


ISSUE DATE November 15, 2021	EFFECTIVE DATE January 3, 2022	NUMBER *See below
SUBJECT Prior Authorization of Pulmonary Hypertension Agents, Oral and Inhaled – 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 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 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 Pulmonary Hypertension Agents, Oral and Inhaled to the appropriate managed care organization.

BACKGROUND:

*01-21-38	09-21-37	27-21-29	33-21-37
02-21-25	11-21-27	30-21-32	
03-21-25	14-21-28	31-21-40	
08-21-40	24-21-35	32-21-25	

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 medical 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 September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Pulmonary Hypertension Agents, Oral and Inhaled:

- Revision of the Statewide PDL class name from Pulmonary Arterial Hypertension (PAH) Agents Oral and Inhaled to Pulmonary Hypertension Agents, Oral and Inhaled;
- Deletion of the guideline for a PDE5 inhibitor that the beneficiary has a diagnosis of PAH;
- Revision of the guideline that the beneficiary 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;
- Revision of the guidelines that beneficiaries less than 18 years of age or who are unable to access a Pulmonary Hypertension Association-accredited center are prescribed the Pulmonary Hypertension Agent by or in consultation with an appropriate specialist skilled in treating pulmonary hypertension;
- Revision of the guideline for a diagnosis of PAH (WHO Group 1) that the beneficiary has chart documentation of right heart catheterization indicating a pulmonary vascular resistance greater than or equal to 3 Wood units;
- Addition of a guideline for idiopathic PAH that the beneficiary has a H₂FPEF score less than 2, a left atrial volume index less than 35 mL/m², or a negative provocative test in a heart catheterization lab (fluid challenge with pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 17 mmHg);
- Revision of the guidelines for a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) that the beneficiary has chart documentation of right heart catheterization indicating a mean pulmonary arterial pressure greater than 20 mmHg AND a pulmonary vascular resistance greater than or equal to 3 Wood units;

- Clarification of the guidelines for a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled that a current history 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; and
- Revision of the requests for renewal of prior authorization guidelines that the beneficiary continues to benefit from the requested Pulmonary Hypertension Agent, Oral and Inhaled based on the prescriber's assessment.

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 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>

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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 level of risk based on current risk calculator assessment (e.g., REVEAL 2.0) 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 less than 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist skilled in treating pulmonary hypertension
 - b. If greater than or equal to 18 years of age, **one** of the following:
 - a. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
 - b. 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

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4. Does not have a contraindication to the prescribed medication; **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:
 - a. A mean pulmonary arterial pressure greater than 20 mmHg,
 - b. A pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
 - c. A pulmonary vascular resistance greater than or equal to 3 Wood units,
 - b. For a beneficiary with idiopathic PAH, **both** of the following:
 - i. **One** of the following:
 - a) Has a H₂FPEF score less than 2
 - b) Has a left atrial volume index less than 35 mL/m²
 - c) Has a negative provocative test in a heart catheterization lab (fluid challenge with pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 17 mmHg)
 - ii. **One** of the following:
 - a) Has chart documentation of acute vasoreactivity testing
 - b) Has a contraindication to vasoreactivity testing or is at increased risk of adverse events during acute vasoreactivity testing (e.g., high risk stratification based on current risk calculator assessment (e.g., REVEAL 2.0), low systemic blood pressure, low cardiac index, or pulmonary veno-occlusive disease),
 - c. For a beneficiary with idiopathic PAH that demonstrates acute vasoreactivity,¹ has a documented history of therapeutic failure, contraindication, or intolerance of 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. A mean pulmonary arterial pressure greater than 20 mmHg
 - b. A pulmonary vascular resistance greater than or equal to 3 Wood units;

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.

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AND

7. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled, **one** of the following:
 - a. Has a history of therapeutic failure, contraindication, or intolerance of 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

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

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heart and lung transplant specialist

- b. If greater than or equal to 18 years of age, **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 medication; **AND**
5. 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.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 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.

D. References

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3. Adempas Package Insert. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; January

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