

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 clinical status and current peer-reviewed 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 under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist or pediatric cardiologist
- b. If 18 years of age or older, **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 drug; **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 (mPAP) greater than or equal to 25 mmHg,
 - ii. A pulmonary capillary wedge pressure (PCWP), left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
 - iii. A pulmonary vascular resistance (PVR) greater than 3 Wood units,
- b. For a beneficiary with idiopathic or heritable 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., presence of severe [functional class IV] symptoms, low systemic blood pressure, low cardiac index, or pulmonary veno-occlusive disease),
- c. For a beneficiary with idiopathic or heritable PAH that demonstrates acute vasoreactivity,¹ has a documented history of therapeutic failure of or a contraindication or an intolerance to 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. An mPAP greater than or equal to 25 mmHg
 - b. A PVR greater than 3 Wood units;

AND

7. For a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3), has **both** of the following:
 - a. Chart documentation of right heart catheterization indicating **all** of the following hemodynamic values:
 - i. An mPAP greater than or equal to 25 mmHg,
 - ii. A PCWP less than or equal to 15 mmHg,
 - iii. A PVR greater than 3 Wood units
 - b. Chart documentation of recent computed tomography imaging demonstrating interstitial lung disease;

AND

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.

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

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:

- Continues to benefit from the requested Pulmonary Hypertension Agent, Oral and Inhaled based on the prescriber's assessment; **AND**
- Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
- One** of the following:
 - If under 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist or pediatric cardiologist
 - If 18 years of age or older, **one** of the following:
 - Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
 - 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

- Does not have a contraindication to the prescribed drug; **AND**
- For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled with a therapeutically equivalent brand or generic that is preferred on the PDL, has a history of therapeutic failure

of or a contraindication or an intolerance to the preferred therapeutically equivalent brand or generic that would not be expected to occur with the requested drug. See the 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.

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.

PULMONARY HYPERTENSION AGENTS, ORAL AND INHALED

PRIOR AUTHORIZATION FORM (form effective 1/5/2026)

<input type="checkbox"/> New request <input type="checkbox"/> 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:			City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:	

CLINICAL INFORMATION

Drug name:	Strength:	Formulation:	
Dose/directions:		Quantity:	Refills:
Diagnosis (<u>submit documentation</u>):		Dx code (<u>required</u>):	
Has the beneficiary been using the requested medication within the past 90 days?		<input type="checkbox"/> Yes <i>Submit documentation of drug regimen and clinical response.</i> <input type="checkbox"/> No	
Is the requested medication prescribed by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center or other specialist skilled in treating pulmonary hypertension (i.e., pediatric or adult pulmonologist or cardiologist, rheumatologist)?		<input type="checkbox"/> Yes <i>Submit documentation of consultation, if applicable.</i> <input type="checkbox"/> No	

Complete all sections that apply to the beneficiary and this request.

Check all that apply and submit documentation for each item.

INITIAL requests

1. For treatment of PULMONARY ARTERIAL HYPERTENSION (PAH) (WHO GROUP 1):

- ☐ Had a right heart catheterization showing ALL of the following hemodynamic values:
- ☐ Mean pulmonary arterial pressure ≥ 25 mmHg
 - ☐ Pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure ≤ 15 mmHg
 - ☐ Pulmonary vascular resistance > 3 Wood units
- ☐ **Also, for IDIOPATHIC or HERITABLE PAH:**
- ☐ Has chart documentation of acute vasoreactivity testing
 - ☐ ONE of the following:
 - ☐ Has a contraindication to vasoreactivity testing
 - ☐ Is at increased risk of adverse events during acute vasoreactivity testing (e.g., presence of severe [functional class IV] symptoms, low systemic blood pressure, low cardiac index, pulmonary veno-occlusive disease)
 - ☐ **For a beneficiary with idiopathic or heritable PAH who demonstrates acute vasoreactivity:**
 - ☐ Has a history of trial and failure of or contraindication or intolerance to calcium channel blockers (i.e., amlodipine, diltiazem, nifedipine)

2. For treatment of CHRONIC THROMBOEMBOLIC PULMONARY HYPERTENSION (CTEPH):

- ☐ Had a right heart catheterization showing BOTH of the following hemodynamic values:
- ☐ Mean pulmonary arterial pressure ≥ 25 mmHg
 - ☐ Pulmonary vascular resistance > 3 Wood units

3. For treatment of PULMONARY HYPERTENSION associated with INTERSTITIAL LUNG DISEASE (PH-ILD) (WHO GROUP 3):

- ☐ Had a right heart catheterization showing ALL of the following hemodynamic values:
- ☐ Mean pulmonary arterial pressure ≥ 25 mmHg
 - ☐ Pulmonary capillary wedge pressure ≤ 15 mmHg
 - ☐ Pulmonary vascular resistance > 3 Wood units
- ☐ Had recent CT imaging demonstrating interstitial lung disease

4. For a NON-PREFERRED Pulmonary Hypertension Agent, Oral and Inhaled:

- ☐ Tried and failed or has a contraindication or an intolerance to the preferred Pulmonary Hypertension Agents, Oral and Inhaled (*Refer to <https://papdl.com/preferred-drug-list> for a list of preferred and non-preferred drugs in this class.*)

RENEWAL requests

Does the beneficiary continue to benefit from the requested medication?

- ☐ Yes *Submit documentation of*
- ☐ No *clinical response.*

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:

Date:

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