

DRUG DETERMINATION POLICY

Title: DDP-24 Pulmonary Fibrosis Agents

Effective Date: 11/09/2021



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 Food and Drug Administration (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 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:
 - a. Duration: one year
 - b. Outcome: less than 10% annual decrease in forced vital capacity (FVC) or less than 200ml decreased FVC.

E. Appropriate medication use [must meet one listed below]:

1. FDA approval status [must meet one listed below]:
 - a. FDA approved: product, indication, and/or dosage regimen.
 - b. Non-FDA approved: compendium support (Lexi comp™) for use of a drug for a non- FDA approved indication or dosage regimen.
2. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Ofev and Esbriet, accessed September 2021.
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: 09/22/2022

Revision Date	Reason for Revision
7/19	Moved to new format; replaced abbreviations
8/20	Annual review, added 2 indications and put in table format, replaced abbreviations.
8/21	Annual review; added appropriate use section

Appendix I: Patient Safety and Monitoring

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