University of Michigan Health Plan

DRUG DETERMINATION POLICY

Title: DDP-24 Pulmonary Fibrosis Agents

Effective Date: 10/23/24

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by UM Health Plan and may not be covered by all UM Health 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 UM Health Plan 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:

I. General Considerations:

A. Appropriate medication use [must meet all listed below]

1. Diagnosis: meets standard diagnostic criteria that designates signs, symptoms, and test results to support specific diagnosis.

2. Food and Drug Administration (FDA) approval status [must meet one listed below]:

a. FDA approved: product, indication, and/or dosage regimen.

b. Non-FDA approved use: Compendium support (Lexicomp®) for use of a drug for a non-FDA approved indication or dosage regimen.

3. Place in therapy: sequence of therapy supported by national or internationally accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

B. Pharmaceutical sample use: The Plan does not recognize samples as a medication trial or for continuation of therapy.

C. Adherence to requested medication required for re-approval [must meet one listed below]:

1. Medications processed on the medical benefit: consistent utilization history documented in claims history or chart notes.

2. Medications processed on the pharmacy benefit: consistent fill history electronically or verbally from pharmacy.

II. Pulmonary Fibrosis

A. Diagnosis and severity [must meet all pulmonary function test 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 (average)	≥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.

4.0 Coding:

COVERED PRODUCTS – PHARMACY BENEFIT	
Drug Name	**Prior Approval Required**
Esbriet	Y
Ofev	Y

5.0 References, Citations & Resources:

1. Lexi comp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Ofev and Esbriet, accessed August 2024
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.
4. An Official ATS/ERS/JRS/ALAT clinical practice guideline: Diagnosis of Idiopathic Pulmonary Fibrosis. American Journal of Respiratory and Critical Care Medicine. 2018;198(5):e44-e68.\
5. Idiopathic pulmonary fibrosis in adults: diagnosis and management. NICE Clinical Guidelines, No. 163, London: National Institute for Health and Care Excellence (NICE); 2017 May.
6. An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline: Idiopathic Pulmonary Fibrosis (an update) and Progressive Pulmonary Fibrosis in Adults. Americann Journal of Respiratory and Critical Care Medicine 2022;205(9):e18-e47

6.0 Appendices:

See page 3.

7.0 Revision History:

Original Effective Date: 06/30/2016

Next Review Date: 11/01/2025

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
10/22	Annual review; Clarified PFT disease parameters, added reference
8/23	Annual review; added general consideration section for appropriate use and others, added two references
8/24	Annual review ; Delete patient safety and Monitoring table; update reference access date