) Patient does not have hepatic impairment as defined below:

- **Nintedanib – Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); or**
- **Pifenidone – Patient does not have severe hepatic impairment (Child-Pugh C); and**

4) Patient does not have renal impairment as defined below:

- **Nintedanib – Patient does not have severe renal impairment (CrCl < 30 mL/min) or end-stage renal disease; or**
- **Pifenidone – Patient does not have end-stage renal disease requiring dialysis; and**

5) Patient does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib; and

6) Patient has a diagnosis of idiopathic pulmonary fibrosis (nintedanib or pirfenidone) as confirmed by one of the following (attach documentation):

- **a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or**
- **b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and**
- **c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and**
- **d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥ 50% predicted; and**
- **e. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30% predicted; or**

7) Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib) as confirmed by the following (attach documentation);

- **a. Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and**
- **b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and**
- **c. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or**

8) Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation):

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a. **Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and**

b. **Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and**

c. **Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and**

d. **Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:**

   i. **A relative decline in the FVC of at least 10% predicted; or**

   ii. **A relative decline in the FVC of 5-9% predicted combined with at least one of the following:**

      1. **Worsening respiratory symptoms; or**

      2. **Increased extent of fibrosis on HRCT; or**

   iii. **Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.**

If criteria for coverage are met, initial authorizations will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. **Adherence to pirfenidone (Esbriet®) or nintedanib (Ofev®) is confirmed; and**
2. **Documentation of a positive response to therapy, defined as meeting at least one of the following:**
   a. **Rate of lung function decline slowed; or**
   b. **Improved or no worsening of symptoms of cough or shortness of breath; and**
3. **Documentation is provided that the patient has remained tobacco-free; and**
4. **ALT, AST, and bilirubin are assessed periodically during therapy.**

Preferred **Non-Preferred**

☐ Ofev ☐ Esbriet ☐ Pirfenidone

Strength_____ **Dosage Instructions**_____ **Quantity**_____ **Days Supply**_____

Is Prescriber a Pulmonologist? ☐ Yes ☐ No

Does patient have moderate to severe hepatic impairment? ☐ Yes, Child-Pugh B ☐ Yes, Child-Pugh C ☐ No

Does patient have moderate to severe renal impairment or end-stage renal disease? ☐ Yes ☐ No

CrCl:_____ Date obtained:_____ Is patient on dialysis? ☐ Yes ☐ No

Does patient utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy? ☐ Yes ☐ No

Has patient been instructed to avoid tobacco products while using pirfenidone or nintedanib? ☐ Yes ☐ No

☐ **Idiopathic Pulmonary Fibrosis (nintedanib or pirfenidone)**

Attach results of HRCT or surgical lung biopsy indicating usual interstitial pneumonia (UIP).

Has prescriber excluded other known causes of interstitial lung disease (ILD)? ☐ Yes ☐ No

Patient has pulmonary function test within the prior 60 days documenting a FVC ≥ 50% predicted:

☐ Yes (attach results) ☐ No

Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30% predicted? ☐ Yes (attach results) ☐ No

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☐ **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) (nintedanib)**

Attach results of HRCT scan showing fibrosis affecting ≥ 10% of the lungs.

Patient has pulmonary function test within the prior 60 days showing FVC ≥ 40% predicted:

☐ Yes (attach results) ☐ No

Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted? ☐ Yes (attach results) ☐ No

☐ **Chronic Fibrosing Interstitial Lung Disease (nintedanib)**

Attach results of HRCT scan showing fibrosis affecting ≥ 10% of the lungs.

Patient has pulmonary function test within the prior 60 days showing FVC ≥ 45% predicted:

☐ Yes (attach results) ☐ No

Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted? ☐ Yes (attach results) ☐ No

Patient has at least one sign of clinical progression of ILD within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:

- ☐ A relative decline in the FVC of at least 10% predicted
- ☐ A relative decline in the FVC of 5-9% predicted combined with at least one of the following
  - ○ Worsening respiratory symptoms
  - ○ Increased extent of fibrosis on HRCT
- ☐ A worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.

☐ **Renewal Requests:**

Patient is adherent to therapy: ☐ Yes ☐ No

Patient has remained tobacco-free: ☐ Yes ☐ No

Patient has a positive response to therapy, defined as meeting at least one of the following:

- ☐ Rate of lung function decline slowed
- ☐ Improved or no worsening of cough or shortness of breath

ALT, AST, and bilirubin are being assessed periodically: ☐ Yes ☐ No Most recent date obtained:_____

Other medical conditions to consider:_____

Attach lab results and other documentation as necessary.

Prescriber signature (Must match prescriber listed above.)	Date of submission

IMPORTANT NOTE: *In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.*