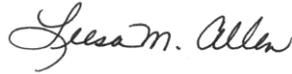


<b>ISSUE DATE</b> May 11, 2015	<b>EFFECTIVE DATE</b> June 15, 2015	<b>NUMBER</b> *See below
<b>SUBJECT</b> Prior Authorization of Idiopathic Pulmonary Fibrosis Agents – Pharmacy Service		<b>BY</b>  Leesa M. Allen, Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers about new requirements for prior authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents.
2. Issue handbook pages that include instructions on how to request prior authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents, including the type of medical information needed to evaluate requests for medical necessity.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

The Department’s Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department’s Prospective Drug Use Review (ProDUR) and Retrospective Drug Use Review (RetroDUR) programs.

*01-15-14	09-15-13	27-15-12	
02-15-12	11-15-12	30-15-12	
03-15-12	14-15-12	31-15-13	
08-15-14	24-15-12	32-15-12	33-15-13

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at  
<http://www.dhs.state.pa.us/provider/healthcaremedicalassistance/index.htm>

**DISCUSSION:**

During the March 18, 2015 meeting, the DUR Board recommended that the Department require prior authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents and proposed guidelines to determine medical necessity to ensure appropriate patient selection and drug utilization of Idiopathic Pulmonary Fibrosis (IPF) Agents. The requirement for prior authorization and guidelines to determine medical necessity, as recommended by the DUR Board, were subject to public review and comment, and subsequently approved for implementation by the Department. The requirements for prior authorization and clinical review guidelines to determine the medical necessity of Idiopathic Pulmonary Fibrosis (IPF) Agents are included in the attached updated provider handbook pages.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapters related to Idiopathic Pulmonary Fibrosis (IPF) Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II

Idiopathic Pulmonary Fibrosis (IPF) Agents

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**1. Requirements for Prior Authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents**

A. Prescriptions That Require Prior Authorization

All prescriptions for Idiopathic Pulmonary Fibrosis (IPF) Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Idiopathic Pulmonary Fibrosis (IPF) Agent, the determination of whether the requested prescription is medically necessary will take into account whether:

1. The requested agent is prescribed by, or in consultation with, a pulmonologist

**AND**

2. The recipient has a diagnosis of IPF documented by the following:

- a. Exclusion of other known causes of interstitial lung disease (ILD) and dyspnea

**AND**

- b. Presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in patients not subjected to surgical lung biopsy,

**OR**

- c. In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF

**AND**

3. The recipient had any potential drug interactions addressed by the prescriber

**AND**

4. The recipient has documented baseline liver function tests (ALT, AST, bilirubin)

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**AND**

5. The recipient is not a current smoker

**AND**

6. For Esbriet, the recipient:

a. Does not have end-stage renal disease requiring dialysis

**AND**

b. Will have liver function tests completed every month for the first 6 months then every 3 months thereafter

**OR**

7. For Ofev, the recipient

a. Does not have any of the following:

- i. Severe renal impairment or end-stage renal disease
- ii. ALT, AST or bilirubin >1.5 times the upper limit of normal
- iii. Active bleeding
- iv. A recent history of myocardial infarction or stroke
- v. Gastrointestinal perforation

**AND**

b. If taking anticoagulation treatment, will be monitored for signs of bleeding

**AND**

c. Will have liver function tests completed every month for the first 3 months then every 3 months thereafter

**AND**

d. If female and of child bearing age, is not pregnant as documented by a negative pregnancy test

**OR**

8. Does not meet the guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

FOR RENEWALS OF PRESCRIPTIONS FOR AN IDIOPATHIC PULMONARY FIBROSIS AGENT - The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Idiopathic Pulmonary Fibrosis Agents, that were previously approved, will take into account whether:

1. The recipient had any potential drug interactions addressed by the prescriber

**AND**

2. Since starting therapy, the recipient had repeat liver function tests (ALT, AST, bilirubin) as described in the initial prior authorization guidelines

**AND**

3. The dose prescribed is appropriate for the recipient's liver function according to package labeling

**AND**

4. For Esbriet, the recipient does not have end-stage renal disease requiring dialysis

**OR**

5. For Ofev, the recipient

- a. Does not have any of the following:

- i. Severe renal impairment or end-stage renal disease
- ii. ALT, AST or bilirubin >1.5 times the upper limit of normal
- iii. Active bleeding
- iv. A recent history of myocardial infarction or stroke
- v. Gastrointestinal perforation
- vi. Severe diarrhea, nausea, or vomiting that persists despite symptomatic treatment

**AND**

- b. If taking anticoagulation treatment, will be monitored for signs of bleeding

**AND**

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- c. If female and of child bearing age, is not pregnant as documented by a negative pregnancy test

**OR**

- 6. Does not meet the guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

**C**     Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for an Idiopathic Pulmonary Fibrosis (IPF) Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

**D.**     Dose and Duration of Therapy

Requests for prior authorization of an Idiopathic Pulmonary Fibrosis Agent will be approved as follows:

- 1. Initial approvals of requests for prior authorization of an Idiopathic Pulmonary Fibrosis Agent will be limited to 3 months of therapy
- 2. Renewals of requests for prior authorization of an Idiopathic Pulmonary Fibrosis Agent will be approved for up to 6 months

References

- 1. King, T.E. et.al, Treatment of idiopathic pulmonary fibrosis. Up To Date, accessed February 3, 2015.
- 2. Raghu G, Collard HR, Egan JJ, et al. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. American Journal of Respiratory Critical Care Medicine 2011; 183:788.
- 3. Esbriet prescribing information. InterMune, Inc. October 2014.
- 4. Ofev prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. October 2014.