Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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:

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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);

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

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

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

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:

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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

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. <u>Clinical Review Process</u>

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

Gateway Health

It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS PRIOR AUTHORIZATION FORM

☐ New request ☐ Renewal request | Total # of pages: ______	Prescriber name:
Name of office contact:	Specialty:
Contact's phone number:	NPI: | State license #:
LTC facility contact/phone:	Street address:
Beneficiary name:	Suite #: | City/state/zip:
Beneficiary ID#: | DOB:	Phone: | Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)	Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other

CLINICAL INFORMATION

Drug Name:	Strength:	Formulation:
Dose/directions:	Quantity:	Refills:
Diagnosis (*submit documentation*):	Dx code (*required*):	
Has the beneficiary been taking the requested medication within the past 90 days?	☐ Yes ☐ No	*Submit documentation of drug regimen and clinical response.*

INITIAL requests

For a non-preferred PAH Agent: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred agents in this class that are approved or medically accepted for treatment of the beneficiary's condition? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred agents in this class.*	☐ Yes ☐ No	*Submit documentation.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

For treatment of PAH:

- ☐ The requested medication is appropriate for the beneficiary's level of risk based on a current risk calculator assessment (e.g., REVEAL 2.0) and current medical literature
- ☐ Has a mean pulmonary arterial pressure greater than 20 mmHg
- ☐ Has a pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg
- ☐ Has a pulmonary vascular resistance greater than 3 Wood units

Also, for idiopathic PAH:

- ☐ Has chart documentation of acute vasoreactivity testing or a medical reason for not having vasoreactivity testing
- ☐ Demonstrates acute vasoreactivity and has a history of trial and failure of or contraindication or intolerance to calcium channel blockers

For treatment of CTEPH:

- ☐ Has a mean pulmonary arterial pressure greater than 25 mmHg
- ☐ Has a pulmonary vascular resistance greater than 3 Wood units

RENEWAL requests

Has the beneficiary experienced a positive clinical response to the requested medication?	☐ Yes ☐ No	*Submit documentation of clinical response.*

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date:

Confidentiality Notice: The documents accompanying this telecopy may contain confidential information belonging to the sender. The information is intended only for the use of the individual named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any telecopy is strictly prohibited.