Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
# Pulmonary Arterial Hypertension

*Effective: May 12, 2026*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

**Public Plans Products**

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

## Overview

**Food and Drug Administration – Approved Indications**

| Drug | Chronic Thromboembolic Pulmonary Hypertension | Pulmonary Arterial Hypertension | Pulmonary Hypertension Associated with Interstitial Lung Disease |
|---|---|---|---|
| Adempas | X | X | |
| ambrisentan | | X | |
| bosentan | | X | |
| Opsumit | | X | |
| Orenitram | | X | |
| sildenafil | | X | |
| tadalafil | | X | |
| Tyvaso | | X | X |
| Uptravi | | X | |
| Ventavis | | X | |
| Winrevair | | X | |

## Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Pulmonary Arterial Hypertension medication for Members when **ALL** of the following criteria are met:

## Chronic Thromboembolic Pulmonary Hypertension

Adempas

1. Documented diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) – World Heather Organization (WHO) Group 4

**AND**

2. Prescribed by or in consultation with a cardiologist or pulmonologist

**AND**

3. Documentation of persistent or recurrent condition following surgery or an inoperable condition

**AND**

4. Documentation diagnosis is confirmed by right heart catheterization or pulmonary angiography

## Pulmonary Arterial Hypertension

Adempas, ambrisentan, bosentan, sildenafil, tadalafil, Opsumit

1. Documented diagnosis of pulmonary arterial hypertension (PAH) – World Health Organization (WHO) Group 1

**AND**

2. Prescribed by or in consultation with a cardiologist or pulmonologist

**AND**

3. Documentation diagnosis is confirmed by right heart catheterization with **one (1)** of the following parameters:
    a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg at rest or greater than 30 mmHg with exertion
    b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    c. Pulmonary vascular resistance (PVR) greater than 3 Wood units

Uptravi, Orenitram, Tyvaso, Ventavis

1. Documented diagnosis of pulmonary arterial hypertension (PAH) – World Health Organization (WHO) Group 1

**AND**

2. Prescribed by or in consultation with a cardiologist or pulmonologist

**AND**

3. Documentation diagnosis is confirmed by right heart catheterization with **one (1)** of the following parameters:
    a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg at rest or greater than 30 mmHg with exertion
    b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    c. Pulmonary vascular resistance (PVR) greater than 3 Wood units

**AND**

4. Documentation of **one (1)** of the following:
    a. The patient is currently taking a phosphodiesterase-5 inhibitor or an endothelin receptor antagonist
    b. The patient has tried and failed a phosphodiesterase-5 inhibitor or an endothelin receptor antagonist
    c. Contraindication to a phosphodiesterase-5 inhibitors and an endothelin receptor antagonists

Winrevair

1. Documented diagnosis of pulmonary arterial hypertension (PAH) – World Health Organization (WHO) Group 1

**AND**

2. Prescribed by or in consultation with a cardiologist or pulmonologist

**AND**

3. Documentation diagnosis is confirmed by right heart catheterization with **one (1)** of the following parameters:
    a. Mean pulmonary artery pressure (PAP) of greater than or equal to 25 mmHg at rest or greater than 30 mmHg with exertion
    b. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
    c. Pulmonary vascular resistance (PVR) greater than 3 Wood units

**AND**

4. Documentation the patient is in Functional Class II or III

**AND**

5. Documentation of **one (1)** of the following:
    a. The patient is currently taking at least two other pulmonary arterial hypertension therapies from the following different pharmacologic categories: endothelin receptor antagonist, phosphodiesterase-5 inhibitor, soluble guanylate cyclase stimulator, and prostacylins
    b. The patient is currently receiving at least one other pulmonary arterial hypertension therapies and is intolerant to combination therapy with an endothelin receptor antagonist, phosphodiesterase-5 inhibitor, soluble guanylate cyclase stimulator, or prostacylins

## Pulmonary Hypertension Associated with Interstitial Lung Disease

Tyvaso

1. Documented diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD) – World Health Organization (WHO) Group 3

**AND**

2. Prescribed by or in consultation with a cardiologist or pulmonologist

**AND**

3. Documentation diagnosis is confirmed by right heart catheterization or pulmonary angiography

## Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. Coverage of sildenafil and tadalafil formulations that do not have an FDA-approved indication for pulmonary hypertension will not be authorized for the treatment of pulmonary hypertension.

## Codes

None

## References


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## Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: No changes
- June 11, 2024: No changes (eff 6/11/24).
- November 12, 2024: Added Winrevair to the Medical Necessity Guideline (eff 12/1/24).
- May 12, 2026: No changes, Administrative update to template to remove CareLink from the Medical Necessity Guideline template.

## Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.