

ISSUE DATE November 10, 2020	EFFECTIVE DATE January 5, 2021	NUMBER *See below
SUBJECT Prior Authorization of Idiopathic Pulmonary Fibrosis (IPF) Agents – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

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. The guidelines to determine the medical necessity of Idiopathic Pulmonary Fibrosis (IPF) Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of IPF Agents to the appropriate managed care organization.

BACKGROUND:

*01-20-31	09-20-30	27-20-26	33-20-27
02-20-24	11-20-24	30-20-23	
03-20-24	14-20-25	31-20-31	
08-20-34	24-20-24	32-20-23	

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 website at <https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and recommends the following:

- Preferred or non-preferred status for 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 or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the August 12, 2020, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of IPF Agents:

- Addition of a guideline that the beneficiary 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;
- Removal of the guideline that the beneficiary has a diagnosis of IPF;
- Revision to the guideline that the beneficiary is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.);
- Removal of the guidelines that the beneficiary has documentation of baseline and repeat liver function tests (ALT, AST, bilirubin);
- Revision to the guideline that if a current smoker, the beneficiary has documentation of being advised by the prescriber to quit smoking;
- Removal of the guidelines specific to Esbriet (pirfenidone);
- Removal of the guidelines specific to Ofev (nintedanib);
- Addition of a guideline for prior authorization renewals that based on the prescriber's assessment, the beneficiary is benefitting from the requested medication and the beneficiary is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); and
- Removal of the Dose and Duration of Therapy section.

The revisions to the guidelines to determine medical necessity of IPF Agents, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

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. 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 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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

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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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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 the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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

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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. References

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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.