Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.557	**Effective Date: 01/01/2020** **Revision Date: 07/2020**
Policy Name: Idiopathic Pulmonary Fibrosis (IPF) Agents	

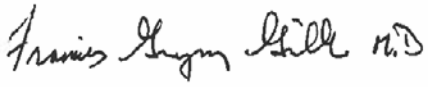
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q3 2020 annual review: no changes.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Idiopathic Pulmonary Fibrosis (IPF) Agents

Reference Number: PHW.PDL.557
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Idiopathic Pulmonary Fibrosis (IPF) Agents are **medically necessary** when the following criteria are met:

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

A. Prescriptions That Require Prior Authorization

All prescriptions for 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 IPF Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a diagnosis of IPF as documented by **both** of the following:

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

   b. **One** of the following:

      i. Presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF in beneficiaries not subjected to surgical lung biopsy
      ii. In beneficiaries subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF;

AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested medication by or in consultation with a pulmonologist;

   AND

5. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

6. Has documented baseline liver function tests (ALT, AST, bilirubin); **AND**

7. Is not a current smoker; **AND**

8. For Esbriet, **both** of the following:

   a. Does not have end-stage renal disease requiring dialysis
   b. Will have liver function tests completed every month for the first 6 months then every 3 months thereafter.

   AND

9. For Ofev, **all** of the following:

   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,

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

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

   AND

10. For a non-preferred IPF Agent, **one** of the following:

    a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred IPF Agents approved or medically accepted for the beneficiary's indication
    b. Has a current history (within the past 90 days) of being prescribed the

same non- preferred IPF Agent;

AND

11. If a prescription for an IPF Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment 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 PRIOR AUTHORIZATION FOR AN IPF AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an IPF Agent will take into account whether the beneficiary:

1. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

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

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the requested medication by or in consultation with a pulmonologist; **AND**

5. For Esbriet, does not have end-stage renal disease requiring dialysis; **AND**

6. For Ofev, **all** of the following:

    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,

    b. If female and of child bearing age, is not pregnant as documented by a

negative pregnancy test;

AND

7. If a prescription for an IPF Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment 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 a prescription for an 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 IPF Agents will be approved as follows:

1. Initial requests for prior authorization of an IPF Agent will be approved for up to 3 months.

2. Renewals of requests for prior authorization of an IPF 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 guideline 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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020