Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.171	**Effective Date: 01/01/2020** **Revision Date: 01/2021**
Policy Name: PAH Agents, Oral and Inhaled	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2021 annual review: no changes.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: PAH Agents, Oral and Inhaled

Reference Number: PHW.PDL.171
Effective Date: 01/01/2020
Last Review Date: 01/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Oral and Inhaled Pulmonary Arterial Hypertension (PAH) Agents are **medically necessary** when the following criteria are met:

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*, has a documented history of therapeutic failure, contraindication, or intolerance of calcium channel blockers (i.e., amlodipine, nifedipine, or diltiazem).
   **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.*

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

   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 PA.CP.PMN.59 Quantity Limit Override.

   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 PA.CP.PMN.59 Quantity Limit Override

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. <u>Approval Duration</u>:
- **New Request: 6 months**
- **Renewal Request: 12 months**

E. 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].
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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].
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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].
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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.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021