Gateway Health
It's Wholecare.
Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

# 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 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:
      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) skilled in treating pulmonary hypertension;

   **AND**

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 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 mmHg,
      iii. A pulmonary vascular resistance greater than or equal to 3 Wood units,

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b. For a beneficiary with idiopathic PAH, **both** of the following:

   i. **One** of the following:
      a) Has a $H_2$FPEF score less than 2
      b) Has a left atrial volume index less than 35 mL/$m^2$
      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-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 20 mmHg
   b. A pulmonary vascular resistance greater than or equal to 3 Wood units;

   **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;

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.

[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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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 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

    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.

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# PULMONARY HYPERTENSION AGENTS, ORAL AND INHALED 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: |

## 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.* |
| Is the medication prescribed by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center or other specialist skilled in treating pulmonary hypertension? | | ☐Yes ☐No | *Submit documentation of consultation, if applicable.* |

### INITIAL requests

| | | |
|---|---|---|
| For a non-preferred Pulmonary Hypertension 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? | ☐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 (WHO Group 1):
- ☐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
- ☐Had a right heart catheterization showing the following:
  - ☐A mean pulmonary arterial pressure greater than 20 mmHg
  - ☐A pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg
  - ☐A pulmonary vascular resistance greater than or equal to 3 Wood units
- ☐Also, for idiopathic PAH:
  - ☐Has an $H_2$FPEF score less than 2
  - ☐Has a left atrial volume index less than 35 mL/m$^2$
  - ☐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)
  - ☐Has chart documentation of acute vasoreactivity testing
  - ☐Has a medical reason for not having vasoreactivity testing
    - ☐High risk stratification based on current risk calculator assessment (e.g., REVEAL 2.0)
    - ☐Low systemic blood pressure
    - ☐Low cardiac index
    - ☐Pulmonary veno-occlusive disease
    - ☐Other *(describe)*: _____
  - ☐Demonstrates acute vasoreactivity
    - ☐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 20 mmHg
- ☐Has a pulmonary vascular resistance greater than or equal to 3 Wood units

### RENEWAL requests

| | | |
|---|---|---|
| Does the beneficiary continue to benefit from the requested medication? | ☐Yes ☐No | *Submit documentation of clinical response.* |

## PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

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|---|---|
| Prescriber Signature: | Date: |