Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 17, 2025	January 5, 2026	*See below

SUBJECT

Prior Authorization of Pulmonary Hypertension Agents, Oral and Inhaled – 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: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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 Pulmonary Hypertension Agents, Oral and Inhaled 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 Pulmonary Hypertension Agents, Oral and Inhaled will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Pulmonary Hypertension Agents, Oral and Inhaled to the appropriate managed care organization.

BACKGROUND:

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

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

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).
- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 25, 2025, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Pulmonary Hypertension Agents, Oral and Inhaled:

- Revision to the guideline that for the treatment of pulmonary arterial hypertension (PAH), the beneficiary is prescribed a Pulmonary Hypertension Agent, Oral and Inhaled that is appropriate for the beneficiary's clinical status and current peer-reviewed medical literature.
- Revision to the guidelines for beneficiaries under the age of 18 that the beneficiary is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist or pediatric cardiologist.
- Revision to the guideline that, for a diagnosis of PAH (WHO Group 1), the beneficiary has chart documentation of a mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mmHg and a pulmonary vascular resistance (PVR) greater than 3 Wood units.
- Revision to the guideline that, for a diagnosis of chronic thromboembolic pulmonary hypertension, the beneficiary has chart documentation of an mPAP greater than or equal to 25 mmHg and a PVR greater than 3 Wood units.
- Revision to the guidelines for the treatment of idiopathic PAH.
- Addition of guidelines for the treatment of heritable PAH.
- Revision to the guidelines related to acute vasoreactivity to apply to beneficiaries with idiopathic or heritable PAH.
- Addition of guidelines related to a diagnosis of pulmonary hypertension associated with interstitial lung disease (WHO Group 3).

The revisions to the guidelines to determine medical necessity of prescriptions for Pulmonary Hypertension Agents, Oral and Inhaled submitted for prior authorization, 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 Pulmonary Hypertension Agents, Oral and Inhaled 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 Pulmonary Hypertension Agents, Oral and Inhaled) 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Pulmonary Hypertension Agents, Oral and Inhaled

A. Prescriptions That Require Prior Authorization

All prescriptions for Pulmonary Hypertension Agents, Oral and Inhaled must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:

    a. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled 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, excluding use to treat sexual or erectile dysfunction
    b. For the treatment of pulmonary arterial hypertension (PAH), is prescribed a Pulmonary Hypertension Agent, Oral and Inhaled that is appropriate for the beneficiary's clinical status and current peer-reviewed medical literature;

    AND

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

3. **One** of the following:

    a. If under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist or pediatric cardiologist

    b. If 18 years of age or older, **one** of the following:

        i. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
        ii. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist) skilled in treating pulmonary hypertension;

    AND

4. Does not have a contraindication to the prescribed drug; **AND**

5. For a diagnosis of PAH (WHO Group 1), **all** of the following:

   a. Has chart documentation of right heart catheterization indicating **all** of the following hemodynamic values:

      i. A mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mmHg,
      ii. A pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
      iii. A pulmonary vascular resistance (PVR) greater than 3 Wood units,

   b. For a beneficiary with idiopathic or heritable PAH, **one** of the following:

      i. Has chart documentation of acute vasoreactivity testing
      ii. Has a contraindication to vasoreactivity testing or is at increased risk of adverse events during acute vasoreactivity testing (e.g., presence of severe [functional class IV] symptoms, low systemic blood pressure, low cardiac index, or pulmonary veno-occlusive disease),

   c. For a beneficiary with idiopathic or heritable PAH that demonstrates acute vasoreactivity,[1] has a documented history of therapeutic failure of or a contraindication or an intolerance to calcium channel blockers (i.e., amlodipine, nifedipine, or diltiazem);

   AND

6. For a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), has chart documentation of right heart catheterization indicating **both** of the following hemodynamic values:

   a. An mPAP greater than or equal to 25 mmHg
   b. A PVR greater than 3 Wood units;

   AND

7. For a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3), has **both** of the following:

   a. Chart documentation of right heart catheterization indicating **all** of the following hemodynamic values:

      i. An mPAP greater than or equal to 25 mmHg,
      ii. A PCWP less than or equal to 15 mmHg,

[1] A positive vasoreactivity test is defined by a decrease in the mean pulmonary artery pressure by at least 10 mmHg to reach an absolute value of 40 mmHg or less without a decrease in cardiac output.

iii. A PVR greater than 3 Wood units

b. Chart documentation of recent computed tomography imaging demonstrating interstitial lung disease;

AND

8. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled, **one** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Pulmonary Hypertension Agents, Oral and Inhaled approved or medically accepted for the beneficiary's diagnosis or indication
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Pulmonary Hypertension Agent, Oral and Inhaled (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred).

   See the Preferred Drug List (PDL) for the list of preferred Pulmonary Hypertension Agents, Oral and Inhaled at: https://papdl.com/preferred-drug-list;

   AND

9. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   NOTE: 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 PRIOR AUTHORIZATION FOR PULMONARY HYPERTENSION AGENTS, ORAL AND INHALED: The determination of medical necessity of a request for renewal of a prior authorization for a Pulmonary Hypertension Agent, Oral and Inhaled that was previously approved will take into account whether the beneficiary:

1. Continues to benefit from the requested Pulmonary Hypertension Agent, Oral and Inhaled based on the prescriber's assessment; **AND**

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

3. **One** of the following:

   a. If under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist or pediatric cardiologist

   b. If 18 years of age or older, **one** of the following:

      i. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
      ii. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist);

   AND

4. Does not have a contraindication to the prescribed drug; **AND**

5. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug. See the PDL for the list of preferred Pulmonary Hypertension Agents, Oral and Inhaled at https://papdl.com/preferred-drug-list; **AND**

6. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled 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.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   NOTE: 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 a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled. 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.

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