## 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.

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| **Plan: PA Health & Wellness** | **Submission Date: 11/2020** |
| **Policy Number: PHW.PDL.557** | **Effective Date: 01/01/2020**<br>**Revision Date: 11/2020** |
| **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:**

Q1 2021: policy revised according to DHS revisions effective 01/05/2021

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| **Name of Authorized Individual (Please type or print):**<br><br>**Auren Weinberg, 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: 11/2020

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. Is prescribed the IPF Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **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. Does not have a history of a contraindication to the prescribed medication; **AND**

5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**

6. 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**

7. If a current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**

8. 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

   See the Preferred Drug List (PDL) for the list of preferred IPF Agents at: https://papdl.com/preferred-drug-list; **AND**

9. 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. Based on the prescriber's assessment, is benefitting from the requested medication; **AND**

2. 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**

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

4. Does not have a history of a contraindication to the prescribed medication; **AND**

5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**

6. 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 for up to 6 months.

E. References

1. De Vries-Bouwstra J, Allanore Y, Matucci-Cerinic M, Balbir-Gurman A. Worldwide Expert Agreement on Updated Recommendations for the Treatment of Systemic Sclerosis.The Journal of Rheumatology May 2019, jrheum.181173; DOI: 10.3899/jrheum.181173.
2. Distler O, Brown KK, Distler JHW, et al. Design of a randomised, placebo-controlled clinical trial of nintedanib in patients with systemic sclerosis-associated interstitial lung disease (SENSCIS™). Clinical and Experimental Rheumatology. 2017 Sep-Oct;35 Suppl 106(4):75-81.
3. Distler O., Highland, KB, Gahlemann M, et.al. (2019). Nintedanib for Systemic Sclerosis–Associated Interstitial Lung Disease. New England Journal of Medicine, *380(26), 2518–2528.* DOI:10.1056/nejmoa1903076
4. Esbriet Package Insert. South San Francisco, CA: Genentech, Inc.; July 2019.
5. Fernández-Codina A, Walker KM, Pope JE. and (2018), Treatment Algorithms for Systemic Sclerosis According to Experts. Arthritis Rheumatol, 70: 1820-1828. doi:10.1002/art.40560
6. Flaherty KR, Wells AU, Cottin V, et al. Nintedanib in Progressive Fibrosing Interstitial Lung Diseases. New England Journal of Medicine, 381:1718-27. DOI: 10.1056/NEJMoa1908681
7. King TE.Treatment of idiopathic pulmonary fibrosis. Waltham, MA: UpToDate Inc. Updated January 7, 2020. Accessed July 23, 2020.
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10. 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.
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12. Varga J. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Waltham, MA: UpToDate Inc. Updated February 7, 2019. Accessed July 23, 2020.
13. Varga J, Montesi S. Treatment and prognosis of interstitial lung disease in systemic sclerosis (scleroderma). Waltham, MA: UpToDate Inc. Updated October 8, 2019. Accessed July 23, 2020.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |
| Q1 2021: policy revised according to DHS revisions effective 01/05/2021 | 11/2020 |