

# DRUG DETERMINATION POLICY

**Title:** DDP-24 Pulmonary Fibrosis Agents

**Effective Date:** 11/10/2020



Physicians Health Plan  
PHP Insurance Company  
PHP Service Company

## Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

### 1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

### 2.0 Background or Purpose:

Ofev and Esbriet are specialty drugs indicated for a specific diagnosis. These criteria were developed and implemented to ensure appropriate use for the intended diagnosis and severity of disease.

### 3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Diagnosis and severity [must meet all parameters for one disease state below]:

Parameter	Idiopathic Pulmonary Fibrosis	Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype*	Systemic Sclerosis-Associated Interstitial Lung Disease*
FVC	≥50%	>45%	>40%
DLCO	30-79% predicted	30-80%	30-89%
FEV1/FVC	>0.7	>0.7	>0.7
HRCT	NA	>10 % fibrotic features	≥ 10% fibrosis
Characteristics	≥40years old, disease duration < 5 years	As above or clinical signs of progression based on FVC	Disease duration <7 years

*FVC - forced vital capacity; DLCO - Carbon monoxide diffusing capacity; FVC Forced expiratory volume in 1 minute; HRCT - high resolution computed tomography.*

*\*Esbriet is only FDA approved for Idiopathic Pulmonary Fibrosis*

B. Other therapies: clinical documentation of non-smoking status or abstinent for at least six weeks.

C. Dosage regimen:

1. Ofev oral (nintedanib): 150mg two times daily with food.
2. Esbriet oral (pirfenidone): increase up to 801mg (three times 267mg tabs) three times daily (total of 2,403mg per day) in two week period.

D. Approval.

1. Initial approval: one year.
2. Re-approval: one year (less than 10% annual decrease in forced vital capacity (FVC) or less than 200ml decreased FVC).

E. Exclusions: Ofev and Esbriet used concomitantly; non-FDA approve indications.

**4.0 Coding:**

None.

**5.0 References, Citations & Resources:**

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Ofev and Esbriet, accessed September 2020.
2. Treatment of Idiopathic Pulmonary Fibrosis. UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed 8/17.
3. An Official ATS/ERS/JRS/ALAT clinical practice guideline: Treatment of Idiopathic Pulmonary Fibrosis. American Journal of Respiratory and Critical Care Medicine. 2015;192(2):e3-19.

**6.0 Appendices:**

See page 3.

**7.0 Revision History:**

Original Effective Date: 06/30/2016

Next Review Date: 10/01/2021

<b>Revision Date</b>	<b>Reason for Revision</b>
7/19	Moved to new format; replaced abbreviations
8/20	Annual review, added 2 indications and put in table format, replaced abbreviations.

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Ofev nintedanib	<ul style="list-style-type: none"> <li>• Gastrointestinal: diarrhea (62%), nausea (24%), abdominal pain (15%), vomiting (12%), ↓appetite (11%)</li> <li>• Hepatic: increased liver function test (14%)</li> <li>• Pregnancy: may be expected to cause fetal harm</li> </ul>	<ul style="list-style-type: none"> <li>• Signs and symptoms of arterial thromboembolism and bleeding</li> <li>• Hepatic: liver function test prior, monthly for 3 months, then every 3 months</li> <li>• Obstetrics and Gynecology: pregnancy test prior</li> <li>• Gastrointestinal (GI): signs and symptoms of GI event</li> </ul>	None Needed
Esbriet pirfenidone	<ul style="list-style-type: none"> <li>• Central Nervous System: fatigue (22-26%), headache (10-22%), dizziness (9-18%)</li> <li>• Dermatology: skin rash (30%), photosensitivity (9-12%)</li> <li>• Gastrointestinal: nausea (33-36%), diarrhea (22-26%), abdominal pain (5-24%), dyspepsia (17-19%), anorexia (9-13%), vomiting (9-13%), GERD (6-11%)</li> <li>• Respiratory: upper respiratory infection (3-27%), sinusitis (1-11%)</li> <li>• Pregnancy Category: adverse events have been observed in animal reproductive studies.</li> </ul>	<ul style="list-style-type: none"> <li>• Dermatology: signs and symptoms of photosensitivity</li> <li>• Gastrointestinal (GI): signs and symptoms of GI events</li> <li>• Hepatic: liver function tests prior, monthly for 6 months, then every 3 months.</li> </ul>	None Needed