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 Arterial Hypertension (PAH) 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 and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to PAH Agents, Oral and Inhaled to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services’ (Department) Drug Utilization Review (DUR)

02-19-107 11-19-106 30-19-105
03-19-106 14-19-105 31-19-113

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 Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.
Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

**DISCUSSION:**

During the September 13, 2019, meeting, the DUR Board recommended that all PAH Agents, Oral and Inhaled require prior authorization. The board also recommended the following revisions to the guidelines to determine medical necessity of PAH Agents, Oral and Inhaled:

- Addition of a guideline that the beneficiary’s diagnosis and prescribed dose are consistent with FDA-approved labeling or medical literature;
- Addition of a guideline that the beneficiary is being prescribed the PAH Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center or, if unable to access a Pulmonary Hypertension Association-accredited center, an appropriate specialist;
- Addition of a guideline that the beneficiary does not have a history of a contraindication to the prescribed PAH Agent, Oral and Inhaled;
- Addition of guidelines that beneficiaries with PAH (WHO Group 1) have chart documentation of right heart catheterization hemodynamic values confirming the diagnosis and beneficiaries with idiopathic PAH have documentation of acute vasoreactivity testing, unless contraindicated;
- Addition of a guideline that beneficiaries who demonstrate acute vasoreactivity have a documented history of therapeutic failure, contraindication, or intolerance to a calcium channel blocker;
- Addition of a guideline that beneficiaries with a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) have chart documentation of right heart catheterization hemodynamic values confirming the diagnosis;
- Revision of the guideline for non-preferred PAH Agents, Oral and Inhaled to take into account the beneficiary’s diagnosis or indication;
- Addition of guidelines for the determination of medical necessity of a request for renewal for a prescription of PAH Agents, Oral and Inhaled; and
- Removal of automated prior authorization of prescriptions for Adcirca (tadalafil) and Revatio (sildenafil).

The revisions to the guidelines to determine medical necessity of PAH Agents, Oral and Inhaled, as recommended by the DUR Board, 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 PAH 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 PAH 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
I. Requirements for Prior Authorization of Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled

A. Prescriptions That Require Prior Authorization

All prescriptions for PAH 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 PAH 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. For a PDE5 inhibitor, has a diagnosis of PAH

   b. For all other PAH Agents, Oral and Inhaled, **one** of the following:

      i. Is prescribed the PAH 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

      ii. For the treatment of PAH, is prescribed a PAH 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 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 PAH Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist

      b. If greater than or equal to 18 years of age, **one** of the following:

         i. Is prescribed the PAH 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 PAH Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist);
AND

4. Does not have a history of 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:
      i. A mean pulmonary arterial pressure greater than 20 mmHg,
      ii. A pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
      iii. A pulmonary vascular resistance greater than 3 Wood units,
    b. For a beneficiary with idiopathic 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., 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 25 mmHg
   b. A pulmonary vascular resistance greater than 3 Wood units;
   **AND**

7. For a non-preferred PAH Agent, Oral and Inhaled, **one** of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred PAH Agents, Oral and Inhaled approved or medically accepted for the beneficiary's diagnosis or indication

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.
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred PAH Agent, Oral and Inhaled

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

AND

8. If the prescription for a PAH 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 PAH AGENTS, ORAL AND INHALED: The determination of medical necessity of a request for renewal of a prior authorization for a PAH Agent, Oral and Inhaled that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the requested PAH 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 PAH Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist

b. If greater than or equal to 18 years of age, **one** of the following:

   i. Is prescribed the PAH 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 PAH Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist);

January 1, 2020
(Replacing January 28, 2019)
4. Does not have a history of a contraindication to the prescribed medication; **AND**

5. If the prescription for a PAH 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](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 PAH 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


January 1, 2020
(Replacing January 28, 2019)


15. Pulmonary Hypertension Association Consensus Statement; Revatio (sildenafil) for Pediatric Use: September 2012.


