pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 23, 2018	July 23, 2018	*See below

SUBJECT

Prior Authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents - Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:
http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Idiopathic Pulmonary Fibrosis (IPF) Agents submitted for prior authorization.

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 delivery system. Providers rendering services under the MA managed care delivery system should address any questions related to IPF Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

*01-18-21	09-18-22	27-18-20	33-18-21
02-18-16	11-18-16	30-18-16	
03-18-16	14-18-17	31-18-22	
08-18-23	24-18-17	32-18-16	

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.pa.gov/provider/healthcaremedicalassistance/index.htm

- New drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended the addition of a guideline in the IPF Agents class of drugs that will avoid an interruption in therapy, and ensure continuity of treatment, with a non-preferred drug that a beneficiary was prescribed within the past 90 days. DHS is also adding the standard guideline for therapeutic failure, intolerance, or contraindication to a preferred drug in the IPF Agents class of drugs to be consistent with the guidelines in other chapters. The proposed changes to the medical necessity guidelines were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of IPF Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to 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

I. 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 beneficiary 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 beneficiary had any potential drug interactions addressed by the prescriber.

   AND

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

   AND

5. The beneficiary is not a current smoker

AND

6. For Esbriet, the beneficiary:

   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 beneficiary

   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

      AND

8. For a non-preferred Idiopathic Pulmonary Fibrosis (IPF) Agent, the beneficiary has a documented history of therapeutic failure or intolerance of or contraindication to the preferred Idiopathic Pulmonary Fibrosis (IPF) Agents approved for the beneficiary's indication.

   OR

9. The beneficiary has a current history (within the past 90 days) of being prescribed the same non-preferred Idiopathic Pulmonary Fibrosis (IPF) Agent.

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

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

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

   AND

2. Since starting therapy, the beneficiary 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 beneficiary's liver function according to package labeling

   AND

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

   OR

5. For Ofev, the beneficiary

   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

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

NOTE: As described in Section C, if the beneficiary does not meet the clinical review guidelines above, but in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

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 beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of prescriptions for 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.

E. 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.