

Reference number(s)
1644-A

## SPECIALTY GUIDELINE MANAGEMENT

### Remodulin injection (treprostinil injection) treprostinil injection (generic)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

- A. Pulmonary Arterial Hypertension  
Treprostinil/Remodulin is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to diminish symptoms associated with exercise.
- B. Pulmonary Arterial Hypertension in Patients Requiring Transition from Epoprostenol  
In patients with PAH requiring transition from epoprostenol, treprostinil/Remodulin is indicated to diminish the rate of clinical deterioration. Consider the risks and benefits of each drug prior to transition.

All other indications are considered experimental/investigational and not medically necessary.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Pulmonary Arterial Hypertension (PAH)**

Indefinite authorization may be granted for treatment of PAH when ALL of the following criteria are met:

- A. Member has PAH defined as WHO Group 1 class of pulmonary hypertension (refer to Appendix).
- B. PAH was confirmed by either criterion (1) or criterion (2) below:
  - 1. Pretreatment right heart catheterization with all of the following results:
    - i. mPAP > 20 mmHg
    - ii. PCWP ≤ 15 mmHg
    - iii. PVR ≥ 3 Wood units
  - 2. For infants less than one year of age, PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed.

##### III. CONTINUATION OF THERAPY

Indefinite authorization may be granted for members with an indication listed in Section II who are currently receiving the requested medication through a paid pharmacy or medical benefit, and who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

##### IV. APPENDIX

##### **WHO Classification of Pulmonary Hypertension 1 PAH**

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- 1.1 Idiopathic (PAH)
- 1.2 Heritable PAH
- 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

**V. REFERENCES**

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