

Remodulin® (treprostinil) injection



When requesting Remodulin® (treprostinil) injection, the individual requiring treatment must be diagnosed with the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

- Remodulin® (treprostinil) is indicated for the treatment of pulmonary arterial hypertension (World Health Organization [WHO] Group I) to diminish symptoms associated with exercise
- Remodulin® (treprostinil) is indicated to diminish the rate of clinical deterioration in individuals with pulmonary arterial hypertension requiring transition from Flolan® (epoprostenol)

Approved Off-Label Compendial Use

- None

Coverage Guidelines

Pulmonary Arterial Hypertension

The individual must meet **all** of the following criteria for approval:

- Has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization
- New York Heart Association (NYHA) functional classification of physical activity is classified by one of the following:
 - o Class II – slight limitation of physical activity due to symptoms
 - o Class III - marked limitation of physical activity due to symptoms. Comfortable only at rest.
 - o Class IV - unable to carry on any physical activity because of symptoms with symptoms occurring even at rest.
- Disease etiology is classified by one of the following:
 - o Idiopathic pulmonary arterial hypertension
 - o Heritable pulmonary arterial hypertension
 - o Pulmonary arterial hypertension associated with congenital systemic-to-pulmonary shunts
 - o Pulmonary arterial hypertension associated with connective tissue diseases

Additional Information for Prescribers

- None

References

1. Remodulin® prescribing information. Research Triangle Park, NC: United Therapeutics Corp.: December 2014. <https://www.remodulin.com/downloads/remodulin-prescribinginformation.pdf>. Accessed April 11, 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed April 11, 2017. <https://www.micromedexsolutions.com>
3. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 Expert Consensus Document on Pulmonary Hypertension. *Circulation*. 2009;119:2250-2294. Accessed April 11, 2017. <https://www.ncbi.nlm.nih.gov/pubmed/19332472>
4. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed, Little, Brown & Co, Boston, 1994. p.253. The Criteria Committee of the New York Heart Association. Nomenclature and Criteria for Diagnosis of Diseases of the Heart and Great Vessels, 9th ed, Little, Brown & Co, Boston, 1994. p.253.