pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 6, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Pulmonary Arterial Hypertension (PAH) 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.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)

*01-19-113	09-19-109	27-19-108	33-19-110
02-19-107	11-19-106	30-19-105	
03-19-106	14-19-105	31-19-113	
08-19-116	24-19-108	32-19-105	

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 catherization 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 catherization 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 catherization 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 mm Hg,
        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-occusive 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 catherization 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);

AND

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.

   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

1. Abman SH. Pediatric Pulmonary Hypertension Network: Implications of the FDA warning against the use of sildenafil for the treatment of pediatric pulmonary hypertension: November 19, 2012.
2. Adcirca Package Insert. Indianapolis, IN: Eli Lilly and Company; May 2017.
3. Adempas Package Insert. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; January 2018.
4. Benza RL, Gomberg-Maitland M, Elliott CG, et al. Predicting Survival in Patients with Pulmonary Arterial Hypertension. CHEST 2019; 156(2):323-337. [DOI: 10.1016/j.chest.2019.02.004].
5. Condon DF, Nickel NP, Anderson R, Mirza S, de Jesus Perez VA. The 6th World Symposium on Pulmonary Hypertension: what's old is new. *F1000Res*. 2019;8:F1000 Faculty Rev-888. Published 2019 Jun 19. [DOI:10.12688/f1000research.18811.1].
6. FDA Drug Safety Communication: FDA recommends against use of Revatio in children with pulmonary hypertension; September 21, 2012.
7. Frost A, Badesch D, Gibbs JSR, et al. Diagnosis of pulmonary hypertension. *EUR Respir J 2019; 53: 1801904* [DOI:10.1183/13993003.01904-2018].

8. Galiè N, Channick RN, Frantz RP, et al. Risk stratification and medical therapy of pulmonary arterial hypertension. *Eur Respir J*. 2019; 53 1801889. [DOI: 10.1183/13993003.01889-2018].
9. Hopkins W, Rubin LJ. Treatment of pulmonary hypertension in adults. Mandel J ed. Waltham, MA: UpToDate Inc. Updated March 22, 2019. Accessed July 26, 2019.
10. Klinger, James R. et al. Therapy for Pulmonary Arterial Hypertension in Adults. CHEST 2019;155(3): 565-586. [DOI: 10.1016/j.chest.2018.11.030].
11. Letairis Package Insert. Foster City, CA: Gilead Sciences, Inc.; November 2018.
12. Mullen MP, Kulik T. Pulmonary hypertension in children: Classification, evaluation, and diagnosis. Fulton DR, Mallory GB eds. Waltham, MA: UpToDate Inc. Updated March 06, 2019. Accessed July 29, 2019.
13. Opsumit Package Insert. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; April 2019.
14. Orenitram Package Insert. Research Triangle Park, NC: United Therapeutics Corp.; January 2017.
15. Pulmonary Hypertension Association Consensus Statement; Revatio (sildenafil) for Pediatric Use: September 2012.
16. Revatio Package Insert. New York, NY: Pfizer Labs; February 2018.
17. Rubin LJ, Hopkins W. Clinical features and diagnosis of pulmonary hypertension of unclear etiology in adults. Mandel J ed. Waltham, MA: UpToDate Inc. Updated May 17, 2019. Accessed July 29, 2019.
18. Simonneau G, Montani D, Celermajer DS, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019;53(1):1801913. Published 2019 Jan 24. [DOI:10.1183/13993003.01913-2018].
19. Tonelli AR, Alnuaimat H, Mubarak K. Pulmonary vasodilator testing and use of calcium channel blockers in pulmonary arterial hypertension. Respiratory Medicine. Volume 104, Issue 4 April 2010, Pages 481-496. [DOI: 10.1016/j.rmed.2009.11.015].
20. Tracleer Package Insert. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; May 2019.
21. Tyvaso Package Insert. Research Triangle Park, NC: United Therapeutics Corp.; October 2017.
22. Uptravi Package Insert. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; December 2017.
23. Ventavis Package Insert. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; October 2017.