

**Remodulin (treprostinil) injection**  
**Treprostinil injection (generic)**  
 Effective 01/01/2026

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Medical Benefit</b> <b>Pharmacy Benefit</b>	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
<b>Exceptions</b>	N/A		

### Overview

#### FDA-Approved Indication

1. Treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH, PAH associated with congenital systemic-to-pulmonary shunts, or PAH associated with connective tissue diseases.
2. Patients with PAH requiring transition from epoprostenol, treprostinil/Remodulin to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition.

### Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### **OR**

Authorization may be granted for treatment when all the following criteria are met:

1. Member has a diagnosis of PAH defined as WHO Group 1 class of pulmonary hypertension (see Appendix)
2. PAH confirmed by ONE of the following:
  - a. Pretreatment right heart catheterization with ALL of the following:
    - i. mPAP > 20mmHg
    - ii. PCWP ≤ 15mmHg
    - iii. PVR ≥ 3 Wood units
  - b. For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.
3. Medication is being prescribed by or in consultation with a pulmonologist or cardiologist.

### Continuation of Therapy

Reauthorization will be granted for a covered indication when there is physician attestation that member is having benefit from the medication as evidenced by disease stability or disease improvement.

## Limitations

1. Initial approvals and reauthorizations will be granted for 24 months

## Appendix: WHO Classification of Pulmonary Hypertension

1. **PAH**
  - 1.1 Idiopathic (PAH)
  - 1.2 Heritable PAH
  - 1.3 1.3 Drug- and toxin-induced PAH
  - 1.4. PAH associated with:
    - 1.4.1 Connective tissue diseases
    - 1.4.2 HIV infection
    - 1.4.3 Portal hypertension
    - 1.4.4 Congenital heart diseases
    - 1.4.5 Schistosomiasis
  - 1.5 PAH long-term responders to calcium channel blockers
  - 1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
  - 1.7 Persistent PH of the newborn syndrome
2. **PH due to left heart disease**
  - 2.1 PH due to heart failure with preserved LVEF
  - 2.2 PH due to heart failure with reduced LVEF
  - 2.3 Valvular heart disease
  - 2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH
3. **PH due to lung diseases and/or hypoxia**
  - 3.1 Obstructive lung disease
  - 3.2 Restrictive lung disease
  - 3.3 Other lung disease with mixed restrictive/obstructive pattern
  - 3.4 Hypoxia without lung disease
  - 3.5 Developmental lung disorders
4. **PH due to pulmonary artery obstruction**
  - 4.1 Chronic thromboembolic PH
  - 4.2 Other pulmonary artery obstructions
    - 4.2.1 Sarcoma (high or intermediate grade) or angiosarcoma
    - 4.2.2 Other malignant tumors
      - Renal carcinoma
      - Uterine carcinoma
      - Germ cell tumours of the testis
      - Other tumours
    - 4.2.3 Non-malignant tumours
      - Uterine leiomyoma
    - 4.2.4 Arteritis without connective tissue disease
    - 4.2.5 Congenital pulmonary artery stenosis
    - 4.2.6 Parasites
      - Hydatidosis



## 5. PH with unclear and/or multifactorial mechanisms

- 5.1 Hematologic disorders: Chronic hemolytic anemia, myeloproliferative disorders
- 5.2 Systemic and metabolic disorders: Pulmonary Langerhans cell histiocytosis, Gaucher disease, glycogen storage disease, neurofibromatosis, sarcoidosis
- 5.3 Others: chronic renal failure with or without hemodialysis, fibrosing mediastinitis
- 5.4 Complex congenital heart disease

## References

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12. Taichman DB, Ornelas J, Chung L, et al. Pharmacologic therapy for pulmonary arterial hypertension in adults. CHEST guideline and expert panel report. *Chest*. 2014;46(2):449-475.
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## Review History

04/12/2023 – Reviewed and Created for April P&T; switched from SGM to custom. Effective 07/01/2023

10/08/2025 – Reviewed and updated for October P&T. Updated policy to indicate it no longer applies to the medical benefit. Effective 01/01/2026.

