

Pulmonary Arterial Hypertension Agents
Remodulin (treprostinil)
Effective 10/01/2024

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Remodulin (treprostinil injection) is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Remodulin (treprostinil injection) is indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. In patients with PAH requiring transition from epoprostenol, Remodulin is indicated to diminish the rate of clinical deterioration.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. Diagnosis of PAH
2. Prescriber is a pulmonologist or cardiologist, or consult notes from pulmonologist or cardiologist are provided
3. ONE of the following:
 - a. Inadequate response, adverse reaction or contraindication to epoprostenol (Veletri) or Flolan
 - b. Member has cognitive or physical issues affecting ability to manage intravenous therapy, need for fluid restriction, low health literacy, risk of infection, or history of IV drug use.

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. McLaughlin VV, Archer SL, Badesch DB, Barst RJ, Farber HW, Lindner JR, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: a report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. *Circulation*. 2009 Apr 28;119(16):2250-94.
2. Klinger JR, Elliott CG, Levine DJ, Bossone E, Duvall L, Fagan K, et al. Therapy for Pulmonary Arterial Hypertension in Adults Update of the CHEST Guideline and Expert Panel Report. *Chest*. 2019 Mar; 155(3): 565-586.
3. Galiè N, Humbert M, Vachiery JL, Gibbs S, Lang I, Torbicki A, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: The Joint Task Force for the Diagnosis and Treatment of Pulmonary Hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS), endorsed by Association for European Pediatric and Congenital Cardiology (AEPC), International Society for Heart and Lung Transplantation (ISHLT). *European Heart Journal*. Aug 29, 2015.
4. Hopkins W, Rubin LJ. Treatment of pulmonary arterial hypertension (group 1) in adults: Pulmonary hypertension-specific therapy. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Oct 14]. Available from: <http://www.uptodate.com/uptd/index.do>.
5. Remodulin® [package insert on the Internet]. Research Triangle Park (NC): United Therapeutics Corp.; 2021 Jul [cited 2021 Oct 13]. Available from: <https://www.remodulin.com/files/remodulin-pi.pdf>.

Review History

Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.

05/10/23 – Reviewed and updated for P&T. Added Tadliq as requiring PA. Reauthorization criteria and approval durations were updated. Revatio susp criteria was updated regarding swallowing disorders. Added sildenafil (generic for Viagra) to off-label indication Raynaud phenomenon. Added appendix for Veletri requests. References were updated. Effective 6/5/23

06/14/23 – Reviewed and updated for P&T. Admin update: clarified that Veletri® (epoprostenol) is available through both pharmacy and medical benefits. Effective 6/30/23

09/11/24 – Reviewed and updated for P&T. Removed other agents that are processed through pharmacy as these will be managed and deferred to MHDL. Decision to remove PA from generic epoprostenol, Brand Flolan, and Veletri from MB – positive change, no notifications necessary. Remodulin will continue to be managed as dual benefit with PA. Effective 10/1/24

