DRUG DETERMINATION POLICY

Title: DDP-24 Pulmonary Fibrosis Agents

Effective Date: 11/14/2019

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 appoval.

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. Idiopathic Pulmonary Fibrosis.

1. Age: at least 40 years old.

2. Diagnosis and severity: idiopathic pulmonary fibrosis (IPF).

   a. Practitioner: pulmonologist.

   b. Interstitial pneumonia: documentation by high-resolution computed tomography (HRCT) or surgical lung biopsy.

   c. Pulmonary function test:

      i. Forced vital capacity (FVC): at least 50% predicted.

      ii. Diffusing capacity for carbon monoxide: at least 30% predicted.

3. Life style: clinical documentation of non-smoking status or abstinent for at least six weeks.

4. Dosage regimen:

   a. Ofev oral (nintedanib): 150mg two times daily with food.

   b. Esbriet oral (pirfenidone): increase up to 801mg (three times 267mg tabs) three times daily (total = 2,403mg/day) in two weeks.

5. Approval.

   a. Initial approval: one year.

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

B. Exclusions: Ofev and Esbrient used concomitantly; non-idiopathic pulmonary fibrosis indications.

4.0 Coding:

None.

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Ofev and Esbriet, accessed Aug 2019.

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:

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Ofev nintedanib	• Gastrointestinal (GI): diarrhea (62%), nausea (24%), abdominal pain (15%), vomiting (12%), ↓appetite (11%) • Hepatic: ↑ LFT (14%) • Pregnancy: may be expected to cause fetal harm	• Signs and Symptoms (S & Sx) of arterial TEs & bleeding • Hepatic: LFT pre, monthly x 3, then q 3 months • OB/GYN: pregnancy test prior to tx • GI: S & Sx of GI events	None Needed
Esbriet pirfenidone	• Central Nervous System (CNS): fatigue (22-26%), HA (10-22%), dizziness (9-18%) • Dermatology: skin rash (30%), photosensitivity (9-12%) • GI: nausea (33-36%), diarrhea (22-26%), abdominal pain (5-24%), dyspepsia (17-19%), anorexia (9-13%), vomiting (9-13%), GERD (6-11%) • Resp: UTI (3-27%), sinusitis (1-11%) • Pregnancy Category: adverse events have been observed in animal reproductive studies.	• Dermatology: S & Sx of photosensitivity • GI: S & Sx of GI events • Hepatic: LFT pre, monthly. x 6, then q 3 mons.	None Needed

7.0 Revision History:

Original Effective Date: 06/30/2016

Next Review Date: 09/23/2020

Revision Date	Reason for Revision
7/19	Moved to new format; replaced abbreviations