


ISSUE DATE November 8, 2022	EFFECTIVE DATE January 9, 2023	NUMBER *See below
SUBJECT Prior Authorization of Antifibrotic Respiratory Agents (Formerly 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 Antifibrotic Respiratory 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 Antifibrotic Respiratory Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCO) 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 Antifibrotic Respiratory Agents to the appropriate MCO.

BACKGROUND/DISCUSSION:

*01-22-48	09-22-47	27-22-35	33-22-45
02-22-32	11-22-32	30-22-38	
03-22-31	14-22-32	31-22-51	
08-22-56	24-22-40	32-22-32	

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) is changing the title of the Idiopathic Pulmonary Fibrosis (IPF) Agents Statewide Preferred Drug List therapeutic class to Antifibrotic Respiratory Agents and is updating the corresponding medical necessity guidelines to remove the guideline related to drug interactions.

The revisions to the guidelines to determine medical necessity of prescriptions for Antifibrotic Respiratory Agents 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 Antifibrotic Respiratory 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 Antifibrotic Respiratory 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 and products 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 Antifibrotic Respiratory Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antifibrotic Respiratory Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifibrotic Respiratory Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antifibrotic Respiratory 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 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 current smoker, has documentation of being advised by the prescriber to stop smoking; **AND**
7. For a non-preferred Antifibrotic Respiratory Agent, **one** of the following:
 - a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antifibrotic Respiratory 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 Antifibrotic Respiratory Agent

See the Preferred Drug List (PDL) for the list of preferred Antifibrotic Respiratory Agents at: <https://papdl.com/preferred-drug-list>;

AND

8. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 ANTIFIBROTIC RESPIRATORY AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an Antifibrotic Respiratory Agent will take into account whether the beneficiary:

1. Based on the prescriber's assessment, is benefitting from the requested medication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the prescribed medication; **AND**
4. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
5. If a prescription for an Antifibrotic Respiratory 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 Antifibrotic Respiratory 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,

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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.