Pharmacy Medical Necessity Guidelines: Pulmonary Hypertension Medications

Effective: December 9, 2025

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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	

COVERAGE GUIDELINES

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

Chronic-Thromboembolic Pulmonary Hypertension

Adempas

1. The Member has a definitive diagnosis of World Health Organization Group 4 pulmonary arterial hypertension and confirmed by right heart catheterization

AND

2. The prescriber is a cardiologist or pulmonologist

AND

3. Documentation of **one (1) of the following**:
    a. The chronic thromboembolic pulmonary hypertension persists or recurs after surgical treatment
    b. Member is diagnosed as inoperable by a center specializing in chronic thromboembolic pulmonary hypertension or pulmonary thromboendarterectomy

Pulmonary Hypertension Due to Lung Disease and/or Hypoxia

Tyvaso/Tyvaso DPI

1. The Member must have a definitive diagnosis of World Health Organization Group 3 (see APPPENDIX) Pulmonary Arterial Hypertension confirmed by clinical assessment and echocardiographic findings or right heart catheterization

AND

2. The prescriber is a cardiologist or pulmonologist

Pulmonary Arterial Hypertension

Adempas, ambrisentan, bosentan tablets, Opsumit, Orenitram, sildenafil, tadalafil, Tracleer tablet for oral suspension, Tyvaso/Tyvaso DPI, Uptravi, or Ventavis

1. The Member must have a definitive diagnosis of World Health Organization Group 1 Pulmonary Arterial Hypertension confirmed by right heart catheterization

AND

2. The prescriber is a cardiologist or pulmonologist

Winrevair

1. The Member must have a definitive diagnosis of World Health Organization Group 1 Pulmonary Arterial Hypertension confirmed by right heart catheterization

AND

2. The prescriber is a cardiologist or pulmonologist

AND

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

AND

4. Documentation of **one (1)** of the following:
   a. The Member 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 Member 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

LIMITATIONS

- The plan does not cover the following brand medications: Adcirca, Letairis, Revatio, and Tracleer tablets. Refer to the Pharmacy Medical Necessity Guidelines for non-covered medications.
- 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

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APPROVAL HISTORY

September 13, 2022: Reviewed by 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).
- December 9, 2025: No changes.

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.